January 7, 2021 | Author: Kir Kahlon | www.scorpioncapital.com

NEVRO (NYSE: NVRO)

A Failed One-Trick Pony At 15X Sales, Reeking of Study Fraud, Kickbacks, And A Covered-Up Explants Crisis That Merits An FDA Recall

$5.8B market cap | $168/share | $65/$188 52wk hi/low | $51M ADV, 30d avg | Short interest 8% of float **as of close 1/06/21 (Bloomberg)*

Scorpion Capital | Nevro (NYSE: NVRO)

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"I got excited by Nevro. I thought it was the Tesla of spinal cord stimulators…I became increasingly frustrated as I began to see a lot of failures with the device. I had dinner with the CEO…I compare notes with 6 to 7 other doctors …Surgeons who used to only use Nevro have all gone back to Medtronic or St. Jude…I used to be a 100% Nevro believer in the beginning. They can say or claim whatever they want but it's not true in clinical practice…Nevro is a one trick pony." ***–Physician #1, a former high volume Nevro implanter***

"Doctors that implanted a lot of devices, they hated Nevro. I don't know doctors who were high volume Nevro implanters that liked it and continued with their device. The implanters today who are involved with Nevro's studies – I saw the guys who went to jail for prescribing the Insys fentanyl drug. An Insys VP was saying how he hired hookers and strippers. You have to remember the doctor runs the show. And the only way I know to change that doctor's practice paradigm is bribing. It works. You give a doctor some money and they will say whatever you want. I would imagine Nevro probably doesn't give them money. They just hire them as consultants, pay them to give lectures and to teach classes. Doctors are whores." ***–Physician #2, a key opinion leader (KOL) in the spinal cord stimulation space***

"We subsequently found out, as we spoke to former Nevro reps who were involved in the Senza study, that the manipulation in statements from the patients was crazy…These were very, very specific questions to manipulate the answer that they wanted. I wasn't the only one who found this out. Other doctors who I respect greatly in the field also got the same input from other reps who were formally working for Nevro. So, it was a big scam. The way that they manipulated the data was criminal. I would say that the bigger names in neuromodulation who weren't getting paid by them, think of Nevro with disgust." ***–Physician #3, a KOL and high volume implanter***

"There were definitely practices at Nevro that pushed patients into implants. They will invariably be audited by Medicare. They're doing other things that are not on the up and up. In the past I worked with a couple of practices where doctors would tell patients they wouldn't get medication if they didn't do a stimulator trial. I had patients show up for a visit and not know they were there for a stimulator…" ***– Former Nevro sales rep***

Source: Consultation calls with experts

"According to a 2019 contract obtained by the German language paper, California-based Nevro…offered Swiss doctors CHF10,000 ($10,181) for each Nevro spinal cord stimulator implanted in a patient…The kickback scheme, which has now been terminated, has been running since 2017 under the auspices of the "Nevro Partnership Program." – ***Swiss Broadcasting Corporation 2/16/2020, "US Company Provided Kickbacks to Doctors in Switzerland," https://www.swissinfo.ch/eng/us-company-provided-kickbacks-to-doctors-in-switzerland/45562136***

"Nevro keeps explant rates very well hidden from the field reps…The explant rate was a hell of a lot higher than [the stated] 2%. I don't know that people asked for it, because ignorance is bliss. I didn't want to know. Don't ask questions you don't want to know the answer to. My peers in the field felt the same way." – ***Former Nevro regional sales director, in charge of a large multi-state region***

"If you put doctors into boxes, Money Mike couldn't care less if there's a high explant rate. It's just about the price you give him for the device. He could care less about whether it works or not. Yes, there are unethical, corrupt doctors. In that population, Nevro is the best thing since sliced bread." ***– Physician #4, a KOL and frequent speaker***

"*A lot of doctors in Germany are saying that Nevro's device only works for 2 to 2 ½ years and then the patient comes back with more pain. They say it fails and then they have to put in an Abbott or Boston Scientific device. It's a big issue here in Germany. These are credible people. People who do a lot of surgeries and are involved with the society. Every time there's a spinal cord stim meeting, this is an issue that colleagues talk about. People have become nervous and become afraid to use Nevro."* ***– Physician #5, a high volume European implanter***

"We went to Nevro's headquarters to discuss the explants…After 18 months I stopped implanting Nevro. I realized this shit doesn't work…I had a good relationship with Nevro…They flew me all over the country to speak, paid me a lot of money…It was just that the patient outcomes never showed up…I worked hard with them to try to accomplish this and I was beating my head against the wall because it just wasn't happening… No question, no question, that anybody who's not in the Nevro cult has the exact same clinical experience that I had with explants. Not a question. Additionally, you should talk to [KOL name redacted]….He was the editor in chief of [redacted] and President of [society name redacted]. He knows every inside story about everything. His take on Nevro is slimy people, falsification of data…I don't understand how Nevro can continue to keep the smoke and mirrors going, I really don't. I mean, it's crazy."
- ***Physician #3, a KOL and high volume implanter***

Source: Consultation calls with experts

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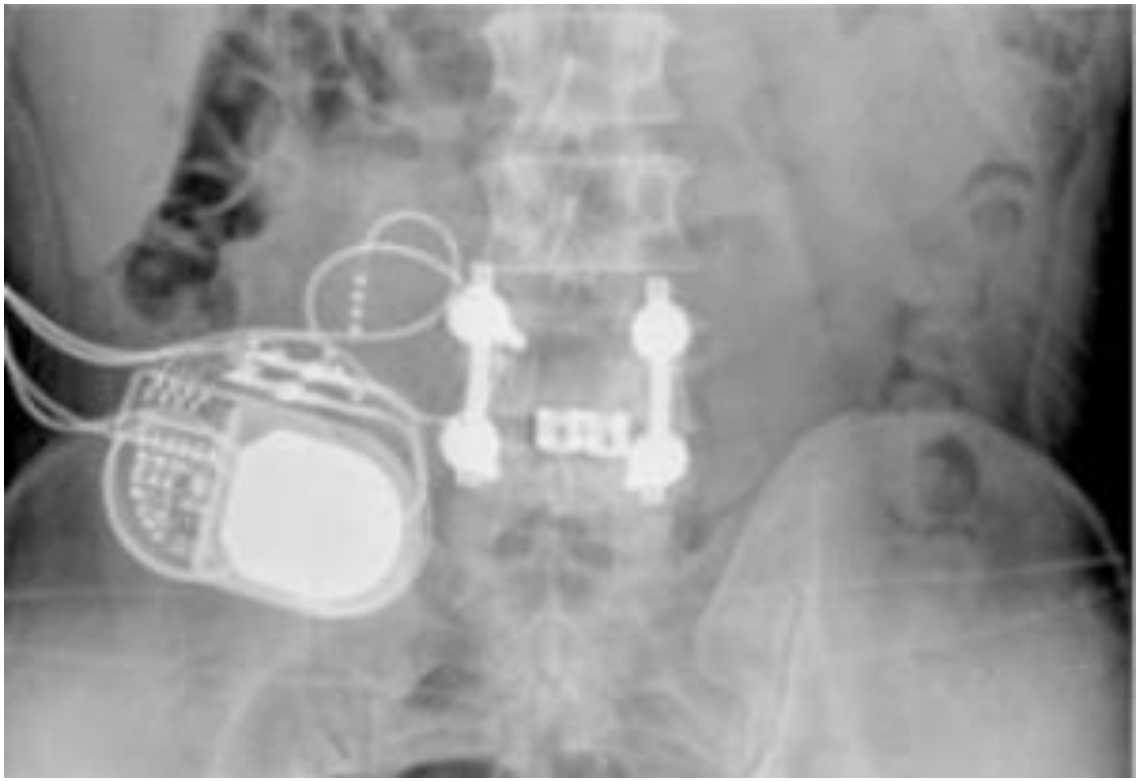
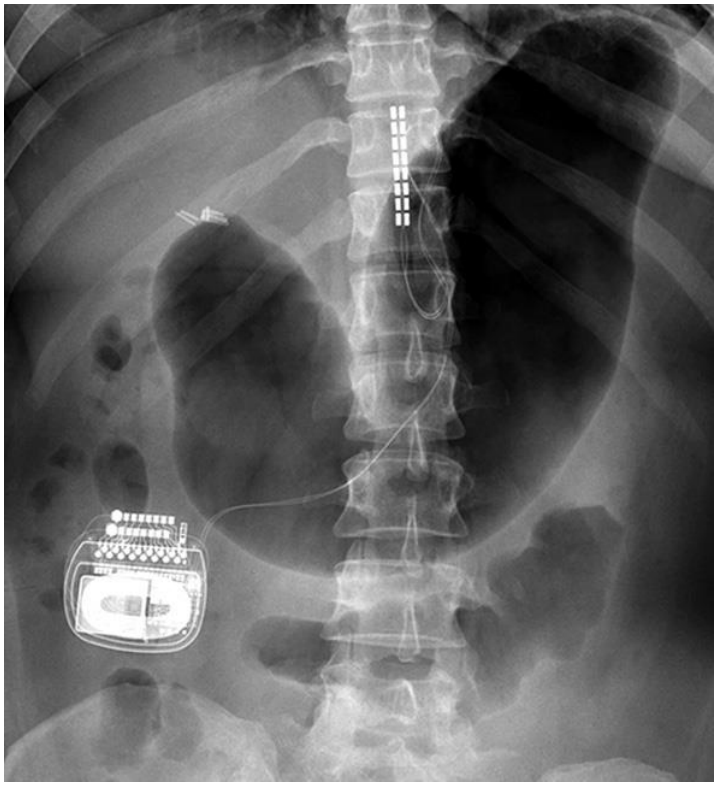
1. Introduction to Nevro

Nevro is a one-product medical device company with a $5.8B market cap. The company's sole offering is a spinal cord stimulator (SCS) for pain relief, which consists of a surgically-implanted battery/pulse generator that delivers current via electrodes placed into the spine. Stimulators are an old technology dating back to at least the 1960's. The purported mechanism of action is still not understood. Had electricity been harnessed during the medieval age, one might characterize stimulators as medieval in their underlying simplicity, crudeness, and adverse effects, despite the field favoring fancier terms like neuromodulation. Stimulators are generally a last-resort Hail Mary option for chronic pain patients who have failed pretty much everything else. An SCS kit typically sells for $20-30K.





Source: https://en.wikipedia.org/wiki/Spinal_cord_stimulator; Image 1 https://www.painnewsnetwork.org/stories/2017/12/20/no-i-dont-want-to-get-a-spinal-cord-stimulator; image 2 https://consultqd.clevelandclinic.org/spinal-cord-stimulation-is-effective-for-chronic-neuropathic-pain/;

1. Introduction to Nevro

Spinal cord stimulation has historically been a backwater space with poor economics and little innovation. Nevro entered the US market in 2015 claiming it had found the holy grail of pain relief: a stimulator that delivered pulses at a higher frequency (10khz) versus the low frequencies (eg, 1kHz) used by traditional devices. Nevro patented its high frequency "HF10" technology, saying that "frequencies above 5kHz have a unique inhibitory effect on pain circuitry." As the first "innovation" in SCS in perhaps decades and armed with clinical data showing superior pain relief, Nevro caught the 3 legacy players asleep and quickly took 15-17% of the market. Launching with the Senza stimulator, Nevro has now bet the company on its Omnia device, which launched in November 2019 and offers both low and high frequencies - an abrupt (and telling…) 180 degree unwind of its HF10-only message.

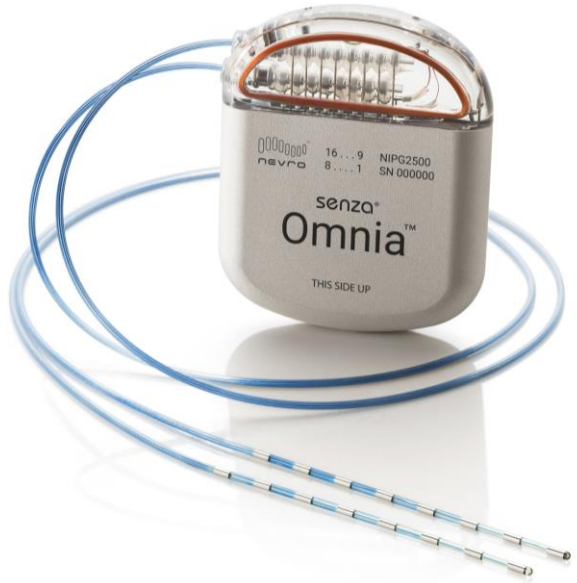
Senza model IPG with remote control and charging unit

Remote control

Charging paddle that must be placed next to implant location. On Facebook groups, patients report spending close to an hour or more daily to re-charge Nevro's stimulators

Battery/IPG implanted inside patient

New Omnia battery/IPG



Source: Image 1 https://www.medgadget.com/2015/05/nevro-senza-high-frequency-spinal-cord-stimulator-gets-green-light-by-fda.html; image 2 https://s24.q4cdn.com/932612397/files/images/media_kit/Omnia_Implantable_Pulse_Generator.jpg

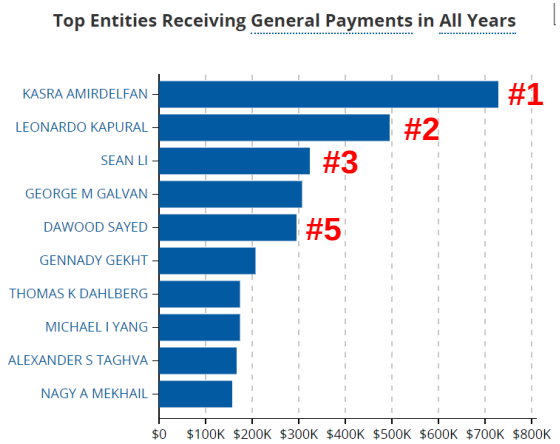
Scorpion Capital | Nevro (NYSE: NVRO)

1. Introduction to Nevro

Nevro would have one believe that no stimulator manufacturer in the last 60 years ever bothered to crank up the frequency to see what happens. Our research suggests that some did and concluded it doesn't work. Nonetheless, Nevro achieved fame with its 2014 SENZA trial that showed that high frequency provides roughly double the pain relief of traditional stimulators. The Carolinas Pain Institute – painted by one KOL as a corrupt trial "factory" – played a central, enabling role in the trial, as it did for the Insys fentanyl trial. We note that Insys executives and high volume prescribers were sent to prison for kickbacks disguised under its "Insys Speakers Bureau," illustrating the genre of pain clinics and practitioners at hand. The same cast of characters that keeps popping up as lead investigators for Nevro's studies, and as some of its highest volume implanters, also has a knack for topping its OpenPayments leaderboard, which appears to consist mostly of…speaking payments.

"When Nevro first started, if you look at the doctors in the forefront, true thought leaders, key opinion leaders, the white shoe reputable people – that's not who they got. They brought in a bunch of guys - ***I wouldn't say they were outcasts, but… it was like a Scientology thing. They did these retreats at some huge mansion, like crazy stuff…Nevro is not science****. It's a cult and I am blown away because every doctor I know that does a lot of implant volume doesn't use Nevro except for a small cult."* ***- KOL, former high volume Nevro implanter***

Top recipients of Nevro payments per CMS OpenPayments data



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Source: expert consultation calls; CMS OpenPayments https://openpaymentsdata.cms.gov/company/100000136428; images https://twitter.com/doctdeer/status/1063875667635376128, https://twitter.com/Nevro_HF10/status/1157021625751130113/photo/1, https://twitter.com/Nevro_HF10/status/1154058966709755904/photo/2

Scorpion Capital | Nevro (NYSE: NVRO)

1. Introduction to Nevro

Nevro's filings peg the global SCS market at $2.5B – making its $5.8B market cap an absurd 2.3X the size of its entire market. Three large device players - Medtronic, Abbott's St. Jude division, and Boston Scientific, with a combined ~$400B of market cap – have long dominated the SCS space. Despite only ~15% share and flat to down sales over the last 2-3 years, Nevro is valued at several times the combined stimulator sales of MDT, ABT, and BSX – even though it's a perpetually money-losing enterprise. Shockingly poor margins, especially for a medical device company, have collapsed even further since 2018 as its growth crashed, evidence of a fatally-flawed business model that survives only by continually raising new equity and debt. As of 9/30, the company had $328MM of long term debt. Having incinerated ~$360MM of cash since 2012, the debt requires new debt or equity to be repaid – in our opinion, a textbook Ponzi.

Income statement	***2012***	***2013***	***2014***	***2015***	***2016***	***2017***	***2018***	***2019***	***LTM 9/30***	***2020E***
Total Revenue	*18*	*24*	*33*	*70*	*229*	*327*	*387*	*390*	*367*	*362*
Growth yoy	*NA*	*29%*	*39%*	*114%*	*228%*	*43%*	*19%*	*0.8%*	*(-4.5%)*	*(-7.4%)*
Gross Profit	*11*	*14*	*21*	*41*	*153*	*228*	*273*	*268*	*255*	*-*
EBITDA	*(19)*	*(25)*	*(28)*	*(62)*	*(21)*	*(27)*	*(38)*	*(92)*	*(67)*	*(16)*
EBIT	*(19)*	*(25)*	*(28)*	*(62)*	*(23)*	*(30)*	*(42)*	*(97)*	*(72)*	*(68)*
Net Income	*(19)*	*(26)*	*(31)*	*(67)*	*(32)*	*(37)*	*(49)*	*(104)*	*(90)*	*(87)*
Cash flows	***2012***	***2013***	***2014***	***2015***	***2016***	***2017***	***2018***	***2019***	***LTM 9/30***	
Cash flowfrom ops	*(23)*	*(21)*	*(31)*	*(100)*	*(59)*	*(14)*	*(6)*	*(50)*	*(24)*	
Capital expenditure	*(0)*	*(0)*	*(1)*	*(5)*	*(3)*	*(4)*	*(8)*	*(4)*	*(5)*	
Free cash flow	*(23)*	*(21)*	*(32)*	*(105)*	*(62)*	*(19)*	*(14)*	*(54)*	*(29)*	
Margins	***2012***	***2013***	***2014***	***2015***	***2016***	***2017***	***2018***	***2019***	***LTM 9/30***	***2020E***
Gross margin	*59%*	*60%*	*65%*	*60%*	*67%*	*70%*	*71%*	*69%*	*69%*	*69%*
EBITDA %	*-105%*	*-107%*	*-87%*	*-89%*	*-9%*	*-8%*	*-10%*	*-24%*	*-18%*	
EBIT %	*-105%*	*-107%*	*-87%*	*-90%*	*-10%*	*-9%*	*-11%*	*-25%*	*-20%*	
Net income %	*-105%*	*-111%*	*-94%*	*-97%*	*-14%*	*-11%*	*-13%*	*-27%*	*-24%*	*-24%*

Source: Capital IQ

1. Introduction to Nevro

Nevro's atrocious economics and leverage are a feature of the space, as illustrated by the other pure play SCS stock and closest comp - Nuvectra (NVTR), which filed for chapter 7 liquidation last year and is a canary in the coal mine. It was a smaller, emerging player with rapid growth and $50MM of sales by 2018. It peaked in late 2018 with a $340MM market cap and the stock at $24. A few months later it was a penny stock. Our interviews with ex-Nuvectra employees suggest that the device problems that led to its demise were fixable, unlike Nevro's which are inherent to its HF10 mechanism of action and terminal. We believe that Nevro has thus far avoided Nuvectra's fate for one reason: it has the funds to pay $3.5MM annually to a core group of doctors, in what we believe to be a kickback-dependent model without which its sales would have collapsed. A high volume doctor can implant 100+ stimulators per year, which drives $2-3MM in sales. With $367MM LTM sales, one can do the math on the small number of doctors upon which its fate rests. With the same toxic combination of leverage and cash burn, we believe investors underestimate Nevro's risk of becoming the next Nuvectra, especially if the FDA takes any action against its product, or if the OIG's Nov 16th Special Fraud Alert on speakers programs is predictive of what's coming.

Nuvectra stock chart

"There's probably 120 global physicians that represent the majority of Nevro's total revenue**. If each of those guys is doing, like a mega Nevro guy doing 70 to 100 devices a year, that's like $300 million. The number of physicians doing more than 40 implants a year would surprise you. It's a very small number." **– Former Nevro executive

***"90% of implants are still done by the top 10% of doctors." –** KOL and high volume implanter*

Source: Capital IQ; Capital IQ stock chart; consultation calls with experts

Scorpion Capital | Nevro (NYSE: NVRO)

1. Introduction to Nevro

Nevro is a top 50 medical device company by market cap and an extreme outlier on two counts. First, it has just about the worst economics in the top 50, a stark reminder of just how atrocious a business it is. Only one company has an EBIT margin lower than NVRO's -20% (IRTC at -21%), but IRTC grew 46% YOY versus Nevro at 0.8% YOY. The average margin of the top 50 is 15%, making Nevro 35 points worse. Only five companies lost money, and except for NVRO and IRTC not by much, indicating the difficulty of losing money as a medtech. Second, NVRO has the most extreme valuation relative to its growth and margin profile. Only 10 companies in the top 50 had a higher sales multiple than Nevro's 15X, yet they generally grew 20-50%+ with double digit margins, versus Nevro with no growth and margins in the gutter.

Top 50 medtech companies by market cap, descending order

#1-25

Company Name	Market cap	EV/LTM Revenue	Growth YOY last annual	LTM EBIT %
Abbott Laboratories (NYSE:ABT)	189,262	6.3	4.3%	14%
Danaher Corporation (NYSE:DHR)	162,513	9.0	5.1%	20%
Medtronic plc (NYSE:MDT)	157,417	6.2	-5.4%	15%
Intuitive Surgical, Inc. (NasdaqGS:ISRG)	94,638	20.9	20.3%	24%
Stryker Corporation (NYSE:SYK)	90,062	6.8	9.4%	22%
Becton, Dickinson and Company (NYSE:BDX)	73,013	5.2	-1.0%	15%
Siemens Healthineers AG (XTRA:SHL)	58,034	3.5	-0.4%	13%
Edwards Lifesciences Corporation (NYSE:EW)	55,120	12.5	16.8%	30%
Boston Scientific Corporation (NYSE:BSX)	51,893	5.9	9.3%	10%
Koninklijke Philips N.V. (ENXTAM:PHIA)	50,360	2.4	7.5%	10%
Align Technology, Inc. (NasdaqGS:ALGN)	42,867	18.5	22.4%	14%
IDEXX Laboratories, Inc. (NasdaqGS:IDXX)	42,416	16.7	8.8%	25%
Baxter International Inc. (NYSE:BAX)	41,489	3.8	2.4%	17%
DexCom, Inc. (NasdaqGS:DXCM)	35,410	19.0	43.1%	17%
Alcon Inc. (SWX:ALC)	32,421	5.1	5.0%	-5%
Zimmer Biomet Holdings, Inc. (NYSE:ZBH)	32,296	5.6	0.6%	13%
Coloplast A/S (CPSE:COLO B)	32,037	10.7	3.4%	32%
ResMed Inc. (NYSE:RMD)	31,100	10.5	13.4%	28%
Sartorius Aktiengesellschaft (XTRA:SRT)	28,714	12.0	16.7%	21%
West Pharmaceutical Services, Inc. (NYSE:WST)	21,514	10.5	7.1%	18%
Hologic, Inc. (NasdaqGS:HOLX)	19,538	5.8	12.1%	31%
Smith & Nephew plc (LSE:SN.)	19,307	4.1	4.8%	11%
Teleflex Incorporated (NYSE:TFX)	18,647	8.2	6.0%	17%
Straumann Holding AG (SWX:STMN)	18,406	11.5	17.1%	20%
The Cooper Companies, Inc. (NYSE:COO)	17,757	8.1	-8.4%	17%

#26-50

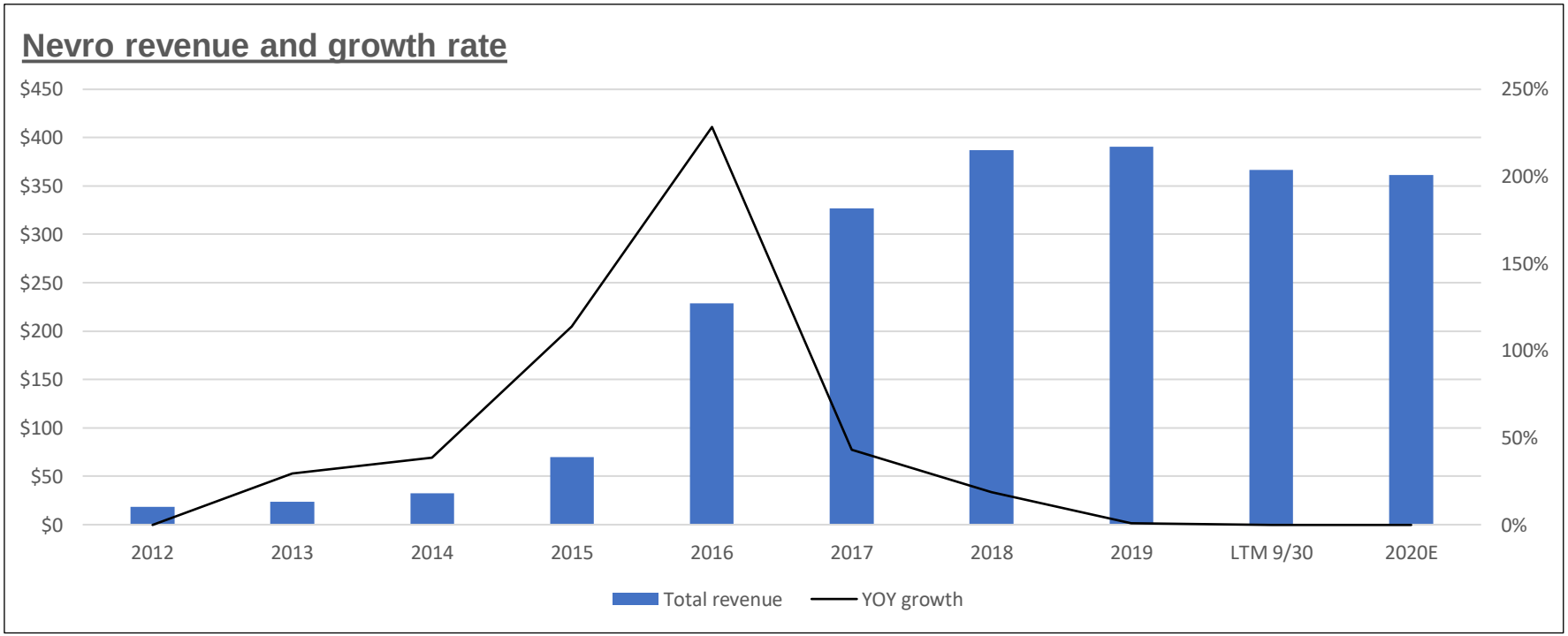
Company Name	Market cap	EV/LTM Revenue	Growth YOY last annual	LTM EBIT %
bioMérieux S.A. (ENXTPA:BIM)	16,825	5.1	10.5%	15%
Insulet Corporation (NasdaqGS:PODD)	16,723	19.3	30.9%	9%
NovoCure Limited (NasdaqGS:NVCR)	16,552	36.3	41.6%	4%
Sonova Holding AG (SWX:SOON)	16,498	5.9	5.6%	16%
STERIS plc (NYSE:STE)	16,367	5.7	8.9%	19%
Varian Medical Systems, Inc. (NYSE:VAR)	16,027	5.0	-1.8%	13%
Masimo Corporation (NasdaqGS:MASI)	14,809	12.9	9.3%	23%
Abiomed, Inc. (NasdaqGS:ABMD)	14,578	17.3	9.3%	28%
DENTSPLY SIRONA Inc. (NasdaqGS:XRAY)	12,084	3.9	1.1%	9%
Carl Zeiss Meditec AG (XTRA:AFX)	11,917	7.3	-8.5%	13%
DiaSorin S.p.A. (BIT:DIA)	10,851	11.3	5.6%	34%
GN Store Nord A/S (CPSE:GN)	10,036	5.2	18.5%	14%
Ambu A/S (CPSE:AMBU B)	9,994	17.4	26.5%	12%
Demant A/S (CPSE:DEMANT)	9,004	4.7	7.2%	5%
Quidel Corporation (NasdaqGS:QDEL)	8,408	8.4	2.4%	48%
Implantica AG (OM:IMP A SDB)	6,966	NM	55.1%	NM
Penumbra, Inc. (NYSE:PEN)	6,691	12.1	23.0%	-4%
Hill-Rom Holdings, Inc. (NYSE:HRC)	6,574	2.9	-0.9%	14%
iRhythm Technologies, Inc. (NasdaqGS:IRTC)	6,472	25.5	45.7%	-21%
Getinge AB (OM:GETI B)	6,445	2.0	9.9%	17%
Globus Medical, Inc. (NYSE:GMED)	6,367	7.4	10.2%	14%
Haemonetics Corporation (NYSE:HAE)	6,091	7.0	2.2%	15%
Tandem Diabetes Care, Inc. (NasdaqGM:TNDM)	5,943	13.0	97.0%	-6%
Nevro Corp. (NYSE:NVRO)	**5,881**	**15.4**	**0.8%**	**-20%**
Convatec Group Plc (LSE:CTEC)	5,653	3.4	-0.3%	13%

Source: Capital IQ, as of 1/6/2021

Scorpion Capital | Nevro (NYSE: NVRO)

1. Introduction to Nevro

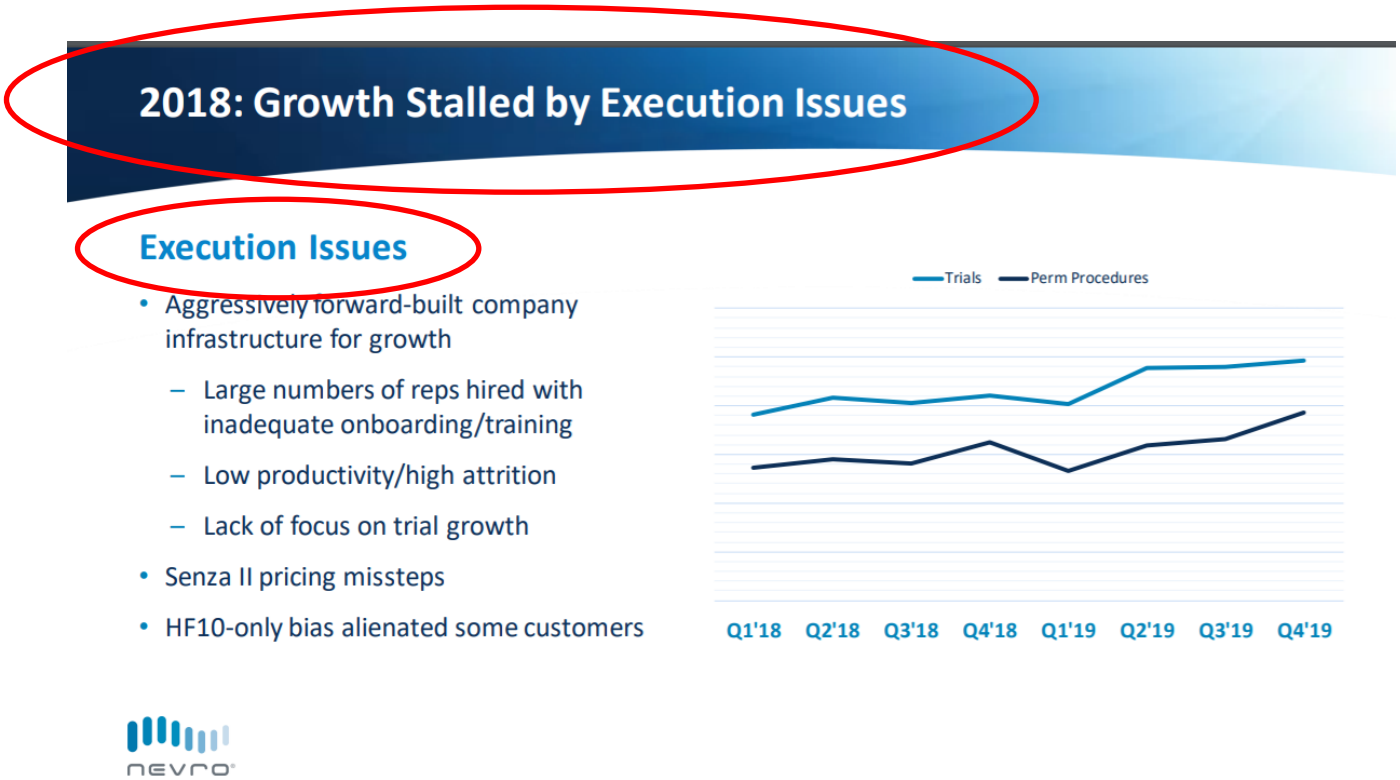
Nevro went public in November 2014 at $18/share, and launched its high frequency device in mid-2015. Sales took off: doctors were eager try a new device, and Nevro poached longtime stim reps from Medtronic, Boston Scientific, and Abbott along with their books of business, as its stock represented the first real money-making opportunity for veterans in a sleepy space. Sales grew from $70MM in 2015 to $327MM in 2017. The sell-side gushed with excitement. The honeymoon would be short-lived, however. By late 2017 – a mere 2 years after launch - growth mysteriously hit a wall. The stock, having peaked at $104 in late 2016, began to tread water. Little explanation was provided. The then-CEO blamed an alleged deceleration of the SCS market, and the stock crashed into the $30's.



Source: Capital IQ

1. Introduction to Nevro

With the stock stuck in the $30's, the CEO was ejected by the Board in March 2019 and replaced by Keith Grossman, a long-time medical device executive. Sell-side analysts tripped over themselves to upgrade and double-upgrade the stock overnight, sainting Grossman as a wizard who would quickly fix and sell the company. The stock narrative has become a simple one: "execution issues" under the previous CEO led to Nevro's growth collapse; Grossman has righted the ship; and the fruits of his turnaround will become apparent post-COVID as Nevro returns to a golden age of growth and share gains. Grossman frequently re-iterates the mis-execution narrative, such as at the JP Morgan conference in 2020 -



**Red ours for emphasis*

Source: Nevro IR page https://s24.q4cdn.com/932612397/files/doc_presentations/NVRO_JPM-2020_011520_Print_vFINAL.PDF

1. Introduction to Nevro

The purported explanation struck us as curious, however: if high frequency provides almost twice the pain relief of conventional stimulators, as claimed, why did growth collapse so abruptly, especially as its share had only hit ~15% with blue skies in front? One could reasonably expect salesforce "training" and "productivity" issues to knock a few points off growth. But for growth to implode to 0.8% YOY by 2019 – because field reps had "inadequate onboarding"? Moreover, Nevro had just stocked its field with the A-team, vacuuming up the most seasoned stim reps in the industry. The other "execution" issues Grossman claims, such as channel stuffing ("stocking"), beg the question: why was stuffing needed in the first place? In order to understand what actually went wrong, we embarked on what we believe to the most intensive and thorough investigation of Nevro to date. Our due diligence included 45+ research calls with 37 sources, representing a broad mosaic of experts on the company and its product, mechanism of action, customers, competitors, and business practices.

21 physicians and KOL's ("key opinion leaders") who implant spinal cord stimulators

- Nevro trial investigators and study authors, including a number of its highest paid per OpenPayments
- Generally high volume implanters, as they drive the vast majority of industry and Nevro volume
- Many of the most well-known and influential implanters in the space
- Broad mix of Nevro users and those who have soured on Nevro, across geographies and practice settings

9 former Nevro executives/employees

- 4 former executives
- 5 former sales personnel in the field, mostly running large territories/regions

7 executives/territory managers/sales reps at Nevro's key competitors, plus other industry experts

An intensive review of the clinical literature, public filings, transcripts, and press releases

All former employees were at least six-months removed from the company, per best practice research and compliance guidelines. All experts agreed to not provide any information which is inconsistent with any non-disclosure, confidentiality, or other agreements or understandings. We mask their names to respect their privacy.

1. Introduction to Nevro

As we interviewed former Nevro sales executives, managers, and reps, an entirely different explanation emerged for the sudden collapse in growth – and why the "attrition" was actually a mass exodus. We spoke with a district sales manager who was part of Nevro's launch team and ran a key multi-state region, which he now runs for a large competitor. His comments on Nevro's trajectory and the root cause of its troubles were echoed by one ex-employee after another – and drastically different than the one Grossman sells and Wall Street parrots: the device failed to work; the company "freaked out"; KOL's and reps fled; and reps like this one felt they could no longer ethically ask for doctor visits nor "look them in the eye."

"Six months in, I started to notice that the implants were not comparing to the outcomes in the trials*…and then, the company started seeing it. We weren't getting the results that we thought we were going to get…****the company realized that at the 18 month mark and they started freaking out. Sort of every KOL was saying the device isn't working.*** *We had this one doctor in New York who implanted 13 Nevro systems. He removed 10 of them within a year. Nevro saw that a lot of these doctors were going away. They saw that their sales reps, like me, were leaving and the number one reason was because the therapy wasn't living up to expectations."*

"They hired a really experienced sales force. They'd tell the field that they missed a step in the algorithm, to go back and start over. ***No matter what we did in the field, it didn't work****. But the company was like, "You guys missed something. We have the level one evidence. It has to work." The field reps were always communicating across the nation. The discussions among the reps were, "We're in a tough situation here." The company treated us very, very well. They paid us well. I appreciated everyone I worked with there, but it was -* ***as months went on, I would have a hard time selling this device when I didn't believe that it's right****. I've been in the spine field for a long time and a lot of these customers are my friends.* ***I couldn't look them in the eye and ask them for visits anymore, because I didn't believe in the therapy."***

"One reason for explants is that patients get sick of recharging, which can cause heating at the site and cause infections. *Patients just get pissed off because they have to recharge. The higher the frequency, the more energy it uses. Patients had to charge once a day for 30 to 45 minutes.* ***A second reason is that the therapy wasn't working so patients would just get fed up****. So they didn't want to charge anymore and they would just have the device explanted, so loss of therapy and just the burden of recharging every day."* ***– Former district sales manager***

Source: Consultation calls with experts

1. Introduction to Nevro

KOL's and ex-employees were remarkably consistent, across several dozen interviews, in explaining why Nevro's sales growth collapsed – yet we failed to see one instance of device failures, lack of efficacy, and explants being asked about or mentioned in ~5 years of earnings calls or effusive sell-side reports. We quote 4 different high-volume KOL's below, each with an eerily similar experience, as we detail in case studies on pages 95-105.

KOL #1 stated that the device stops working in months, with almost all of his Nevro implants explanted, and that other doctors have had 70-80% explant rates

"When Nevro launched in 2015, I was really interested in the data and how much better it worked than regular spinal cord stimulation. So I used it and was very impressed in the beginning. ***But then the failures just kept coming. People just kept getting explanted or the pain just kept coming back …After three to six months it was like clockwork that patients just started shitting the bed****. So I just stopped using it…It was between three to six months almost across the board…****I didn't have a single patient that made it past a year …I might have 2 back patients that still have it out of 90 I implanted with Nevro. That's not unheard of****. There are a lot, a lot, of doctors who have had that experience.* ***I know of a lot of doctors who had a 70-80% explant rate****. My overall explant rate is very low. No one can say that my Nevro explants were due to my patient selection."*

KOL #2, a former Nevro consultant, said the rapid drop-off in efficacy led doctors to sour on the device

*"I've consulted at length for Boston Scientific, Abbott, Nuvectra, and of course `Nevro over the course of my career. I have been doing implants for 20 years. I've put in probably several thousand…****What I noticed is that initially almost everybody did really well and subsequently there was a big fall off****. We would hold round tables where we would have 15 implanter leaders and I and two other moderators would talk about the space in general and* ***I found that I was not alone and that other busy implanters also had the same experience****, where initially things looked good and then there was a significant drop off to where many doctors were hesitant to use the product.*

Source: Consultation calls with experts

1. Introduction to Nevro

KOL's #3 and #4 repeated the same, indicating a widespread explants problem with Nevro's device and an actual rate far higher than the 33% finding in a recent NANS paper – potentially 50-60%. One indicated that the high frequency mechanism of action not only failed to provide pain relief, but was "hurting patients" – a finding we shall shortly detail – and causing "the nerves to become hypersensitive": "The company just lies. They're full of it."

KOL #3 confirmed Nevro's explants problem, having spoken with "hundreds of physicians" as a speaker

*"Some of the engineers at Boston Scientific went to Nevro. I know a couple of them very well. There was a pretty significant falloff in Nevro usage after the honeymoon…I made the decision that Nevro can't really be used, based on the problems we're seeing. So, the percentage of my implants that are Nevro is zero. None….**I can tell you from talking to hundreds of physicians across the United States and internationally, because I did speaking programs internationally, it's about explants.** The number of explants that you see…you can do the math. Why doesn't Nevro publish its explant data? We've asked them to do that, and they refused. You put a stimulator in, life is good for a little while. Then the honeymoon's over. Nevro doesn't talk about explant data long-term, and you need that because that's real life."*

KOL #4 stated that the 33% explant rate in a recent paper is low, and that the actual rate could be 50-60%,

*"Everything was great for a few months. But then I noticed that for a lot of the patients, **the device stopped working after three to six months…And then I noticed that the high frequency started hurting patients.. It went from being great to not working to irritating**…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**…I've been implanting for a long time and I rarely explant. Sure, sometimes stimulators don't work. But rarely do they stop working and irritate a patient. I mean, it's happened but not at the numbers we saw with Nevro. I would rarely explant people. I would say 1 or 2%, if that."*

Source: Consultation calls with experts

1. Introduction to Nevro

A longtime executive in the SCS space explained a surprising dynamic: most Nevro implanters are blissfully unaware that they have an explants problem, as they outsource all patient follow-up to Nevro reps, who then lie to the doctor about how patients are faring. We heard similar color from many implanters, which we discuss in depth in later sections. He added that Nevro's recent Omnia launch, which essentially repudiates the high frequency message it's pushed for a decade, renders the company as "hypocrites" and "liars."

"A physician friend of mine had implanted almost a hundred Nevro's at the time and I said, ***"How many of your Nevro-implanted patients still have pain relief?" He said, "All of them." I said, "How do you know that?" And he said, "Well, my Nevro rep told me that****." I said, "When's the last time you talked directly to one of your patients about how their stimulation is doing?" And he got quiet and he looked at me and he said a swear word and I said, "You've got to go back and do some research because I've dissected that study and here's why it's flawed. I'll be surprised if your statistics are as good as you say they are."*

*"****So, five weeks later, he called me up and he said, 'You were right. My Nevro rep is no longer allowed in my account****. I called one of my patients who came to me because his Nevro system wasn't working.' The Nevro rep had called my buddy to tell him the results of six patients he said are all doing fantastic. One of those patients was the patient my buddy called who needed an explant,* ***so the rep was lying to the doctor. "***

"My doctor friend ***went through all of his patients, almost a hundred of them, called them up personally, and 45% of his patients were not doing as well as the Nevro rep told him they were doing,*** *and he wound up explanting a bunch of them and trying a different product that wasn't just high frequency and those products worked.* ***The doctors that weren't on Nevro's payroll that had implanted Nevro's product, they were starting to verbalize that they were having the same problem."***

"Nevro obviously through their actions knew that their metrics were flawed, because they were saying, 'We have the panacea. It's a car with five wheels and everybody with four wheels is behind." What does Nevro do now? They've introduced a four-wheel product and they've shut their mouth about their five-wheel and basically stopped selling it. They now offer not only a high-frequency IPG, but they offer a low frequency. ***They're hypocrites. They're liars."*** ***– Longtime executive in the SCS space***

Source: Consultation calls with experts

Scorpion Capital | Nevro (NYSE: NVRO)

1. Introduction to Nevro

We are unsure whether Keith Grossman, during his ongoing ~2 year repetition of "execution issues" as the driver of no growth in 3 years, is ignorant of high frequency's lack of efficacy and resulting explants, or simply lying to investors. Although he has been portrayed as the patron saint of med-tech turnarounds, former Nevro executives and other senior executives in the space – individuals we believe to be friendly with management and the Board – speculated that Grossman did little diligence before taking the job, was sold "hook line, and sinker," remains naïve about the space, and now finds himself up the creek in a role he didn't expect, given he mistakenly presumed he could "put lipstick on a pig" and quickly flip it.

"Grossman doesn't have a strategy. This is what concerns me. This is why I don't own a penny of Nevro. Keith Grossman may have wanted to flip it in six months. *If you do not know the neuromodulation space and you're listening to the Board tell you that Rami [prior CEO] screwed this up. You think, I've talked to Kasra Amirdelfan [implanter who is the #1 recipient of Nevro payments*] and David Caraway, their Chief Medical Officer, these guys are high on it. I can come in here and look like a rock star and just not be an [redacted] like Rami, and I can flip this thing in no time because I know the investment community because of my history.* ***I would bet that that's about the due diligence that Keith Grossman did, and he was sold hook, line, and sinker. Now he's going to have to roll up his sleeves and say, 'What do I do with this thing?'"*** ***–Longtime C-level executive in the space***

*"****Grossman has a history of working with Bess Weatherman of Warburg Pincus*** *who's on the board…They move some people in, move some people out, but at the end of the day, they really control cost.* ***They don't really add true value and that's kind of how I see Grossman…I'm very underwhelmed… he's all about flipping the company*** *and making as much money as possible in the shortest amount of time.* ***I don't think there's a long-term plan there...*** *Nevro has boxed themselves into a corner and* ***now they'll die of a thousand cuts…*** *I think there's* ***a lot of window-dressing with Grossman and that's why you're not seeing this big uptake in revenue****...When I listen to earnings calls, it's 'the business has stabilized, we're excited about all these new platforms and new disease states, we're going to do more of this' but* ***at the end of the day, I just don't see it. I really don't see it."*** ***– Former Nevro executive***

Source: Consultation calls with experts; *CMS OpenPayments data for 2019, https://openpaymentsdata.cms.gov/company/100000136428

1. Introduction to Nevro

Another former Nevro executive implied Grossman is already checked out and "very busy on a lot of other things" with "other people who are running the ship." An industry executive stated his belief that even Grossman is confused by the stock, and suggested Nevro staff are skeptical of "the substance" of his efforts. The executive opined that Grossman lucked out with COVID, as it gave him a free pass for 2020, describing him as shifting from one excuse to another during his ~2 year tenure - adding that his moment of truth is imminent as the pandemic fades and the gravity of Nevro's situation becomes obvious to Wall Street.

"I also got a sense this wasn't a role that he was expecting and that he's very busy on a lot of other things he's doing. *A lot of other things, and I don't know how much attention - I mean obviously he's spending a lot of time on Nevro - but* ***I think there are other people who are running the ship*** *largely and that's sort of the sense I got from these people on the leadership team"* **– Former Nevro executive**

"I study a leader's history to see what adversity they've dealt with. Did they pull a company out of the hole against all odds? Grossman's product sold itself at Thoratec. ***I don't think he has an appreciation for what motivates the spinal cord stimulator customer****…I know for a fact, on the inside,* ***Grossman has said he's scratching his head over why the stock has done what it's done****. He may have bitten off more than he can chew…Internally at Nevro, I don't think they see the substance, based on what I've been told, and they're scratching their heads and saying, "Hey, whatever. I'll take it. I hope the stock keeps going." There aren't fundamentals behind it."* ***–Longtime C-level executive in the space***

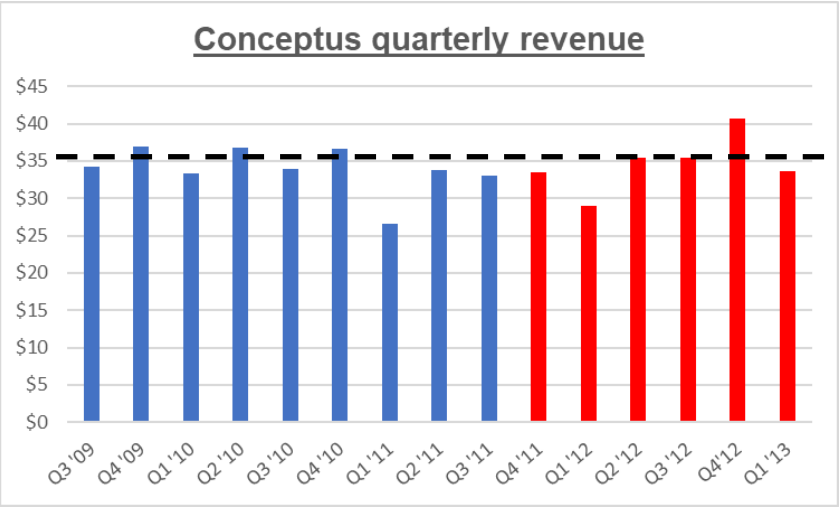
"On his first two quarterly calls he basically said, 'I'm too new to give you numbers. I'm not going to commit to anything.' ***I've said all along: eventually, this guy is going to have to perform. His timing [in getting a pass from COVID] is pretty damn good because I know the people on the street at Nevro who are selling product, and I know the roadblocks they're up against****. They haven't out-performed from a revenue standpoint. They've been given a 24-month pass. Rami was the scapegoat, and then it was, "Okay, let's give Grossman a year to get his feet under him," and now it's COVID. So, when does Nevro actually have to perform in Wall Street's eyes? They were the first company to say that that SCS market was shrinking and that just wasn't true.* ***It's that they were losing market share, and they didn't know how to explain it away."*** ***– Longtime C-level executive in the space***

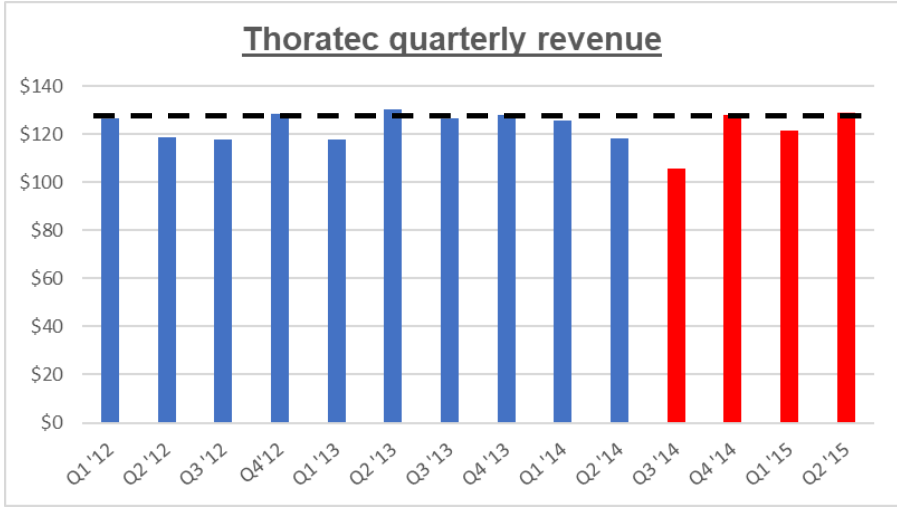
Source: Consultation calls with experts

1. Introduction to Nevro

We delved into the ex-Nevro executive's skepticism of Grossman's playbook – cutting costs and window dressing for a quick sale – by looking at the two acquisitions that are the source of his acclaim. From 1996 to 2006, Grossman was CEO of Thoratec, which sold a ventricular assist device for heart failure. By 2014, following a spate of injuries and fatalities, the stock collapsed and Grossman returned as CEO for a little over a year, flipping the company and doubling the stock. In December 2011, he joined as CEO of Conceptus, which sold a birth control device and had also hit the skids, flipping it in ~1.5 years. The quarterly trajectories at both Thoratec and Conceptus during his brief tenures show that he trimmed some costs but failed to return either company to growth. Grossman's skill is not in fixing companies, but in smearing lipstick and punting as fast as possible – in other words, a promoter. He has now been at Nevro longer than either of his last two flips, which makes us wonder: having presumably scrambled to flip Nevro since 2019 and failed, and with no skill at returning failed device companies to growth, what exactly are Nevro investors betting on after a 3-4X run?

Quarterly trend at Conceptus and Thoratec during Grossman's stints (in red) showed zero "turnaround" – canaries in the coal mine for Nevro investors





Source: Capital IQ

1. Introduction to Nevro

For those who disagree with our assessment of Grossman as just another stock promoter, we encourage them to look past his polished delivery on earnings calls and to study his last pump, Conceptus, The company sold a controversial metal birth control device called Essure, which expanded after insertion into the fallopian tube. Grossman actively promoted the supposed safety of the device long enough to find a patsy, Bayer, which paid $1.1B in 2013. Sales fell 70% a few years later with FDA action, leading Bayer to remove the device from the market - perhaps qualifying the sale as the greatest pump and dump in medtech history. The grotesque scale of the injuries – by some accounts tens of thousands to 100K+ women affected, with Bayer facing 39K lawsuits – suggests a second and equally dubious distinction: possibly the worst human catastrophe in the recent history of medical devices.

Representative Keith Grossman comments on Essure's safety

*"**First, the safety and efficacy profile of the Essure product is uniquely compelling. I mean, it really is just a terrific product** and it continues, by the way **by any medical device measure I think**, and continue to be most effective option available for permanent birth control for women." – Capital IQ earnings transcript, 2/23/2012*

Bayer to pay $1.6B to settle 90% of Essure injury claims

Source: https://www.fiercebiotech.com/medtech/bayer-to-pay-1-6-billion-to-settle-90-essure-injury-claims

Sales of Essure birth control implant to be halted by Bayer; U.S. last to sell controversial device

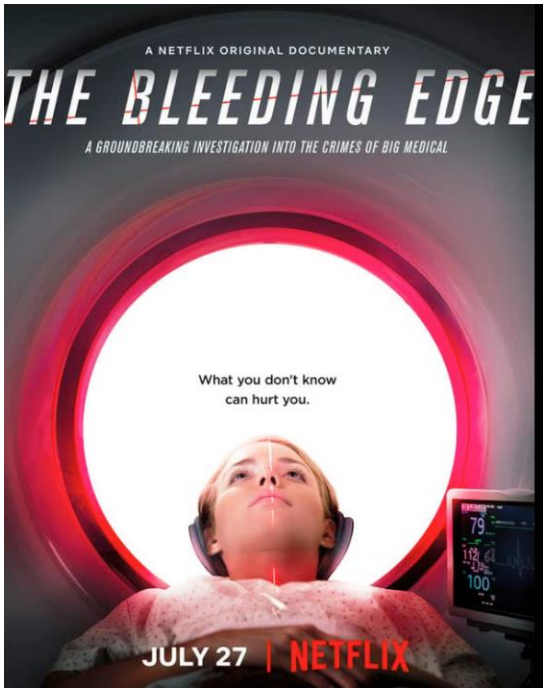
Source: https://www.washingtonpost.com/news/to-your-health/wp/2018/07/20/sales-of-essure-birth-control-implant-halted-by-bayer-u-s-was-last-to-sell-controversial-device/

Essure PMA Was Fraudulent, Patient Group Says

Source: https://www.mddionline.com/essure-pma-was-fraudulent-patient-group-says

1. Introduction to Nevro

Given the hushed reverence with which certain Wall Street analysts still speak of Grossman, notably the one who landed Nevro's last offering. we suggest watching the 2018 Netflix documentary The Bleeding Edge, which focuses on the Conceptus device and the lives that it destroyed. We found it disturbing and difficult to stomach. We get that Grossman didn't invent the device – he just pimped its safety and pushed it in other ways while trying to get a stock up – and was not alone in enabling this catastrophe. But it indicates his playbook, which we encourage investors to note, as they gauge the veracity of his claims regarding Nevro's supposed safety, efficacy, and lack of explants, particularly next week at the JP Morgan conference.



New York Times review

"But it's the interviews — watching patients recount agonies they've suffered from poorly researched and regulated medical devices — that are hardest to sit through…The Bleeding Edge" isn't an anti-medical film, but ***a look at calamities caused when the obsession for profit overwhelms an industry."*** *Source: https://www.nytimes.com/2018/07/26/movies/bleeding-edge-review-medical-devices.html*

Clips from documentary

[11:05 minutes in] "My husband has gone with me to the hospital and we're in a room…and just ***blood exploded out of me…it looked like a horror scene… there were large clots all over the floor****. And he went out into the hallway and just screamed for someone to come…I was really thinking about what's going to happen to my kids if I don't wake up."*

1. Introduction to Nevro

Devices with Essure's profile - lack of efficacy plus severe side effects – are inherently high-risk businesses that tend to gradually fade or abruptly implode. We note Penumbra's device recall the other week following an investigative short report. While Wall Street has endowed spinal cord stimulation with institutional respectability, now that there's a pure play stock that pays banking fees, Nevro is just another menu offering at the same sketchy pain clinics responsible for some of the worst abuses in healthcare, such as the opioid crisis and the Insys fentanyl racket. We note a number of long-form investigations of abuses in the stimulator space, which report that the devices typically fail to work and have one of the worst safety records of all medical devices.

Associated Press investigation

Patients shocked, burned by device touted to treat pain

By MITCH WEISS and HOLBROOK MOHR November 26, 2018

"But the stimulators — devices that use electrical currents to block pain signals before they reach the brain — are ***more dangerous than many patients know, an Associated Press investigation found. They account for the third-highest number of medical device injury reports to the U.S. Food and Drug Administration, with more than 80,000 incidents flagged since 2008****. Patients report that they have been shocked or burned or have suffered spinal-cord nerve damage ranging from muscle weakness to paraplegia, FDA data shows. Among the 4,000 types of devices tracked by the FDA, only metal hip replacements and insulin pumps have logged more injury reports.* ***The FDA data contains more than 500 reports of people with spinal-cord stimulators who died****, but details are scant…"*

"The AP reported on spinal stimulators as part of a nearly yearlong joint investigation *of the global medical devices industry that included NBC, the International Consortium of Investigative Journalists and more than 50 other media partners around the world. Reporters collected and analyzed millions of medical records, recall notices and other product safety warnings, in addition to interviewing doctors, patients, researchers and company whistleblowers."*

Source: https://apnews.com/article/38145385944248b5bf8d442579505258

1. Introduction to Nevro

Aside from lack of efficacy and side effects, the AP's investigation found – as did ours as we detail on pages 218-233 - that the stimulation space is driven by rampant manipulation and exploitation of chronic pain patients. The AP states that of 40 stimulator patients they interviewed, "nearly all" indicated their pain returned, 28 said they were worse off after the implant, and more than half said "they feared their doctors would cut off their pain medications" – a pressure tactic that ex-Nevro executives and sales reps indicate is widespread. Another investigation that queried insurers came to similar conclusions, with a workers comp firm saying that stimulators are their "most frequent failed medical device" and cause complications "90% of the time." We note that Washington state recently ended reimbursement for stimulators, publishing a detailed study slamming the devices as useless.

Associated Press investigation

*"Taft is one of **40 patients interviewed by the AP who said they had problems with spinal-cord stimulators…Twenty-eight of them said their spinal-cord stimulators not only failed to alleviate pain but left them worse off** than before their surgeries…More than half the patients interviewed by the AP said they felt pressured to get stimulators because they **feared their doctors would cut off their pain medications** — the only thing helping them…The experience of nearly all the 40 patients interviewed by the AP mirrored McJunkin's: Their pain was reduced during the trial but returned once their stimulators were implanted."*

Insurance trade article commenting on stimulators

"Spinal cord stimulators are some of the most problematic implants, according to various insurers, with a recent study showing a high removal rate**…"[W]e don't see a lot of success with them at all," she said. "It's frustrating…"…Spinal cord stimulators are **the most frequent failed medical device** for workers compensation claimants at Portland…The devices **"more often fail than succeed,"** and he estimates that they **cause complications in MEMIC comp patients 90% of the time…"

Washington state study of SCS outcomes and side effects

*"[W]eak evidence exists that SCS may provide temporary improvement of pain in some patients, but **there is no evidence of mid or long term pain improvement."***

Source: https://apnews.com/article/86ba45b0a4ad443fad1214622d13e6cb; https://www.nbcnews.com/health/health-care/spinal-cord-stimulators-help-some-patients-injure-others-n940131; https://www.businessinsurance.com/article/20190701/NEWS08/912329205/Comp-payers-wary-of-implanted-pain-relievers-; https://www.hca.wa.gov/assets/program/spinal-cord-stimulation-signal-update-20180807.pdf

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In 2014, the Wall Street Journal investigated spinal cord stimulators, analyzing adverse-event reports submitted to the FDA and finding over 100 cases of partial or permanent paralysis after implantation – we wonder how many more cases have occurred since 2014. The article referenced a Duke paper which reviewed 12K insurance claim records and found that 1 out of every 100 stimulator patients experienced "some degree of spinal-cord or spinal nerve-root damage, which typically results in injuries ranging from muscle weakness to complete paraplegia." A neurologist/pain doctor critical of the space referenced the article and noted a comment by a long-time surgical nurse, who detailed the slew of adverse effects she has witnessed and described the stimulator industry as a hustle that preys on desperate patients.

When Spine Implants Cause Paralysis, Who Is to Blame?

Spinal-Cord Simulators Are Intended to Relieve Pain

Mr. Greenwood, 66 years old, is among more than 100 patients who have experienced partial or permanent paralysis in recent years after having spinal-cord stimulators inserted in their backs, according to a Wall Street Journal analysis of adverse-event reports submitted to the U.S. Food and Drug Administration, and a review of medical

*"I have been a surgical nurse for 40 years and have seen many patients receive SCS…and many, many fail, or return to surgery for fractured electrode wires, misplaced wires, or infected battery pockets…spinal fluid leaks…severe headaches…**[they] find out in 2-8 months that they wish they never had agreed to it …***

Comments by a nurse on a blog discussing the WSJ article

06/07/2012 at 11:25 pm I have been a surgical nurse for 40 years and have seen many patients receive SCS…and many, many fail, or return to surgery for fractured electrode wires, misplaced wires, or infected battery pockets, besides complicated problems, or "lack of positive results, or battery revisions, or electrode repositionings." Some patients have even developed spinal fluid leaks when the spinal dura layer has been torn during implanting the electrode wires, and they develop severe headaches, and have to return to surgery for the leak to be repaired. Many pain management doctors are convincing patients that this is a great way to treat their pain, and they find out in 2-6 months that they wish they never had agreed to it. Sure, there are some patients that get some relief, but this procedure has been pushed on the population of chronic pain patients, when they are at their worse condition, and willing to try anything….at any expense, and the companies and implanting doctors are getting the money. More patients need to learn the truth about these devices! Anonymous…. and never allowed them to put one of those things in me…but many tried!

Source: https://www.wsj.com/articles/SB10001424052702304512504579493843647492538; https://painsandiego.com/2014/08/06/spinal-cord-stimulators-paralysis-adverse-effects/

1. Introduction to Nevro

It is therefore not surprising that Nevro and its peers appear downright paranoid about doing any long term studies, preferring to cease evaluation at the 3-12 month mark lest they blow up reimbursement. The "Clinical Evidence" page on Nevro's site has a chart for "Long-Term Responder Rates," which the footnotes indicate refer to only 12 and 24 month data – an eon in the stim space. We quote one of Nevro's consultants and highest volume implanters, who despite his enthusiasm notes the rapid fall off in efficacy within 1-2 years; admits that 50% of patients need to consider an explant by year 5; and that stimulators fail to reduce the need for pain medications like opioids. A second Nevro implanter stated that "long term, stimulators don't work as well."

"All of the SCS devices at the five-year mark really start to drop off. I'm always curious about what it is that happens after a year or two for these patients…No one has really studied that. That's the problem*. For all SCS devices, I would say 50% have reached the point at 5 years where it's no longer helpful enough to keep using them and maybe even consider an explant. At 5 years they're explants or they move on to a different therapy but continue to use the stim, or they may even stop using the stim. We've seen patients say I am using the stim but I still need injections every three months. Or I need oral opioids. Some go on to have pumps. SCS was originally sold as a good opportunity to avoid having to return to ongoing injections or opioids. There was a retrospective review of changes in opioid use with stim because many companies would say "Oh, you know, you just how to solve the opioid crisis", but they found that you know* ***with stim opioids don't necessarily go down."***
– High volume Nevro implanter

*"****Long term, stimulators don't work as well. Patient are desperate****, say it works, then say it doesn't work. It's usually a misleading trial in a patient. The published data says stim doesn't work in 30% of patients."* ***– High volume implanter and moderate Nevro user***

"There were less than 10 neuromodulation studies in 50 years, only 6 even worth quoting. ***There's not much evidence."*** ***– Longtime Medtronic executive in SCS***

Source: Consultation calls with experts

1. Introduction to Nevro

For those who dismiss journalistic investigations and insurer studies in the face of a stock that's worked, we caution that reimbursement (as we detail on pages 198-206) as well as regulatory scrutiny of stimulators have escalated in recent months. First, in June, Public Citizen published a high-profile report slamming the FDA's lack of oversight of stimulators, citing their lack of efficacy, shoddy studies, and "evidence of substantial harm," calling out Nevro in particular. Second, in August, CMS noted their overuse and proposed a new prior authorization requirement for stimulators. Third and most ominously, in September, the FDA issued a relatively rare "Letter to Healthcare Providers" specifically on spinal cord stimulators. The letter's tone suggests alarm, noting ~108,000 MDR's (medical device reports) received by the FDA including ~78k injuries, 29k malfunctions, and 500 deaths – and concludes by urging providers and patients "to report any adverse events…with SCS" to the FDA.

BRIEF

FDA flags 428 spinal cord stimulator patient deaths, urges more tests before implant

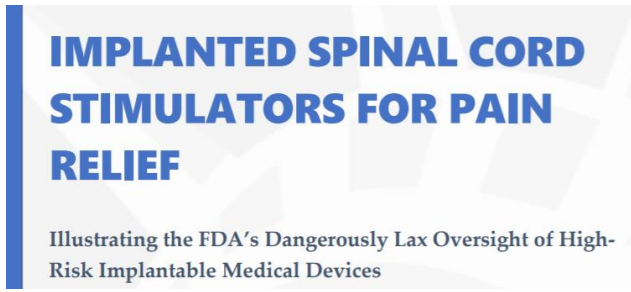
Source: https://www.medtechdive.com/news/fda-flags-428-spinal-cord-stimulator-patient-deaths-urges-more-tests-befor/584714/

FDA "Letter to Healthcare Providers"

The FDA recently reviewed the medical device reports (MDRs) received between July 27, 2016 and July 27, 2020 associated with spinal cord stimulation devices intended for pain. During this period, the FDA received a total of 107,728 MDRs related to spinal cord stimulators intended for pain, including 497 associated with a patient death, 77,937 with patient injury, and 29,294 with device malfunction. The MDRs include Patient Problem Codes (PPCs) and Device Problem Codes (DPCs), which describe serious side effects on a

Source: https://www.fda.gov/medical-devices/letters-health-care-providers/conduct-trial-stimulation-period-implanting-spinal-cord-stimulator-scs-letter-health-care-providers

Public Citizen report



Source: https://www.citizen.org/wp-content/uploads/2526_200610_Spinal-Cord-Stimulator-Report_FINAL.pdf?eType=EmailBlastContent&eId=765162c2-baeb-41db-a6ae-0694813ad96c

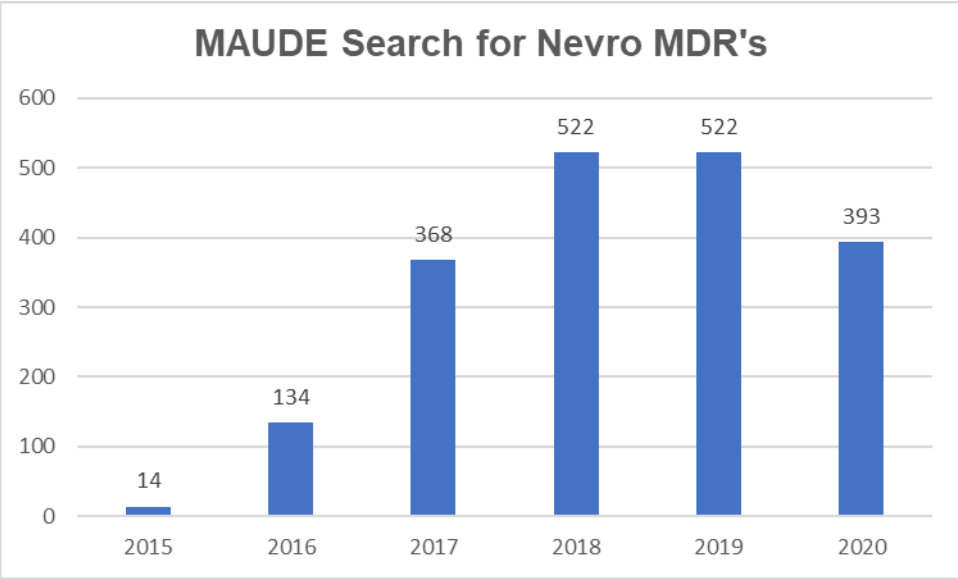
Lax testing of spinal cord stimulators threatens patient safety, consumer group warns

"These deficiencies have resulted in serious injury to tens of thousands of patients"

Source: https://www.icij.org/investigations/implant-files/lax-testing-of-spinal-cord-stimulators-threatens-patient-safety-consumer-group-warns/

1. Introduction to Nevro

The FDA's move signals that the SCS space finally has a target on its back. A recall is the last risk on any Nevro investor's mind, but as a poster child for abuses in the space, its high frequency technology strikes us the obvious and lowest hanging fruit for the FDA . With explant rates that KOL's indicate dwarf other stimulators; KOL commentary such as "smoke and mirrors," "a big scam," "criminal" data manipulation, and "falsification of data"; and KOL's and ex-employees suggesting adverse effects unique to high frequency and an internal cover-up, we suspect all it would take for Nevro's endgame to begin would be for whistleblowers to come forward. The recent Public Citizen report criticized the lack of Class 1 recalls in the SCS space, and recommended that the FDA re-assess their safety and determine "whether any of them should be removed from the market." We presume such an analysis would begin with MDR's including for Nevro's device. Our MAUDE search returned 219 events from 2015 to 2020 under "Event Type: Death" and "Manufacturer: Nevro" and ~2000 MDR's in total since 2015.



Public Citizen recommendations on SCS recalls

"Given the large number of serious adverse events associated with the use of implanted spinal cord stimulators, the relatively small number of recalls and the lack of any Class 1 recalls is troubling and suggests dangerously inadequate postmarket surveillance of these devices."

"Reassess the safety of all implanted spinal cord stimulators for pain relief and determine whether any of them should be removed from the market"

Source: FDA MAUDE database searches; https://mkus3lurbh3lbztg254fzode-wpengine.netdna-ssl.com/wp-content/uploads/2526_200610_Spinal-Cord-Stimulator-Report_FINAL.pdf

1. Introduction to Nevro

A number of KOL's stated their belief that Nevro's high frequency mechanism of action is uniquely dangerous versus conventional low frequency stimulators, a finding supported by extensive posts in Nevro patient support groups on Facebook. One KOL indicated that he and "a lot of other doctors" now believe that overwhelming the spinal cord with high frequency backfires and induces rapid tolerization and loss of efficacy. He noted an emerging consensus in the field against high frequency approaches, with key players now shifting to lower energy devices. He noted that "the pathological changes" caused by Nevro's device – such as inflammation and cell formation – are actively being studied. Any such studies, on top of papers we believe may be in peer review regarding Nevro's explant rate, would be devastating – given that its fate remains inextricably tied to high frequency, with even its new Omnia device as nothing more than a high frequency stimulator in disguise (p.130-152).

*"**You can only beat on the spinal cord so long before a refractory response happens. Look at drugs –** ones that effect the nervous system lead to tolerance. If you take two Vicodin a day you need four a day after 6 months to get the same effect because your nervous system is plastic. It accommodates when you put in that much energy. **The pathological changes that may have occurred in patients with Nevro's HF10 therapy are being studied."***

*"**I believe, and a lot of other doctors believe, that you can only pound on the spinal cord so much. You're seeing a shift now**, where other companies are pulsing the energy where it's on for 30 seconds, off for a couple of minutes, repeat, as a potential way **to mitigate the tolerance that occurs in the nervous system."***

*"I'm saying it's just too much energy and you have to back off. **Either the cells are down-regulating and can't hear the noise anymore, or there's an inflammatory response to high frequency and you are get cell formation that's impeding the electrical signal**. I don't know, but there's definitely something happening neurologically. **We've seen this in people who have had chronic stimulation at very high frequencies**. If you crank it up to 8 millivolts, which is a lot, that works but the patient will burn out in a few years. There's only so much you can hit the cord with. It's either downregulation, tolerance which is similar but not the same, or an inflammatory response that's impeding the signal." **– KOL and former Nevro consultant***

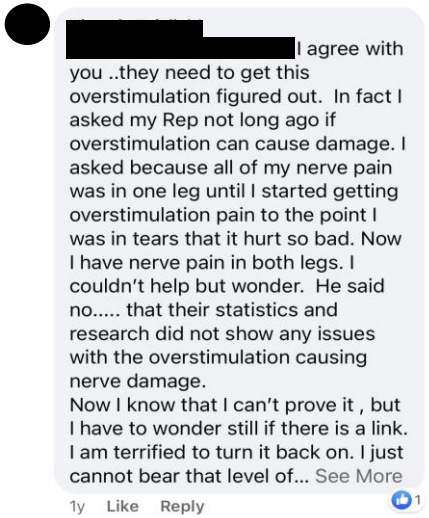
Source: Consultation calls with experts

Scorpion Capital | Nevro (NYSE: NVRO)

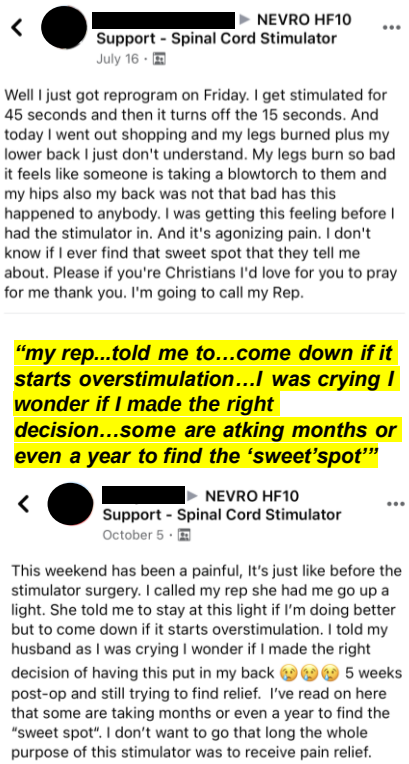
1. Introduction to Nevro

Patients posts on Facebook groups corroborate KOL's concerns of flooding the spine with high frequency, indicating alarming and widespread problems with Nevro's device. Patients use the term "overstimulation" or "overstim" to describe the phenomenon and indicate it subsides when the device is turned off. The seemingly endless number of posts point to its scale: "I was in tears from the level of overstimulation"; "over two years straight, brutal as hell"; "terrified to turn it back on"; "feels like someone hit my legs with a baseball bat; legs and back "burn so bad" like a "blowtorch"; "I was crying" wondering "if I made the right decision" to have the implant; and "nobody will admit to it," presumably the company.

"I started getting overstimulation pain to the point I was in tears that it hurt so bad…I am terrified to turn it back on…I just cannot bear that level…"

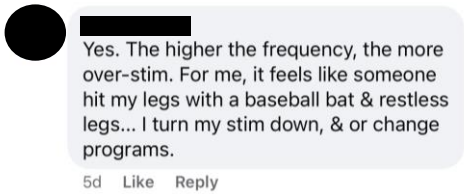


"my legs burn so bad it feels like someone is taking a blowtorch to them"

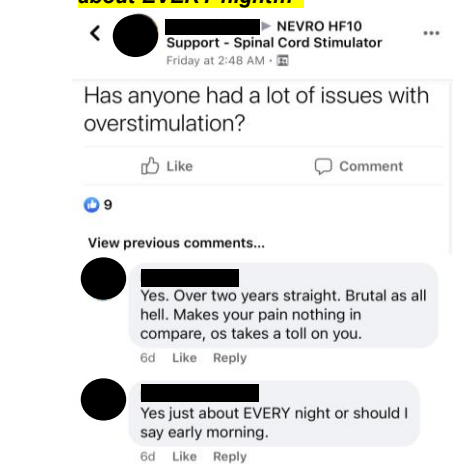


"my rep…told me to…come down if it starts overstimulation…I was crying I wonder if I made the right decision…some are atking months or even a year to find the 'sweet'spot'"

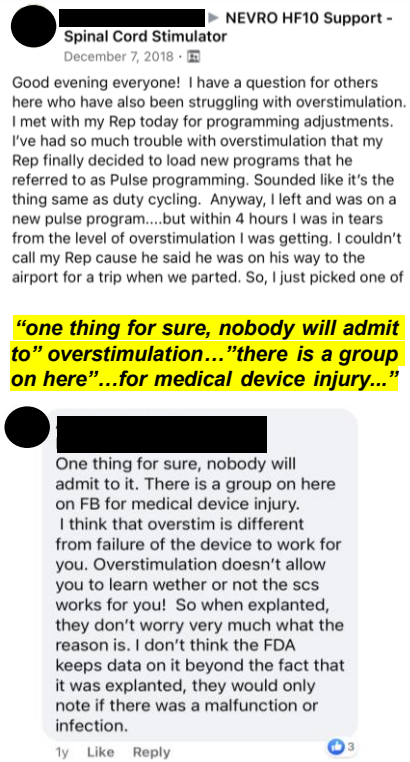
"the higher the frequency, the more over-stim…feels like someone hit my legs with a baseball bat…I turn my stim down…"



"over two years straight" of overstimulation…"make your pain nothing in compare [sic] or takes a toll on you."; overstimulation "just about EVERY night…"



"I've had so much trouble with overstimulation that my rep finally decided to load new programs…but within 4 hours I was in tears from the level of overstimulation I was getting"



"one thing for sure, nobody will admit to" overstimulation…"there is a group on here"…for medical device injury…"

Source: Nevro Facebook supports groups –https://www.facebook.com/groups/213633049377315; https://www.facebook.com/groups/us.nevro; https://www.facebook.com/groups/886079031527511;

Scorpion Capital | Nevro (NYSE: NVRO)

1. Introduction to Nevro

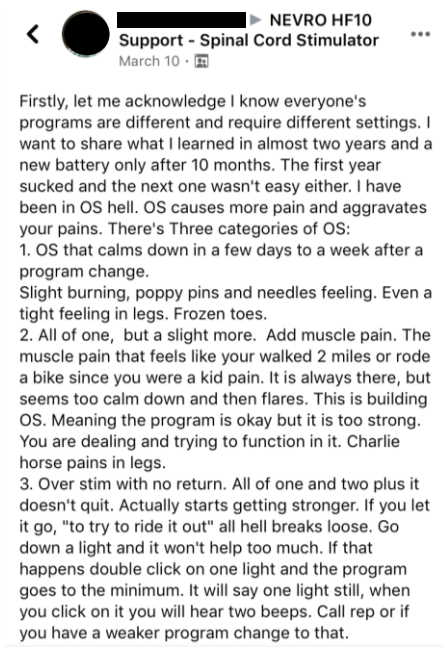
One patient states her device has been reprogrammed "at least 40 times over a year by a very experienced rep" in a futile attempt as her "legs continue to be overstimulated brutally to a point I have to turn it off every time," reporting "NO overstimulation pain with device off" and that "I just can't go back to that overstimulation pain. I just can't." Another details two years of "OS hell" with variants like burning, frozen toes, or simply "all hell breaks loose." We find it telling that patients report overstimulation symptoms vanish when they turn off the device,

"overstimulation pain is unbearable..reprogrammed at least 40 times…we're tried everything…my rep has not reached out to my since my surgery…the overstimulation pain is so brutal I just can't continue to test high frequency programs indefinitely…"

[redacted] ▶ NEVRO HF10 Support - Spinal Cord Stimulator
July 25, 2019 ·

Hi Everyone ! First I want to say how much I value everyone's opinion here. My permanent implant was August 2018 almost a year ago. Unfortunately I'm one of those people who is easily overstimulated by this Nevro device. Not mild but the overstimulation pain is unbearable. I've been reprogrammed at least 40 times by a very experienced Rep. We've tried everything. Pulse programming. Finally he loaded Dual programs, one for my lumbar and one for my legs with pulse....but my legs continue to be overstimulated brutally to a point I have to turn it off every single time. [..]
recovering well. My pain meds were not only controlling my post op pain but a fair job of controlling my lumbar and leg pain....and NO overstimulation pain with the device off was huge. I found myself actually NOT wanting to turn it back on. I have truly hit a wall. I just can't go back to that overstimulation pain. I just can't.
My Rep has not reached out to me since my surgery and now I don't even want to talk to him. My last reprogramming was a few days before my surgery and I asked him at the time if he would load at least one low [..] frequency program that I could try to maybe get through my surgery with no overstimulation pain and he flat out refused
Saying we are not there yet.
Well, I AM there. I guess he doesn't care because he still refused.
The overstimulation pain is so brutal I just can't continue to test high frequency programs indefinitely.
I saw my pain doctor on Monday and told him I can't continue to test high frequency programs. He knows how I've suffered with the overstimulation pain. He suggested that maybe I should just let him take it out.....But it seems like a no brainer to me...since I

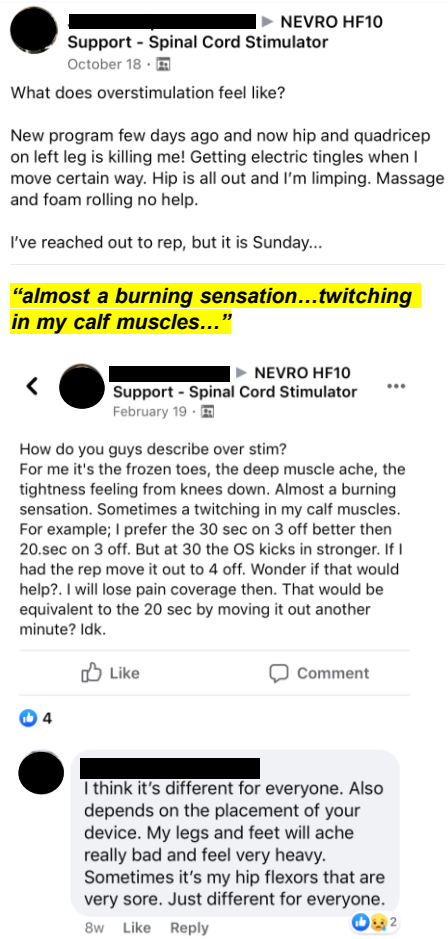
"I have been in OS hell. OS causes more pain and aggravates your pains…frozen toes…charle horse pains in legs…all hell breaks loose…"



[redacted] ▶ NEVRO HF10 Support - Spinal Cord Stimulator
March 10 ·

Firstly, let me acknowledge I know everyone's programs are different and require different settings. I want to share what I learned in almost two years and a new battery only after 10 months. The first year sucked and the next one wasn't easy either. I have been in OS hell. OS causes more pain and aggravates your pains. There's Three categories of OS:
1. OS that calms down in a few days to a week after a program change.
Slight burning, poppy pins and needles feeling. Even a tight feeling in legs. Frozen toes.
2. All of one, but a slight more. Add muscle pain. The muscle pain that feels like your walked 2 miles or rode a bike since you were a kid pain. It is always there, but seems too calm down and then flares. This is building OS. Meaning the program is okay but it is too strong. You are dealing and trying to function in it. Charlie horse pains in legs.
3. Over stim with no return. All of one and two plus it doesn't quit. Actually starts getting stronger. If you let it go, "to try to ride it out" all hell breaks loose. Go down a light and it won't help too much. If that happens double click on one light and the program goes to the minimum. It will say one light still, when you click on it you will hear two beeps. Call rep or if you have a weaker program change to that.

"electric tingles…I'm limping…"



[redacted] ▶ NEVRO HF10 Support - Spinal Cord Stimulator
October 18 ·

What does overstimulation feel like?

New program few days ago and now hip and quadricep on left leg is killing me! Getting electric tingles when I move certain way. Hip is all out and I'm limping. Massage and foam rolling no help.

I've reached out to rep, but it is Sunday...

"almost a burning sensation…twitching in my calf muscles…"

[redacted] ▶ NEVRO HF10 Support - Spinal Cord Stimulator
February 19 ·

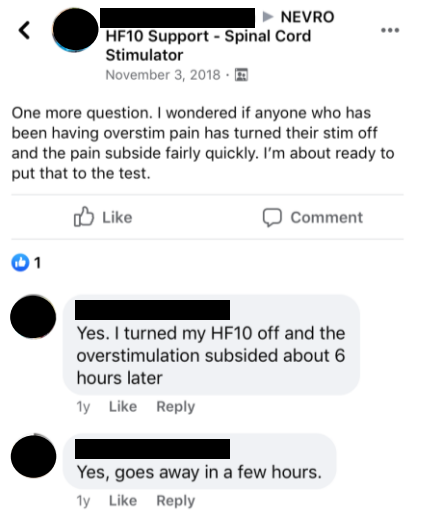
How do you guys describe over stim?
For me it's the frozen toes, the deep muscle ache, the tightness feeling from knees down. Almost a burning sensation. Sometimes a twitching in my calf muscles. For example; I prefer the 30 sec on 3 off better then 20.sec on 3 off. But at 30 the OS kicks in stronger. If I had the rep move it out to 4 off. Wonder if that would help?. I will lose pain coverage then. That would be equivalent to the 20 sec by moving it out another minute? Idk.

Like Comment

4

[redacted]
I think it's different for everyone. Also depends on the placement of your device. My legs and feet will ache really bad and feel very heavy. Sometimes it's my hip flexors that are very sore. Just different for everyone.
8w Like Reply 2

"I turned my HF10 off and the overstimulation subsided about 6 hours later"; "goes away in a few hours" after turning off the device



[redacted] ▶ NEVRO HF10 Support - Spinal Cord Stimulator
November 3, 2018 ·

One more question. I wondered if anyone who has been having overstim pain has turned their stim off and the pain subside fairly quickly. I'm about ready to put that to the test.

Like Comment

1

[redacted]
Yes. I turned my HF10 off and the overstimulation subsided about 6 hours later
1y Like Reply

[redacted]
Yes, goes away in a few hours.
1y Like Reply

Source: Nevro Facebook supports groups –https://www.facebook.com/groups/213633049377315; https://www.facebook.com/groups/us.nevro; https://www.facebook.com/groups/886079031527511;

Scorpion Capital | Nevro (NYSE: NVRO)

1. Introduction to Nevro

High frequency stimulation rapidly drains the battery, requiring daily recharging, and patients report heating and burning at the battery site as they re-charge, discussing infections, swelling, redness, and other problems that appear to be related to its power intensity. One person described it "as if I am being branded" "at least 2-3 times per week" which he appears to blame for sudden-onset leg paralysis and 3 falls. We note the number of posts where patients regret getting the device and say they can't wait to have it explanted.

"feel as if I am being branded…at least 2-3 times per week…I have fallen 3 times…zero feeling on my left leg…I have no warning"

[redacted] ▶ NEVRO HF10 Support - Spinal Cord Stimulator
November 25, 2018 ·

I have said nothing public about my problems with my scs. But I have had a issue where my battery is since my surgery a year ago in December. Basically the only way to describe it, is I feel as if I am being branded. This happens at least 2-3 times per week. My contact rep and physician have been aware, no answer was given. This past week the rep looked at it and I may have a wire between battery and my skin is how I understood the conversation. Now, for the most important issue. They don't believe it's related but, this never happened prior to my implant. I have fallen three times since my scs surgery. It is the same thing each time. I will get up from a setting position, I will lead with my left leg to walk, I have zero feeling on left leg from my hip down. I have no warning ⚠️ of any type ~to know this is about to happen, it is complete paralysis. Not to sound grateful, but I am thankful it is my left leg and not my right. I thought~if I was driving, those five seconds could cost me and someone else their life. This also has been reported to my rep. Again, no answer. I am grateful that I did not injure myself but a few bruises and a small cut. I also was caught on two of the falls, just prior of hitting my head on the concrete. I hope everyone has good things

"charging site…sore…pocket burn….where battery site is…"

[redacted] ▶ NEVRO HF10 Support - Spinal Cord Stimulator
May 23, 2019 ·

went for my 3 month check up as i have been suffer from lower back burning and right leg burning and very painful also had trouble with charging site veru sore and very uncormable
doctor say now im suffer from pocket burn ie where the battery site is so off to get some from the

"battery site is red and hot and sore"; "people here have said that their battery sites get hot when they charge…"

[redacted] ▶ NEVRO HF10 Support - Spinal Cord Stimulator
January 23, 2019 ·

Infection??? I do not have much redness but my battery site is red and hot and sore. How do you know if it might be infected? Surgery Dec.12, 2018

Like Comment

[redacted]
Other people here have said that their battery sites get hot when they charge. Is there swelling, if so have someone draw an outline around it and if the swelling gets worse go to ER. To be totally safe I would at least put a call in to your doctor.
1y Like Reply 1

"I'm a year in…and I get burning, shocks…resetting it hasn't worked…I'm mentally and physically drained"

[redacted]
I'm a year in already and I get burning,shocks and pressure pain😔I really keep trying to have it removed because resetting it hasn't worked and I'm so frustrated that I actually leave it off and when I recharge to put it back on,it all starts again.Im mentally and physically drained
8w Like Reply 1

"burning at and around the battery site…still having it happen a lot"

[redacted] ▶ NEVRO HF10 Support - Spinal Cord Stimulator
October 27 ·

Does or did anyone experience burning at and around the battery site? I am 3 weeks post op from the permanent implant, and still having it happen a lot.

"burning sensation at the battery site"

[redacted] NEVRO HF10 Support - Spinal Cord Stimulator
February 6 ·

Has anyone had a burning sensation at the battery site and in the center of your back had to call my Rep he told me to turn it off for 48 hrs. I hope it helps I have to go to the surgeon Monday to check Hope it does not have to be removed Horrible

"random burning…same side as the stimulator"

[redacted] ▶ NEVRO HF10 Support - Spinal Cord Stimulator
July 13 ·

Hi group has anyone had random burning without injury in their leg same side as the stimulator ? Last few days and it's going right down from the middle of the outside of my thigh to my knee

"battery site never stopped hurtin and wasn't getting relief so it's going to be taken out"; "mine feels like it burns me"

[redacted]
My battery site never stopped hurting and wasn't getting relief so it's going to be taken out in a few weeks. I kept getting overstimulated hope you get it figured out soon.
33w Like Reply

[redacted]
Kimberlee Titus-Bean yah mine feels like it burns me. How long did you have it in. Don't they charge twice for the surgery and removing it. Then go through recovery again. It sucks that with the trial it worked but it was just the leads. We didn't experience a battery inside us. Kind of wish I stuck with my decision of never doing it
33w Like Reply 1

"pain was so bad…couldn't walk, sit, lay….battery area so swollen where they drained blood"

[redacted] ▶ NEVRO HF10 Support - Spinal Cord Stimulator
August 24, 2019 ·

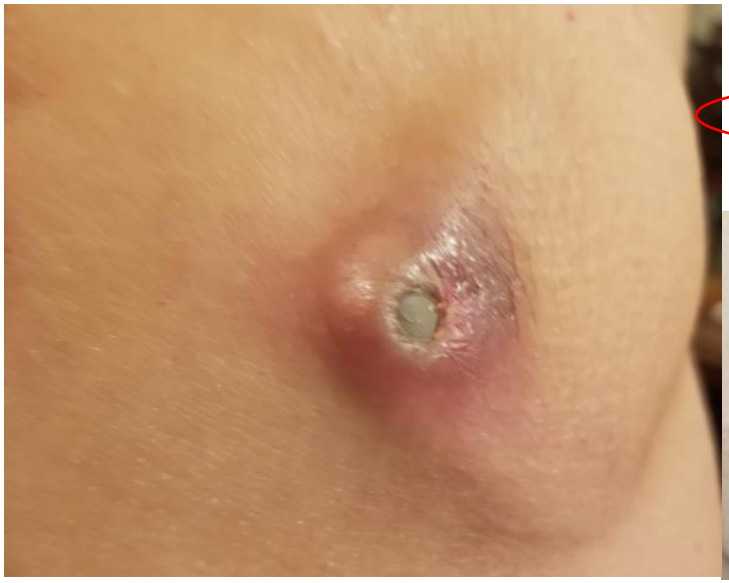
So I am 12 days post op. I have had so much trouble. The pain has been unbearable. Battery site is annoying. Yesterday I went in. Because I couldn't do anything without being in tears. The pain was so bad. Couldn't walk, sit , lay so I was told to go in. My battery area so swollen where they drained blood. Said could be a few more times. Which it is hurting again So over it already. What I been worried about before this surgery has happened. Can't get any sleep or get comfortable.

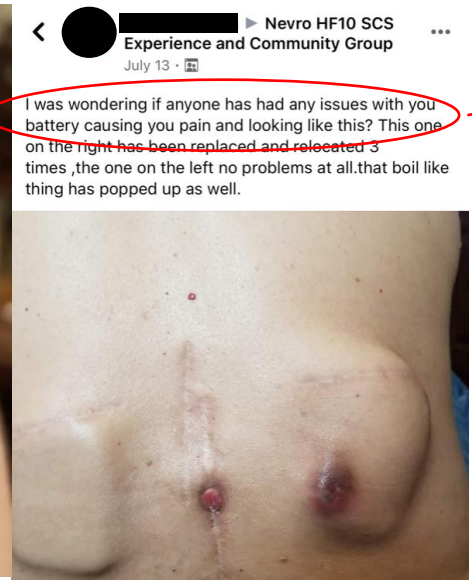
Source: Nevro Facebook supports groups –https://www.facebook.com/groups/213633049377315; https://www.facebook.com/groups/us.nevro; https://www.facebook.com/groups/886079031527511;

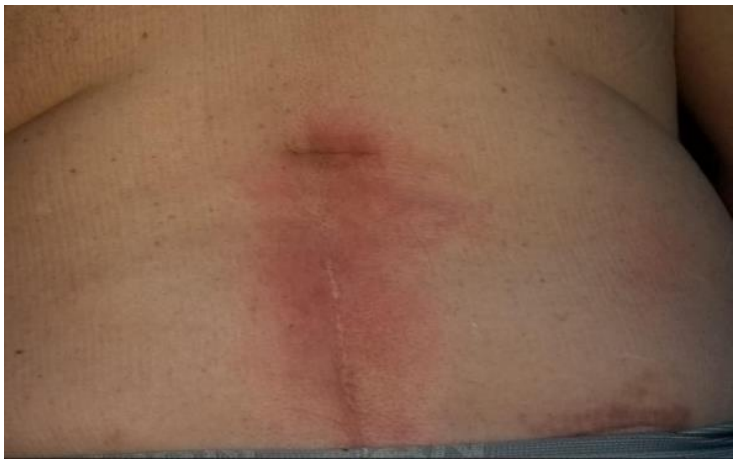
Scorpion Capital | Nevro (NYSE: NVRO)

1. Introduction to Nevro

Heating and burning at the battery site appear to cause holes, boils, infections, indicated in pictures in Nevro FB groups. A patient recently posted pictures to show the progression, asking if anyone else had their "battery causing you pain and looking this?" – to which a number said yes. Note the two batteries protruding in her back – evidence of doctors implanting "one stimulator and then another and another" to make money (p.230-232).







Patient asked if others had similar experiences, to which a number said yes

[redacted]
My wife has one of these and if it looked like that, she would be at the emergency room. She had sepsis in January 2017, and it started out looking much better than that. In 4 days when she had surgery to remove it, she had a hole that was 3" x 5" and 1 3/4" deep. Don't wait...

[redacted]
One quick question.... do you smoke? I do and I had a very similar wound that had to be cleaned and a stitch put in. Took it a while to heal.. Drs had told me and i believe it stemmed from smoking..

[redacted] please do I got a hole where my battery was put in old picture but it still look like this but is opening up now. My battery was not place in deep enough.

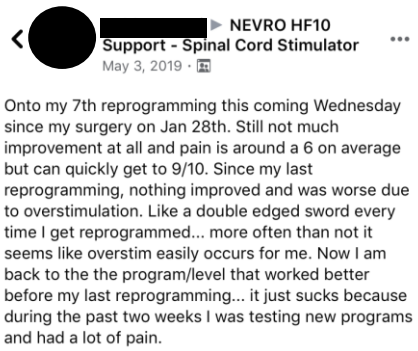
Source: Nevro Facebook supports groups –https://www.facebook.com/groups/213633049377315; https://www.facebook.com/groups/us.nevro; https://www.facebook.com/groups/886079031527511;

Scorpion Capital | Nevro (NYSE: NVRO)

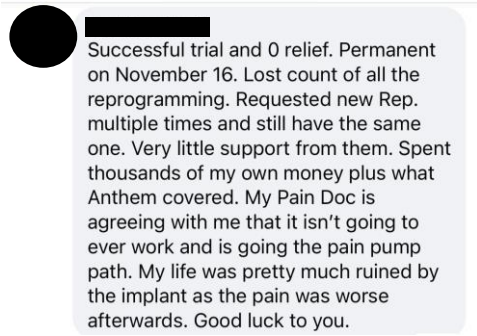
1. Introduction to Nevro

Aside from "overstimulation" and burning, patients detail endless reprogramming cycles in futile attempts to get the device to work, sometimes going in circles for years until the device is explanted or permanently switched off. Former Nevro employees describe reprogramming as a key area of billing fraud, where the rep does it but the doctor bills for it, on top of stretching programming across multiple appointments to bill repeatedly for the same task. The sense one gets from Facebook posts is not of HF10 programming as a scientific process, but of something akin to shamanism, divination, or witchcraft – in other words, quackery or a hustle.

"onto my 7th reprogramming…still not much improvement at all…since my last reprogramming, nothing improved and was worse due to overstimulation…like a double edged sword every time I get reprogrammed"

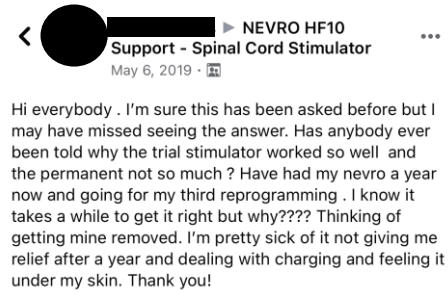


"lost count of all the reprogramming…my pain doc is agreeing with me that it isn't going to ever work….my life was pretty much ruined by the implant as the pain was worse afterwards…"



"…it's been nothing but having it reprogrammed…"

"…have had my nevro a year now and going for my third reprogramming…I know it takes a while to get it right but why???? Thinking of getting mine removed…"



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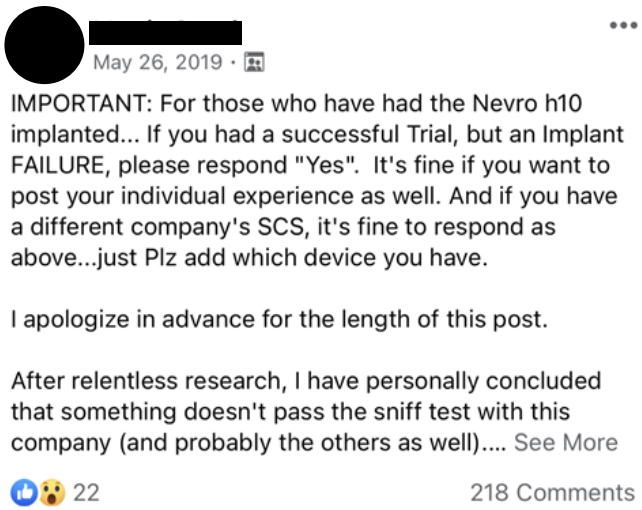
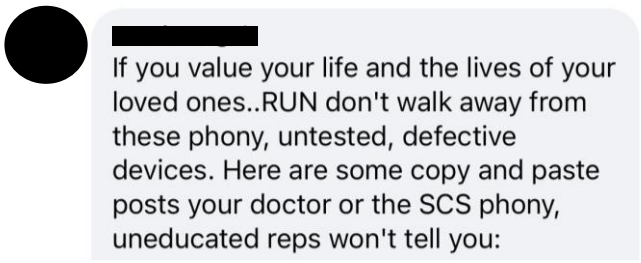
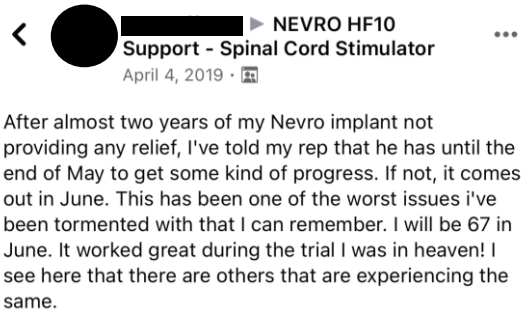
Scorpion Capital | Nevro (NYSE: NVRO)

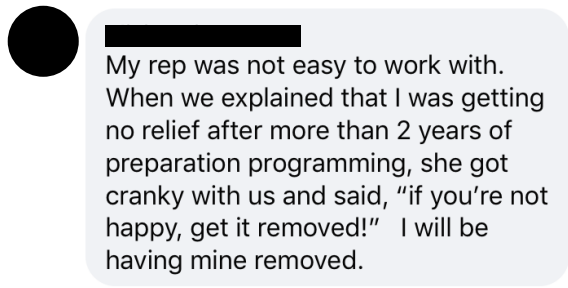
1. Introduction to Nevro

We add two final pages of Facebook posts that leave little doubt as to why Nevro has an explants crisis, merits an FDA recall, and echoes Nuvectra before its sudden implosion – though we could perhaps fill hundreds with patients despondent at ever having gotten Nevro's device, rejoicing at having it explanted, accusing the company and its reps of being a scam, lamenting abusive reps or those who ghost them after the implant, or describing being hustled by pain clinics that push Nevro. There are of course posts by enthusiastic patients, some using the hashtag #NevroAmbasador and who appear to troll those who are critical. Nevro does appear to be have an "ambassador" program, but we don't know if it's paid.









Source: Nevro Facebook supports groups –https://www.facebook.com/groups/213633049377315; https://www.facebook.com/groups/us.nevro; https://www.facebook.com/groups/886079031527511;

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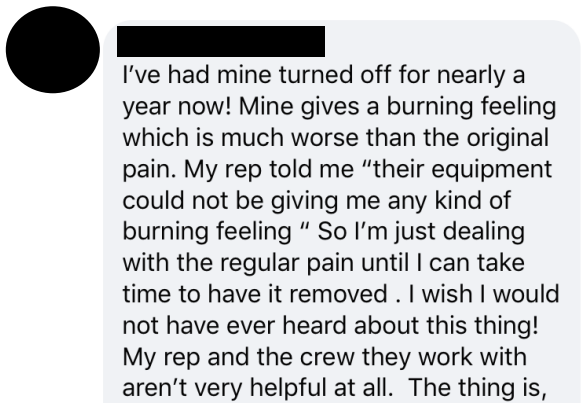
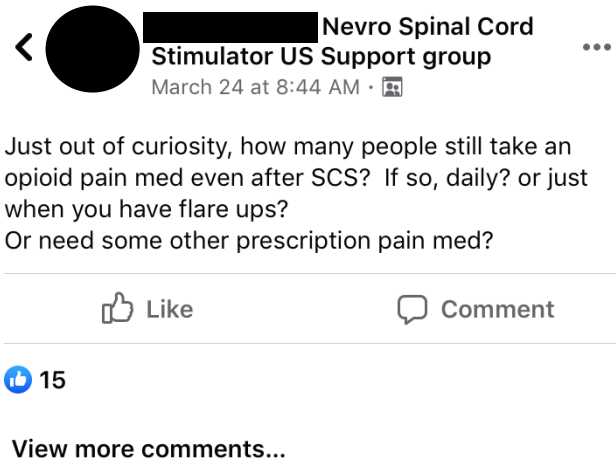
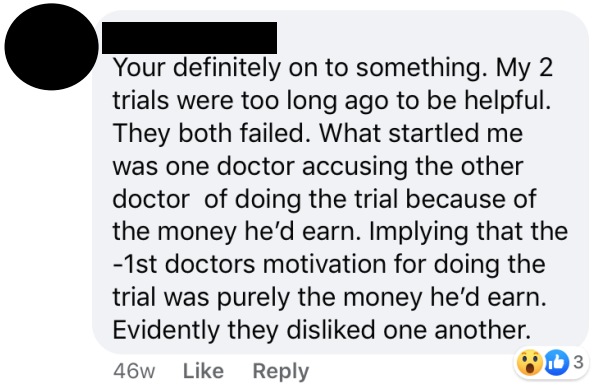
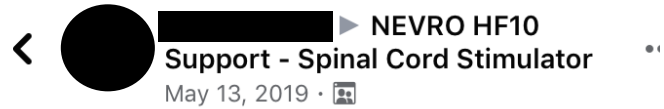
We were simply amazed at the number of patients indicating that they turned off Nevro's device, sometimes years ago, without even explanting it. Many said they wish they'd never heard of it; "thank goodness" that "it's coming out in a week"; that they still need opioids for pain relief; that they were "startled" as one doctor accused the other of doing the implant purely to make money; and that they experienced "absolutely no relief whatsoever…I am contacting the FDA….people are being taken advantage of with these…"









After almost two years of 3 reps lying to me and unable to program it to provide the excellent relief I got during the trial, it is coming out i June.

I suspect NEVRO implants a lower grade of unit after very successful trial. Absolutely no relief whatsoever after the implant on 8/31/17. I am contacting the FDA to see if they can get actual success rates vs poor results.

People are being taken advantage of with these IMO.

Source: Nevro Facebook supports groups –https://www.facebook.com/groups/213633049377315; https://www.facebook.com/groups/us.nevro; https://www.facebook.com/groups/886079031527511;

1. Introduction to Nevro

Irrespective of existential risks due to lack of efficacy, explants, and regulatory scrutiny, we expect 2021 to be a disaster for Nevro and a reckoning for the bull case. Consensus expects comical 26% yoy growth, as sales normalize post-COVID and are turbocharged by a bolus of deferred procedures, Omnia "share gains," and a 2H21 PDN launch. We expect reality to be far more harsh: 1) the steady, structural sales erosion of the last 3 years continues as the Nevro HF10 fad continues to fade; 2) rebound drivers like Omnia, PDN, and Grossman's "turnaround" are exposed as flops; 3) Nevro is kicked off a cliff as Saluda poaches its reps and highest volume implanters; and 4) prices continue to tank amidst an industry price war. We expect an even sharper decline in 2021 than the -8% consensus estimate for 2020, at which point – after a fourth year of flatlining sales – its stock will reflect the obvious. We note telling developments: the CEO talked down Q4 hopes at a Nov 30 event, an abrupt reversal after implying a flattish Q4 on Nov 5; a likely failure to pre-announce Q4 at JPM, as is its custom; and the Dec 2 departure of a founding investor and longtime director. We quote a territory manager for one Medtronic's largest regions – in the trenches as a key competitor – explaining the simple, grim reality that we expect Nevro investors to finally grasp in 2021…

"To be honest, we watch their stock and we're like 'What are we missing?' *In our market, we don't see a ton of good outcomes. Omnia has really not done anything. We hear rumbling from Caraway [Nevro Chief Medical Officer] that they're researching more indications, and we just don't know how a one-trick pony makes any headway.* ***We can't figure it out - they continue to do well on Wall Street, but I do not see any movement or any changes here. If anything, they're shrinking here. Frankly, there's very little discussion of Nevro at this point at Medtronic****, at our national sales meeting. or really any talk about their taking business away. A lot of the reps that they hired away are now either back with Medtronic or have moved on. That's pretty common from what I can tell in territories across the country."* ***– Longtime Medtronic territory manager***

Source: Consultation calls with experts

2. Summary of key findings

We summarize the key findings of each chapter that follows, which lead us to conclude that the bull case – centered on a turnaround and return to growth – is misguided, and that Nevro faces existential risks which the market has failed to appreciate.

- **We researched each of the key claims underpinning the bull case and conclude that they lack credibility and reflect deep investor misunderstanding of Nevro's product, market, business practices, and prospects.**
  - That **Nevro's high frequency technology is superior** to traditional stimulators and clinically differentiated
  - That Nevro's sales growth crashed to a halt in 2018/2019 because of **fixable execution problems under the previous CEO**
  - That the ongoing lack of growth in 2020 is the result of **COVID-19 reducing patient interest** in elective procedures, prior to which there were supposedly green shoots in Q4 2019 indicative of a return to growth
  - That the **new CEO is a turnaround magician** who will flip the company to an acquirer and save the day
  - That **the new Omnia stimulator**, the centerpiece of his turnaround plan, is a differentiated product in the middle of successful launch
  - That new indications for high frequency, notably **painful diabetic neuropathy (PDN)**, will expand the TAM and boost growth
  - That **a new utopia is right around the corner post-COVID**, as a bolus of deferred procedures, the Omnia rollout, the PDN launch, and Grossman's magic create a perfect storm that re-ignites growth and restores Nevro to its former glory

- **The SENZA-RCT pivotal trial, the foundation upon which Nevro's entire high frequency gimmick is built, was so distorted by cherry-picking, patient manipulation, and other red flags that ex-employees and KOL's described it as essentially a fraud to get FDA approval**
  - KOL's suggested that the pain center that led the trial is known as a study **"factory" run by "corrupt" individuals** that one pays to deliver positive "data"
  - **A critical and influential investigator in the pivotal trial**, one of the most prominent physicians in the pain space and whose proximity to the trial cannot be overstated, detailed his **personal discomfort** with the conduct of the study, that he **didn't believe** the results, that he **won't use Nevro's device**, and his belief that Nevro's **entire high frequency premise is a sham.**
  - Our research indicates that **disbelief and mistrust of Nevro's study is widespread** among high volume implanters and leading KOL's - including recipients of payments from Nevro - as well as among the company's former executives and sales reps. That the study's results were a sham appears to be an open secret in the SCS field.
  - A former executive stated that Nevro's approach to studies was in general **"highly unethical"** and suggested that Nevro **suppresses data** which contradicts it's high frequency claims. A KOL stated that Nevro "**has always played a lot of games"** with another adding the study was **"rigged" and not reproducible**.

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2. Summary of key findings

- **Contrary to the astonishing SENZA study data showing nearly twice the efficacy of traditional low-frequency stimulation, high frequency was quickly proven to be the exact opposite: a phony premise, as too-good-to-be-true study results were disproven by real-world clinical experience after Nevro's 2015 launch, as well as by a number of recent studies sharply contradicting Nevro's trial data and undermining the company's entire foundation.**
  - KOL interviews indicate **widespread skepticism of high frequency's superiority**, including among recipients of study/consulting fees from the company. Representative comments by a Nevro implanter: high frequency was **nothing more than a marketing ruse**; **even Nevro knows it's a dud**; and there's no difference versus 70-90% lower frequencies.
  - Dismissiveness towards Nevro now appears to be the norm in the SCS field, as one implanter after another stated that all stimulators are a commodity: **"They're all the same. It's like buying a car."**
  - Numerous KOL's pointed to **tolerization as a reason for high frequency's failure**, suggesting that Nevro's device overwhelms the spinal cord with current, which **backfires by creating a faster adaptive response** than older stimulators.
  - At least **three influential studies in recent years sharply contradict Nevro's trial data** and corroborate the underwhelming clinical results doctors began to witness. Unknown to most investors, the studies were a critical turning point in Nevro's trajectory and coincided with its sales and stock crash. Although Nevro has allegedly tried to trash these studies, our interviews indicate widespread belief in their findings.
  - One particularly **devastating study compared a high frequency stimulator against a sham** arm with the device turned off, and **shockingly found no meaningful difference** in pain scores. We note that the study was double-blinded, unlike Nevro's pivotal trial, and remains to our knowledge the sole study comparing high frequency to a sham device.
  - An ex-Medtronic employee stated that they too had studied high frequency but concluded it was no better than placebo.

- **Far worse than just being clinically undifferentiated and me-too, high frequency was instead a fatal flaw, undermining Nevro's growth as the honeymoon period from its 2015 launch began to fade by 2017/2018. Massive problems unique to high frequency – not execution problems under the previous CEO - are the reason why sales have been flat over two years and why no turnaround is realistic. We cannot recall a situation where a one-trick company's only trick is actually an albatross around its neck. The CEO admits that their new multi-frequency Omnia device is still programmed for high frequency 85-90% of the time, a grim fact underscoring that Nevro stock remains just a one-way bet on 10kHz.**
  - Traditional stimulators mask pain with paresthesia (tingling) which occurs at lower frequencies. **Nevro's entire value proposition is based on "paresthesia-free,"** as the tingling disappears at high frequencies. Nevro claimed that patients find paresthesia uncomfortable and wish to avoid it. "Paresthesia-free" is so central to Nevro's existence that the term is used interchangeably with "high frequency."
  - Although Nevro centered its technology and messaging on "paresthesia-free," former sales reps and executives describe quickly discovering after launch that **a large percentage of doctors and patients strongly prefer the sensation of paresthesia**, without which they can't tell if stimulation is working or if the device is even turned on.

2. Summary of key findings

- **High frequency is a fatal flaw (cont'd)**
  - High frequency **rapidly drains the implanted battery**, with patients reporting **daily charging burdens** of an hour or more versus once every 1-2 weeks with competing devices, resulting in **pervasive non-compliance and dissatisfaction**.
  - Former executives and sales reps describe how the lack of paresthesia makes it difficult or **impossible for reps to program the devices**, creates "chaos" in the field organization, and led to an exodus of sales talent.
  - With the most onerous programming burden in the industry and **patients reporting dozens of failed programming sessions**, Nevro tried to stem the crisis by creating a centralized call center that played whack-a-mole in an attempt to get devices working. Ex-executives describe how **"paresthesia-free" has backfired** and resulted in a patient/doctor support infrastructure that renders the business model broken and permanently unprofitable.
  - A former regional sales director, who oversaw one of Nevro's largest territories and now runs the same region for a key competitor, stated that **"paresthesia-free" is a fatally flawed concept** and that he observed **over half of patients failing to improve** and virtually all experiencing lack of efficacy at various times.
  - He explained what happened next: Nevro found itself "in a bind" with the **CEO and management refusing to accept that high frequency is a dud,** leading to conflict with the field and sales reps leaving "in droves" despite the best compensation in the industry. He added that **Nevro's message no longer resonates and that the space has moved on.**

- With a sham pivotal trial and its sole product based on a false theory, reality predictably dawned as Nevro **soon faced a device failure crisis leading to its stimulators being surgically removed ("explanted") in droves**. Nevro took the space by storm at launch in 2015, on the heels of exciting "data" that led doctors to try the device. Numerous KOL's report that they **began to notice high frequency stimulation failing within months**. Nevro's explants problem is well-known among leading implanters and an escalating topic of research/discussion, but generally unknown to investors, given what we believe to be an **ongoing cover-up** and what KOL's described as **retaliation against doctors** who openly raise the issue.
  - Nevro has attempted to gaslight doctors by **claiming it has the lowest explant rate** in the industry at 1.2 to 3.7%, based on a barely-disguised marketing brochure masquerading as a legitimate study, written by 4 of its employees.
  - A **January 2020 paper** at the annual neuromodulation meeting (NANS), presented by a Harvard-affiliated implanter, **indicated explant rates of 22% within 1-2 years and 33% within 2-3 years for Nevro's product** "despite repeated reprogramming sessions in the effort to achieve therapeutic optimization" – or about **10-30x the rates Nevro claims**. The study indicated that Nevro's claims "differ greatly from the results we have found in real world practice."
  - The **paper generated significant buzz** at the annual meeting as we believe it was the first time that doctors publicly confronted the elephant in the room regarding Nevro's explant rates. KOL's in attendance or familiar with the research stated that **the talk attracted an overflow crowd**, and that numerous **attendees confirmed seeing similar explant rates.**
  - A KOL suggested that Nevro may have tried to **sabotage the presentation**, sharing his suspicions of who prevented the explants paper from being listed in the program and **tore the data presentation from the wall**. The doctor referenced previous behavior he described as retaliatory and "disinformation" regarding explants, labeling Nevro's conduct as "slimy."

2. Summary of key findings

- **The 33% explant rate in the NANS paper was corroborated by one KOL after another during our 20+ interviews, across a sample constructed broadly by geography, practice setting, and current or prior use of Nevro. Several indicated that actual explant rates may be even higher at >50-70%, with some stating they explanted virtually every Nevro device they implanted. Widespread lack of efficacy and explants, on top of other flaws unique to Nevro's device, are the primary driver of Nevro's ongoing collapse. We share five detailed case studies of KOL's we interviewed, each of whom was initially excited by Nevro's device only to experience an explant crisis, and who provided remarkably consistent and damning feedback about Nevro's technology and conduct. One stated that he expects other papers on Nevro's alarming explant rates "to be published shortly."**
  - **Case study #1**: A high volume implanter described his initial experience as "almost miraculous," only to sour after seeing **rampant failures within 3-6 months**. He states that the **32% rate in the NANS paper is massively underreported**, that Nevro "just lies"; that's he's never seen anything like this with other stimulators, and that **"patients hate the Nevro device."**
  - **Case study #2**: A second KOL was also initially impressed with Nevro's data, only to see **patients fail "like clockwork."** He stated that only 2 out of 90 patients he implanted with Nevro still have the device – **an explant rate approaching 100%**. He added that "**a lot, a lot of doctors" have had the same experience with a "70-80% explant rate."**
  - **Case study #3**: One of the most prominent KOL's in the field – a former Nevro consultant and speaker – described his initial enthusiasm for Nevro's device only to see **75% of patients experience a quick collapse in efficacy**. He stated the device failed so often that **high volume implanters became "hesitant to use the product."** He suggested with hindsight that Nevro's study was fraudulent, calling the company **"a big scam" with "criminal" data manipulation and "smoke and mirrors"**, adding that other KOL's came to a similar conclusion and viewed Nevro with "disgust." Although Nevro "paid me a lot of money," he concluded their technology just 'didn't work" and slammed Nevro's ethics.
  - The KOL offered detail on why he and "a lot of other doctors" now believe **Nevro's technology is actually harmful to the spinal cord** and indicated an **emerging consensus in the field against high frequency** stimulation. He noted that "the pathological changes" caused by Nevro's device are being actively studied. We presume that any such papers, on top of ones we believe to be in peer review regarding Nevro's explant rates, would be devastating for the company's "turnaround."
  - **Case study #4**: A fourth KOL corroborated the accuracy of these accounts based on his conversations with "hundreds of physicians" as a speaker/educator, stating that **Nevro simply "can't be used, based on the problems we're seeing,"** and questioned Nevro's refusal to publish real explant data.
  - **Case study #5:** A fifth KOL, who spent time with Nevro's CEO, began as "**a 100% Nevro believer," followed by rapid device failures** and explants the likes of which he "had never had before." He described **widespread disillusionment among implanters**, said Nevro's clinical claims are false, that it's a "one-trick pony," and expressed skepticism of doctors who claim otherwise, saying their purported lack of explants is not credible.

2. Summary of key findings

- **Nevro's response to its explants crisis appears to be marked by denial, cover-up, retaliation, and attempts to manipulate and pressure doctors and patients into believing the device works – behavior suggestive to us of a company sitting on an explosive, existential secret.**
  - In disturbing contrast to prominent KOL's, the Nevro consultants/speakers we spoke to **refused to acknowledge the existence of any explants**, including two of their highest volume implanters and go-to study sites. One declared he has never seen or heard of a single Nevro explant, and then **falsely proclaimed that he has no financial connection** with the company. Comically, a colleague of his told us that he's actually **skeptical of Nevro after experiencing explants himself.**
  - The second Nevro-aligned KOL claimed to have only one explant out of hundreds, logarithmic magnitudes below Nevro's own purported rates. He exhibited **belligerence at the slightest question** and accused us of working for a competitor.
  - The more credible implanters we interviewed stated their belief that Nevro is **aware of its explant problem but "couldn't care less."** A former sales director stated that Nevro **kept explant rates "very well hidden from the field reps"** and detailed a **"don't ask, don't tell" culture**. Several KOL's who met with management to escalate the problem described a **disinterested CEO** and a company strategy of **denial, deflection, and blaming the patient or the implanter**.
  - Others reported **retaliatory behavior such as trying to "discredit" doctors** who raise the issue, and several KOL's used the words **"cult" and "Scientology" as analogies for Nevro's conduct**. Another alleged that Nevro planted doctors in conference audiences and gave them talking points.
  - We presume Nevro will supply the sell-side with **doctors who deny any explants problem**. One KOL after another dismissed these implanters as being **"bribed" by Nevro, "lying," or "not following" up** with their patients and advised us to be **skeptical**. One KOL stated that these **Nevro doctors were on the fringe**, and another stated that the device is **tailor-made for "unethical, corrupt doctors" who "couldn't care less if there's a high explant rate."**
  - Our research interviews revealed a hidden dynamic behind some Nevro implanters claiming they don't have explants: they're **simply unaware**, as they outsource almost all patient follow-up to Nevro reps. Numerous KOL's detailed how reps then feed the doctor **misinformation about how patients are doing**. Others pointed to a related driver: when a Nevro device fails, that patient goes to a different doctor for explant, and the **original implanter remains blissfully ignorant**. One KOL indicated it took him **1-2 years to discover that a third of his Nevro patients had the device removed** by other doctors.

- In the aftermath of a 1) sham study, 2) a phony high-frequency premise, and 3) rampant explants, KOL's, former executives, and competitors indicated **where Nevro finds itself now - a one-trick pony crippled in a ditch – in contrast to investors who believe it's on the cusp of a rebound**. The two-year honeymoon after its 2015 launch is now a distant memory, and 2020 consensus sales estimates are lower than 2018 and barely above 2017 – a 3-year period of wandering in the wilderness. We detail **drivers of Nevro's predicament and ongoing growth collapse**, without which investors cannot handicap its future
  - **High volume implanters, who drive 90% of the industry's volume, have soured on Nevro and moved on**. One of Nevro's highest volume implanters stated that his usage is down, echoed by others we interviewed; that doctors are skeptical the device works; and that there's **no growth left in Nevro's shrinking base of loyal users.**

2. Summary of key findings

- **Nevro's current predicament – a one-trick pony stuck in a ditch – and drivers of its ongoing growth collapse (cont'd)**
  - A former high-volume Nevro implanter stated that **competition has hobbled the company**: Nevro was "the first kid on the block" with paresthesia-free but doctors who "were enthralled with Nevro are not as enthralled" now. Other KOL's stated that the **"sheen is off"** and that **the story is "stale."**
  - One of Nevro's most senior ex-executives stated that **the legacy SCS incumbents** – Medtronic, Boston Scientific, and Abbott – **quickly struck back and neutralized Nevro.** A KOL added that Nevro is a "one-trick pony" and that **everyone now offers paresthesia-free as an option**, negating any differentiation.
  - Several Medtronic executives and sales managers **corroborated Nevro's predicament from their vantage point as competitors**. The head of a key region stated that Nevro poached Medtronic's reps and "whale implanters" at launch in 2015, but within two years, **"almost all Nevro devices" were explanted** and **Nevro quickly forfeited its market share gains**. **The doctors they poached are all "done with Nevro. They won't even listen to them"** due to explants and lack of efficacy. **He observes Nevro's sales shrinking and added that Medtronic has written off Nevro as a competitor.**
  - A senior ex-Nevro sales manager, one of the first employees hired at launch and now running a large region for a key competitor, described Nevro's trajectory and current plight in identical terms: **initial excitement among reps and doctors followed by a rapid reckoning within 6 months** as patients failed to improve. He stated that **internally Nevro "started freaking out"** at poor HF10 outcomes and that he **couldn't look doctors "in the eye** and ask them for visits anymore, because **I didn't believe in the therapy."**
  - The ex-Nevro sales manager's comments reveal the severity of what we believe the company has covered up: that **"sort of every KOL was saying the device isn't working"**; that sales reps across the country came to the same conclusion; and that the resulting chaos and conflict with headquarters – which blamed the field – led to **an exodus of sales talent**.

- **The centerpiece of Nevro's turnaround plan – the Omnia stimulator launched in Nov 2019 – is a Hail Mary and colossal flop that has not only failed to re-ignite growth but undermined the high frequency/HF10 message that Nevro has pushed for a decade. Across 35+ research interviews, KOL's and ex-Nevro employees consistently slammed Omnia as a me-too and irrelevant device, with several suggesting that the only people who thought differently were on Wall Street. Even Nevro's most ardent users – KOL's who receive significant payments from the company and play key roles in its trials – offered reactions that ranged from indifference to outright mockery and disparagement.**
  - Nevro's entire premise and sole point of differentiation is high frequency stimulation, in contrast to traditional stimulators which employ lower frequencies. **Omnia offers both low AND high frequency options, a 180 degree change in strategy.**
  - Nevro has spent its history **disparaging lower frequency devices as useless and dangerous** ("unpleasant," "71% of patients" "experienced discomfort," "lack of evidence supporting efficacy," "causes a shocking or jolting sensation"). The sudden reversal and embrace of a technology is trashed **suggests desperation and, we believe, admits HF10's lack of efficacy and alarming explant rate.**
  - The clearest indication that Omnia has bombed comes from the CEO directly, who's admits that it's **still programmed for high frequency 85-90% of the time**. Over a year into launch, Omnia has failed to alter how Nevro is perceived and used.

2. Summary of key findings

- **The centerpiece of Nevro's turnaround plan – the Omnia stimulator launched in Nov 2019 – is a Hail Mary and colossal flop (cont'd)**
  - One KOL stated that **"Omnia is a joke I think to most doctors**…even the doctors that were loyal Nevro users." One of Nevro's highest volume implanters belittled it as just **"a marketing move"** that "won't move the needle." A former Nevro user called it **"an attempt to save market share with a beleaguered cohort of doctors that are sick of explanting the device."**
  - A broad sample of **former Nevro executives and sales reps concurred** with doctors in their scathing assessments of Omnia's potential, labeling it as mere **"window dressing with Grossman"** and **"just re-packaging of an old product,"** implying that **"nobody's going to buy Omnia" unless bribed**.
  - Ex-Nevro territory managers, some now at key competitors, stated that Omnia is **a dud and that they're seeing no market impact**. Executives, regional managers, and sales reps at **Nevro competitors offered identical ground-level color**.
  - Interestingly, former employees and KOL's stated that Nevro's **previous stimulators already included the capability to offer low-frequency**, which the company downplayed for fear that it would undermine its claims of high frequency's superiority. Nevro, in our opinion, has pushed **a fraudulent narrative that Omnia represents a new technology.**
  - KOL's explained why Omnia's "One System, All Frequencies" positioning is **clinically illogical and risky**, as different frequencies and waveforms require **surgical lead placement at different points in the spine**. When doctors implant Omnia leads at the vertebrae used for high frequency stimulation, they render it **irrelevant and/or dangerous for low-frequency stimulation**. KOL's highlighted the lead insertion issue as rendering Omnia's multi-frequency messaging disingenuous and **"a lie."** One stated that **"it's impossible to capture" both low and high frequency fields** and that "you can't have it both ways," saying it's not a "real world" scenario and that Nevro's Omnia claims make him "shake my head."

- **Painful diabetic neuropathy (PDN) and other new indications that Nevro has recently begun to hype are as unlikely to re-start growth or a turnaround as its failed Omnia launch. A key part of the bull case hinges on Nevro expanding the TAM for high frequency stimulation via label expansion. The number of times PDN was hyped by the CEO and others on the recent Q3 earnings call - 19 mentions - is suggestive of its importance to the story. Our research found widespread skepticism and outright ridicule among KOL's and Nevro's former executives and sales reps at the notion that PDN is a meaningful commercial opportunity. Nevro's PDN claims are so dubious that we consider them to be misleading and promotional.**
  - One KOL after another, including some of Nevro's most loyal users, stated that **spinal cord stimulators have already been widely used for decades for PDN and are already approved by Medicare**, blasting the company's claims that it's a "new indication" as **"so stupid"** and **"just dopey."** One stated that Nevro's PDN study has "**value to Wall Street and no one else."**
  - The level of derision that Nevro's PDN study and claims of a new indication elicited were striking, with comments such as "putting lipstick on a pig," **"smoke and mirrors"** and commercially irrelevant, **"trying to hoodwink,"** and "I mean, please. It **won't change my use or anyone else's of stimulators in any way."**

2. Summary of key findings

- **Painful diabetic neuropathy (PDN) and other new indications are unlikely to re-start growth or a turnaround (cont'd)**
  - **Studies using stimulators for PDN have been published for decades**. We note various examples, **one ~25 years old** with results similar to Nevro's supposedly groundbreaking PDN study, using ancient devices from 1990's. One high volume Nevro user stated that **"In the 1980's, half of the patients we implanted with stimulators were for PDN."**
  - While many KOL's indicate that they already use stimulators for PDN, others stated that **diabetics who have deteriorated to the point of neuropathy are too risky as stimulator patients** and suffer far higher complications when implanted. Our research suggests that the **PDN opportunity is already played out with doctors firmly entrenched in two camps**: those who already code it and it implant it today, and those who are wary and unlikely to be swayed by label tweaking.
  - Leading KOL's and ex-Nevro executives exhibited **deep mistrust and skepticism of the company's recent PDN study**, slamming it for using the same tricks and gimmicks as the SENZA trial. Several indicated that the PDN study was the latest example of Nevro's **suspect pattern of clinical trial conduct** and making up new indications. One stated **"no one buys their data"** while another was more blunt: **"I don't believe anything they say…every Nevro study is the same."** A third questioned **"the ethics of their study design."** One KOL called it "**the dumbest study design"** and "greaseball."
  - KOL's stated that although spinal cord stimulation has long been used for PDN, it doesn't work well given **difficulties in reaching the lower extremities and is in fact "notoriously very bad for the foot,"**, and explained why Nevro's high frequency mechanism is particularly ill-suited for PDN and will backfire.
  - Doctors pointed out a **critical flaw specific to Nevro's high frequency stimulator if used for PDN**: high frequency leads are placed at the T9/10 vertebrae, which is not the correct spot on the spine for PDN. For Nevro to say its doing both high frequency and PDN is **so contradictory that one KOL bluntly stated: "I think they're lying."**
  - KOL's and ex-Nevro executives emphasized that **PDN referral patterns render any commercial opportunity dead-on-arrival**, as primary care doctors and endocrinologists are gatekeepers with a financial disincentive to refer
  - In addition to PDN, Nevro has begun to dangle **a second indication expansion** as part of its turnaround plan: **non-surgical refractory back pain (NSRBP)**, for which it will present 3 month data later this January. Not surprisingly, one KOL after another – including Nevro loyalists – **ripped the "indication expansion" as a delusion and outside the standard of care.**

- **With Omnia a flop and PDN a mirage, we expect investors betting on a Keith Grossman-driven turnaround to shortly face a rude awakening. We interviewed three former Nevro executives and a longtime C-level executive in the space, each of whom offered similar and damning commentary on his purported turnaround and playbook, describing a dire situation with a CEO more focused on optics than substance.**
  - Grossman joined as CEO in March 2019, **almost two years ago**. After three full quarters under his leadership, 2019 sales were flat vs. 2018. 2020 consensus estimates are even lower. Yet the stock is still up 3-4X, making it little more than a bet on his assurances. While he blames his predecessor and COVID-19, **the actual drivers are the failure of his signature Omnia initiative, the lack of a playbook, and the unfixable, ongoing collapse of Nevro's core HF10 business.**
  - While investors appear to view Grossman as a savior, the executives painted him as "all about flipping the company" with **"no long term plan there,"** describing him as **"naïve" and lacking an understanding of the SCS market.**

Scorpion Capital | Nevro (NYSE: NVRO)

2. Summary of key findings

- **Investors betting on a Keith Grossman-driven turnaround will shortly realize that the emperor has no clothes (cont'd)**
  - One former executive stated he is **"very underwhelmed" at Grossman's efforts**, which he called **"window-dressing**," indicating Nevro has "boxed themselves into a corner and now they'll **die of a thousand cuts."** He anticipates **an exodus of sales reps at the end of this year – "a bloodletting" - as options expire and they flee to new competitors** such as Saluda. He added that **the momentum Grossman hypes on earnings calls is a mirage**, pointing to massive market share losses and a company he detailed as on the precipice.
  - A second former executive, now at a key competitor, was equally dismissive of a turnaround, sharing his sense from members of the management team that **Grossman is "busy on a lot of other things" and questioned who's running Nevro day to day.** He implied that Grossman was **looking for a quick-flip**, which hasn't materialized, and that he **now finds himself in a role he didn't expect**. We note the number of executives who characterized Grossman as seeking to dress up and punt the company, and now finding himself stuck in an unexpected quagmire.
  - A third former executive was similarly skeptical and described Nevro's **predicament as structural and not operational**, doubted the possibility of any growth or turnaround, and stated that **the business model is unfixable: "I would not invest in Nevro today."**
  - A longtime C-level executive in the space offered **extensive insights into Nevro's plight**, describing **Nevro staff as skeptical of Grossman's efforts and confused by the stock**. He stated "**Grossman doesn't have a strategy,"** characterized his chief commercial officer as ignorant of the market, and shared his belief that he did little diligence on Nevro before taking the job and was **"sold hook line and sinker."**

- **Nevro's stock has been partly fueled by investor hopes of a take-out, which our research suggests are far-fetched and misinformed. Although the sell-side has sainted Grossman as a magician, former Nevro executives and senior executives in the space offered more realistic opinions of potential M&A and dumped cold water on these fantasies.**
  - A former senior Nevro executive **bluntly dismissed the company's appeal to potential acquirers**, particularly Stryker, often speculated upon as the most probable savior, He stated that Nevro's **value as a "one-trick pony" is now diminished** because it's a "commodity business" in a "price war"; that **acquirers would rather buy new, smaller entrants**; that J&J was a major investor in Nevro yet never bought them; and that large acquirers with an interest in the space, such as Medtronic and Abbott, are instead **paying "absolute pennies on the dollar" for emerging, inexpensive stimulator companies**.
  - The former executive provided a particularly damning data point that illustrates the depth of investor misunderstanding of Nevro's M&A potential, opining that the hot new stimulator play – Saluda Medical, the "next Nevro" - has **found no buyers despite being shopped for 18 months, given price erosion and value destruction in the stimulator market**. He speculated that Saluda would have taken a ~$200MM acquisition – a reality check given Nevro's current $__B market cap – and added that there **"too many emerging spinal cord stimulation technologies out there."**

Scorpion Capital | Nevro (NYSE: NVRO)

2. Summary of key findings

- **Investor hopes of a Nevro acquisition are delusional and misinformed (cont'd)**
  - A longtime C-level executive in the spinal cord stimulator space provided an **equally devastating assessment of Nevro's M&A prospects**. He echoed that Nevro is a one-trick company that companies like Stryker or J&J would have no interest in, and corroborated that the space **"is becoming increasingly competitive" with a "line of" new entrants "behind Saluda" that are also looking to get bought**. He added that Biotronik, a leading privately-held European medical device company with 9,000 employees, is also shortly entering the stimulator space but building in-house versus acquiring.

- **The launch of Saluda Medical's "closed loop" spinal cord stimulator – supported by the best pain relief data ever published in the space - is an impending disruptive threat to Nevro within 6 to 12 months. The company has raised $125MM, with investors that include Medtronic and Abbott, two of Nevro's three largest competitors. Saluda's approach - to personalize stimulation not only by patient but second by second – is the polar opposite of and a frontal challenge to Nevro's entire reason for existence: a gimmicky one-size-fits-all approach based on a fixed 10khz frequency. Comments by SCS executives regarding an influx of new entrants and "too many emerging spinal cord stimulation technologies out there" foreshadow an imminent 2021 share loss scenario unknown to most Nevro investors.**
  - Interviews with KOL's, Nevro ex-executives/reps, and competitors indicate **tremendous enthusiasm and anticipation for Saluda's device**, including among some of Nevro's highest volume implanters, with an impending disruption that one executive estimated **could eradicate 18-33% of Nevro's business**. Whether Saluda's efficacy is as spectacular as the data suggest or not, our research indicates that mass trialing of their device is imminent, followed by a sales disaster for Nevro.
  - As **an ominous sign that share loss may be far worse than this estimate**, we note that the authors of Saluda's US study – published earlier this year – are the lead investigator for Nevro's pivotal SENZA trial as well many of its highest volume implanters, including **all 3** of its highest compensated KOL's per OpenPayments.
  - A Nevro ex-executive stated that **Nevro is the most vulnerable among SCS players to Saluda**, given that it attracted a fickle implanter base that quickly bounces to the next hot launch.
  - The **superlatives used by KOL's**, including high-volume Nevro implanters, when we asked about Saluda **suggest an impending fervor and reinforce the severity of the threat**: **"never seen anything like it"**; **"very exciting"**; **"the best tonic data ever"**; **"beats Nevro's data."** In a space driven by the trendy new device, the color suggests that Saluda is the "new Nevro" while Nevro is yesterday's fad.
  - Industry executives and KOL's stated that **Saluda has locked up the most influential KOL's**, whose control and leverage over papers, conferences, and other doctors **ensures that Saluda will drive substantial conversion to its device**.

Scorpion Capital | Nevro (NYSE: NVRO)

2. Summary of key findings

- **A critical driver of Nevro's ongoing growth collapse is price pressure and discounting, which the sell-side and investors appear unaware of. Former Nevro executives, competitors, and KOL's describe an industry "price war" as the major stimulator companies fight over a small group of price-sensitive ASC accounts that drive most of the industry's volume. A former Nevro executive stated that "discounting is part of Nevro's approach now" and pointed to prices dropping by up to $5,000 per year – a stunning minus ~20%. Industry executives stated that the price war will only accelerate post-COVID, as ASC's seek even deeper reductions to make up for lost revenue, in contrast to investor hopes of a bolus of deferred procedures driving a rebound. The price war is yet another nail in the coffin of Nevro's illusory turnaround and acquisition prospects.**
  - Discounting began under the prior CEO in 2018 as Nevro stuffed the channel as sales tanked, **conditioning accounts to expect ongoing price reductions**. An ex-executive described the **price conditioning as ruinous: "a stupid move"; "one of the dumbest moves you could ever make."**
  - Research interviews suggest that the **new CEO has doubled down and also "drastically" cut pricing in an attempt to gain market share, which kicked off a new round of industry discounting** – "cutting off your nose to spite your face" according to a competitor. With Omnia pricing still too high, competitors expect further discounts. KOL's confirmed seeing price reductions and a former Nevro rep described a recent 20% price cut by Medtronic and then being undercut by Abbott – providing field-level color into the current price war in stimulators.
  - An ex-Nevro executive corroborated the price war and offered extensive insights into **Nevro's predicament**, painting a grim picture of **dependence on a small number of high-volume, price-seeking ASC's with little loyalty**, who pit stimulator companies against each other, who then **slash pricing to offer "deals."** He stated he **can't see how "Nevro really wins this"** and that he's "pessimistic" about its future. He cast it as a structural problem as ASC's are owned by **doctors and therefore price-sensitive: "it's a price war because none of the stim companies have created great customers."**

- **The SCS market growth story pushed by Nevro and Wall Street is false and undermined by escalating payor backlash**
  - Former Nevro employees, including one involved in calculating the growth rate the company promoted, described it as **data fabrication** in order to push a stock narrative, with our research indicating that the **SCS market already hit a wall pre-Covid**, due to reimbursement, cannibalization from new entrants, pricing pressure, and cannabis as an alternative.
  - Interviews with KOL's and competitors indicate that the reimbursement environment is deteriorating as **insurers crack down, viewing stimulators as ineffective** and lacking in clinical evidence; expensive with no ROI; and as driving additional costs given their widespread adverse effects.
  - One KOL after another indicated that reimbursement is now **"the hardest it has ever been"**; that payors are escalating denials and making it "impossible"; and that reimbursement has become so onerous that many **doctors have stopped implanting stimulators altogether**. One KOL, speaking of insurers, stated there's so much abuse that "I don't blame them."
  - Contrary to the notion that Nevro is a do-gooder alternative to opioids, its volumes depend on sketchy pain clinics "baiting" patients with opioids and pushing them into stimulators, and as states like FL crack down on opioids, Nevro volume tanks. One of its highest volume implanters stated his implants have dropped 50% as FL changed opioid prescribing rules.

Scorpion Capital | Nevro (NYSE: NVRO)

2. Summary of key findings

- **We believe that Nevro's business hinges on kickbacks to high-volume implanters, who otherwise would have stopped using its HF10 technology due to lack of efficacy and explants. In our opinion, based upon research we detail, Nevro's payments to doctors are inducements and blatant violations of the anti-kickback statute, which makes pay-to-play a criminal offense. We believe that in the absence of these payments, Nevro's sales would have collapsed over the last 2-3 years versus being merely flat.**
  - The DOJ's Office of Inspector General issued a **Special Fraud Alert on November 16. 2020 that "highlights the fraud and abuse risks associated with…speaker programs** by pharmaceutical and medical device companies." We believe that Nevro's practices are a poster child for the illegal practices detailed in the Alert, and that the company is one whistleblower or DOJ attorney away from its business model being in the crosshairs.
  - CMS OpenPayments data paints a **troubling picture of Nevro's "general payments" to doctors** – about $3.5MM/year - which are separate from any potential inducements via "research payments." The breakdown suggests that most of this spend is for a speakers program. We note the recent criminal convictions of Insys Therapeutics executives and doctors, in connection with the "Insys Speakers Bureau."
  - KOL's and former executives described the space as driven by a small number of **high volume implanters who will only use your device if you pay them to do so**. Some used the word kickbacks, while others described the same dynamic with phrases like **"they'll throw a lot of money your way"** or "**it's basically like a reward system."**
  - A former Nevro district manager described the **pervasiveness and centrality of payments** to doctors, and agreements around them as **hushed and never in writing**. He detailed internal conversations about **linking payments to volumes.**
  - Nevro's **payments in Europe may be more accurately described as brazen bribery**, in our opinion. A Swiss German-language article in February 2020 alleged that **Nevro paid doctors ~$10,000 per device implanted. Journalists obtained a 2019 Nevro contract and stated that "the kickback scheme" began in 2017**. We interpret the article to imply that Nevro terminated the program "with immediate effect" when asked and did not dispute its existence. The program appears to us to have remained in effect for about a year following Grossman's appointment as CEO.
  - We believe **Nevro's European scheme violates the Foreign Corrupt Practices Act**, based upon a review of FCPA enforcement actions brought against medical device companies, which suggests that **Nevro's conduct is a textbook case**. We note that FCPA matters may be **criminal and/or civil**, with penalties routinely in the hundreds of millions of dollars.
  - We asked two former Nevro executives to comment on the alleged kickbacks program in Europe. One stated his belief that it couldn't have had happened without **participation by the US headquarters ("everyone knows")**; and that the staff Nevro terminated in the aftermath were "sacrificial lambs." **He called the program "crazy."**
  - A former Nevro consultant and one of their highest volume implanters described their **payments to doctors as aggressive and replied "100%" when asked if they were kickbacks.** A second high volume implanter said the speakers program was tied to volume and that he **observed reps engage in improper or illegal behavior "all the time."**
  - KOL's and executives in the space listed various prominent Nevro implanters by name as **"their whore for California," "a guy who takes money,"** "borderline unethical," doctors you could "**blow the whistle on,"** or as **"coin-operated."**

Scorpion Capital | Nevro (NYSE: NVRO)

2. Summary of key findings

- Numerous Nevro former executives, sales reps, and KOL's described **over-utilization, unnecessary implants, and the exploitation of patients – particularly the psychiatrically vulnerable - as key drivers** of the spinal cord stimulation business and of Nevro's sales in particular, describing unethical or illegal practices with troubling incentives driving corporate, sales rep, and doctor behavior. **We detail four in particular**: **1) pushing unnecessary trial implants and pressuring patients** into a permanent implant even if the trial indicated no pain relief; **2) gaming mandatory psychiatric evaluations** prior to implant; **3) "flipping" implants and pushing unnecessary "upgrades,"** with a former employee estimating that **25-50% of Nevro's revenue** comes from surgery centers pushing patients into **"one stimulator and then another and then another,"** and **4) implanters pressuring patients into simulators by withholding pain medication** and other disturbing tactics.
  - Insurers require patients to begin with a trial simulator for a few days to a week, where temporary leads are attached to an external battery/generator. If the trial indicates at least 50% pain relief, the patients undergoes a permanent implant. On his first earnings call as CEO in May 2019, **Grossman singled out trial implants as a key lever of his strategy**, declaring his intentions around "directing and incentivizing" the sales force to **"grow trials" "very intensely."**
  - We find Grossman's incentivizing of trial implants as troubling, given that ex-employees and KOL's describe **trials as the mechanism for misuse, over-utilization, and patient manipulation**. First, doctors push as many patients into trials as possible, whether medically indicated or not, given **far more lucrative reimbursement for trials** than for permanent implants. Second, sales **reps then badger and manipulate patients during the trial** to pressure them into a permanent implant, given that the conversion ratio drives their compensation.
  - Former employees detailed toxic incentives and a **company culture of "over-aggressive" reps pushing trials and stimulators when not indicated**, implying that **misuse is "incentivized as a big part of the business" and a "wink wink."** Others suggested that a **Medicare audit is inevitable**, with a KOL implying that Nevro is **"corrupt"** and that clinics are **"bamboozling patients."** Others described it as **"straight up fraud"** and **"a big problem,"** saying that doctors "pump bodies" through stimulator clinics, particularly in high-abuse states with **"giant billboards" for stimulators**.

- **Investors are oblivious to one of Nevro's greatest risks: its business model, far more than any other stimulator company, is predicated in our opinion on reps and other employees engaging in the unauthorized practice of medicine. Giving medical advice or treatment without a professional license is a criminal offense. While sales reps in the OR are a common, albeit disturbing, practice in the spine implant industry generally, we believe Nevro reps traffic - by design - in more aggressive and dangerous terrain: exercising medical judgment and/or participating in treatment.**
  - A former sales manager stated that reps spend **only 20% of their time on sales with 80% in the operating room and in patient visits**. His description of reps' role – such as using diagnostics to determine the correct lead placement in the spine - suggests to us that Nevro is one internal whistleblower or DOJ attorney away from its business model imploding..
  - A KOL took the rep's characterization even further, stating that stimulator reps have a **"very unique" role versus typical reps because "You have clinic hours" and "You actually have patients."** He stated what reps are "legally, ethically, appropriately" supposed to do versus their actual conduct. One of Nevro's highest volume implanters stated that "**the rep is kind of an extension of your practice."**

2. Summary of key findings

- **Nevro's business model is predicated in our opinion on reps and other employees engaging in the unauthorized practice of medicine (cont'd)**
  - Another of Nevro's highest volume implanters stated that he **simply outsources patient care to reps if they still have pain**. He stated that reps **use x-rays to diagnose the patient and to re-program the device**, and that if the rep fails, that a central call center – the "Therapy Optimization Team" – takes over.
  - A former Nevro executive described the role of the central team – and that of reps generally – in a manner we believe to be **identical to the practice of medicine: having "a list of patients they were in charge of"; "high patient contact**"; using trial and error to **determine and direct the correct dosage** of stimulation – we note that dosage goes to the heart of practicing medicine.
  - Two former Nevro executives detailed why **"reps engaging in the practice of medicine has always been the concern,"** suggesting that the risk is well-known inside the company. One stated that programming their device is so time intensive that its **entire value proposition and business model are predicated on doctors outsourcing patient care** to Nevro.
  - The second ex-executive stated that **Nevro's reps and clinical specialists are "not health care providers in any way, shape, or form" but are "responsible for the care of patients."** He added that **patients would be "pretty concerned" if they knew the credentials** of these employees.

3. Trial investigators, KOL's, and ex-employees painted the SENZA pivotal study as a fraud

The SENZA-RCT pivotal trial is the foundation upon which Nevro's high frequency gimmick is built. The data from this trial enabled the company to claim dramatic superiority versus traditional low-frequency stimulators, thereby enabling not only its IPO and FDA approval but its entire commercial existence to date. The headline claim from the study was that Nevro's HF10 "was nearly twice as successful" for back pain and 1.5x for leg pain over traditional SCS, at 3 months. Nevro described it as a "landmark": "the first pivotal RCT in the history of SCS and the only randomized study with a head-to-head comparison of SCS systems."

Nevro IPO prospectus

"Key highlights of our SENZA-RCT pivotal study are as follows:

• HF10 therapy was nearly twice as successful in treating back pain as traditional SCS therapy, with 84.3% of patients receiving HF10 therapy, as compared to 43.8% of patients receiving traditional SCS therapy, reporting 50% or more pain relief at three months, results that were statistically superior based on our post-hoc analysis.

• HF10 therapy was 1.5 times as successful in treating leg pain as traditional SCS therapy, with 83.1% of patients receiving HF10 therapy, as compared to 55.5% of patients receiving traditional SCS therapy, reporting 50% or more pain relief at three months, results that were statistically superior based on our post-hoc analysis.

• HF10 therapy provided a 69.2% reduction in back pain as measured by the Visual Analog Scale, or VAS, versus 44.2% for traditional SCS therapy, at three months, results that were statistically superior based on our post-hoc analysis.

• HF10 therapy provided a 72.8% reduction in leg pain as measured by VAS, versus 51.5% for traditional SCS therapy, at three months, results that were statistically superior based on our post-hoc analysis."

Source: Press release https://www.nevro.com/English/us/investors/investor-news/investor-news-details/2014/Nevro-Corp-Announces-Publication-of-24-month-European-Clinical-Data-on-HF10-Spinal-Cord-Stimulation-SCS-Therapy-for-Chronic-Back-and-Leg-Pain/default.aspx; prospectus https://www.sec.gov/Archives/edgar/data/1444380/000104746914008881/a2222100z424b4.htm.

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3. Trial investigators, KOL's, and ex-employees painted the SENZA pivotal study as a fraud

Nevro claims that the SENZA-RCT data showed ongoing, dramatic back and leg pain reduction at longer intervals of 12 and 24 months versus traditional low-frequency stimulators. A Nevro press release touted the paper's selection by the journal Neurosurgery as its "Top Pain Paper of the Year."

SENZA-RCT 24 month outcomes paper

Comparison of 10-kHz High-Frequency and Traditional Low-Frequency Spinal Cord Stimulation for the Treatment of Chronic Back and Leg Pain: 24-Month Results From a Multicenter, Randomized, Controlled Pivotal Trial

Leonardo Kapural, MD, PhD, Cong Yu, MD, Matthew W. Doust, MD, Bradford E. Gliner, MS, Ricardo Vallejo, MD, PhD, B. Todd Sitzman, MD, MPH, Kasra Amirdelfan, MD, Donna M. Morgan, MD, Thomas L. Yearwood, MD, PhD, Richard Bundschu, MD ... Show more

Neurosurgery, Volume 79, Issue 5, November 2016, Pages 667–677,
https://doi.org/10.1227/NEU.0000000000001418
Published: 06 September 2016 **Article history**

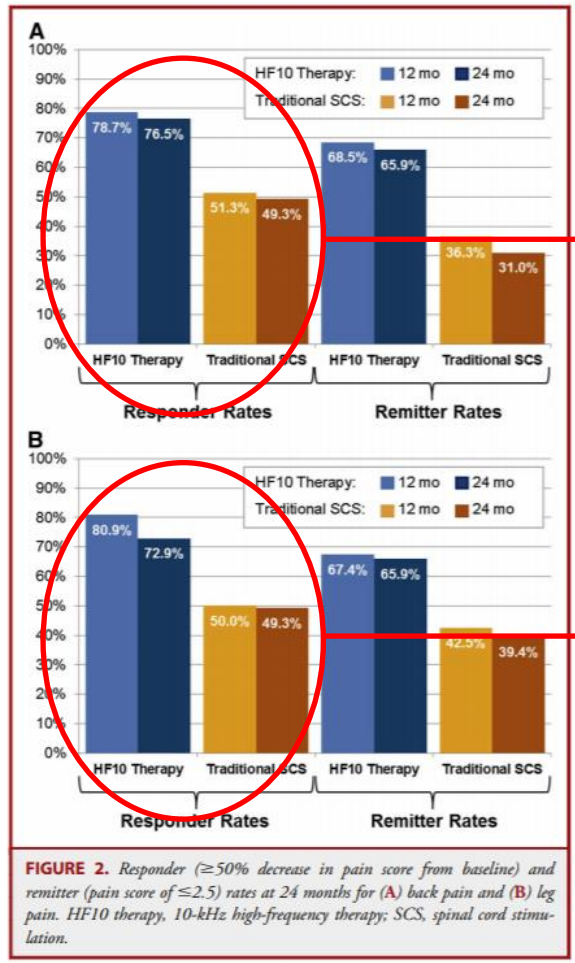

FIGURE 2. *Responder (≥50% decrease in pain score from baseline) and remitter (pain score of ≤2.5) rates at 24 months for (A) back pain and (B) leg pain. HF10 therapy, 10-kHz high-frequency therapy; SCS, spinal cord stimulation.*

Back pain responder rates of ~80% for HF10 vs. ~50% for traditional SCS

Leg pain responder rates show roughly similar superiority

Source: https://academic.oup.com/neurosurgery/article/79/5/667/2835700; https://www.nevro.com/English/us/investors/investor-news/investor-news-details/2017/Neurosurgery-Selects-the-SENZA-RCT-24-Month-Outcomes-Publication-as-the-Top-Pain-Paper-of-the-Year/default.aspx.

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3. Trial investigators, KOL's, and ex-employees painted the SENZA pivotal study as a fraud

Red flags in the study design are apparent at the outset, as one might expect in a sham exercise designed to enable an IPO and FDA approval. The study compared Nevro's new high frequency device against the Boston Scientific Precision Plus - a legacy, low frequency stimulator system launched many years prior in 2007. Notably, the study wasn't blinded: patients knew whether they were the unlucky ones being implanted with an ancient stimulator or the fortunate few receiving the latest breakthrough.

Boston Scientific July 2, 2007 press release

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Boston Scientific Announces Launch of New Precision Plus™ Spinal Cord Stimulation System

Hardware and software innovations offer new benefits to physicians and patients

SENZA-RCT paper describing comparator arm and study limitations due to lack of patient and investigator blinding

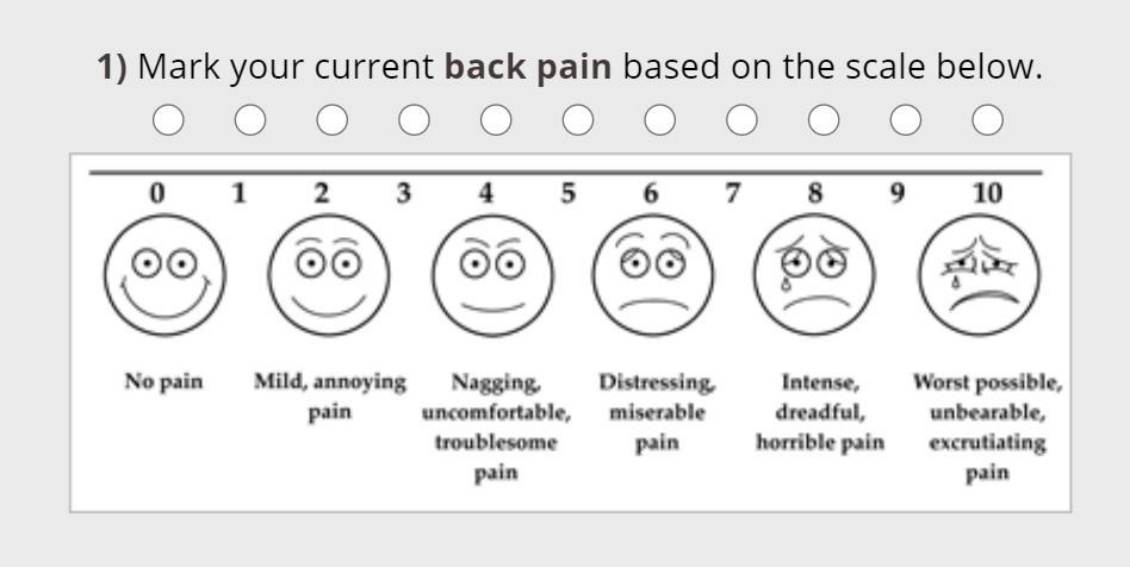
Subjects were randomized 1:1 to receive stimulation with either an HF10 therapy system (Senza system; Nevro Corp., Redwood City, California) or a commercially available SCS system (Precision Plus system; Boston Scientific, Natick, Massachusetts). Both SCS systems consisted of two 8-

As with any clinical trial, there are limitations. Study investigators and subjects were not masked to the assigned treatment group. Subject masking was impractical because low-frequency SCS produces paresthesias, whereas high-frequency SCS does not; thus, the therapies themselves become immediately known to the subjects. Due to the differences in stimulator lead placement, intraoperative testing, and device programming between the treatment groups, the study investigators could not be masked. The effect of the lack of masking in this randomized study is not known; nonetheless, the protocol was based on best practices guidance for comparative efficacy trial designs.[14-16]

Source: https://news.bostonscientific.com/news-releases?item=58980; SENZA-RCT paper https://s24.q4cdn.com/932612397/files/doc_downloads/Comparison_of_10_kHz_High_Frequency_and.97253.pdf

3. Trial investigators, KOL's, and ex-employees painted the SENZA pivotal study as a fraud

The potential for bias and patient manipulation is self-evident as the primary endpoint was based on a patient questionnaire called a "Visual Analog Scale" (VAS). Patients needed to report VAS pain score reductions of 50% to be considered a responder. A typical VAS pain scale questionnaire illustrates the fuzzy, subjective design of the study – where a nebulous change from "dreadful" and "horrible" pain to "uncomfortable and "troublesome" pain would count as a 50% reduction.



"This was all nebulous because pain management and neuromodulation are subjective. The primary endpoint in the Nevro trials was VAS reductions. The problem is it's very subjective. Patients' pain and location can change hour to hour and day to day. *It's such a tough specialty because it's so nebulous. If the diagnosis is an ACL tear, the surgeon can confirm it with imaging. The problem with chronic pain is that it's not one specific modality. There's a major psychological component, which is why a psychiatric evaluation is required for permanent implant."* ***– Former Nevro regional sales director, head of a large multi-state territory***

Source: http://www.ericlinmd.com/back-vas-form.php; expert consultation calls

3. Trial investigators, KOL's, and ex-employees painted the SENZA pivotal study as a fraud

We conducted a detailed interview with a key, influential player in the SENZA-RCT trial, a prominent physician in the pain space. His proximity to the trial cannot be overstated, making him intimately knowledgeable about what actually occurred. Shockingly, he conveyed personal discomfort with the conduct of the study, that he didn't believe the results, that he hadn't moved his patients to Nevro's device, and that the entire high frequency premise was false. We have never seen a trial investigator – a recipient of money from Nevro and someone friendly with and sympathetic to Nevro's management – so readily contradict the party line. His comments were so blunt that we simply asked "Do you think the Nevro pivotal study you conducted was bs?" to which he replied:

"There was a lot of bias in the Nevro pivotal trial*. We had to talk people into the study, and then they'd go home and pray they got the new stimulator and then they'd get the old one and be grumpy.* ***It wasn't a pristine way to set up a study."***

"I hope the study wasn't bs. It does bother me*. I'm going to say it was done honestly. It's just that as the study unfolded,* ***I could see the bias."***

"I'm different than most guys Nevro markets to. I need higher evidence. I haven't switched my patients over to Nevro." ***– KOL and key player in the SENZA-RCT pivotal trial***

Source: Consultation call with expert

3. Trial investigators, KOL's, and ex-employees painted the SENZA pivotal study as a fraud

The KOL stated that European implanters were skeptical of the US pivotal study's results, which came out in 2014. Nevro's HF device had launched in 2010 in Europe, achieving some minor sales and providing European doctors with years of real-world outcomes data unavailable in the US - which never matched the dramatic results claimed in the SENZA-RCT trial. He stated that Nevro "launched a disinformation campaign" in response to European implanters' incredulity at data from the US pivotal trial. He further characterized Nevro's 10kHz frequency – the core of its IP – as a meaningless gimmick in which he didn't believe.

"European implanters scratched their heads and said that we've been using Nevro for 3 to 4 years and our experience is not like your Nevro pivotal study*. I was at [redacted] and I mentioned to [redacted] that we were getting calls like this.* ***Nevro knew about this and launched a disinformation campaign."***

"Nevro took 10kHz as a frequency and threw a dart at the wall. They chose it because they could get IP on it. 10kHz is not a magic number. The PROCO study by Simon Thompson shows that. *It was a crossover study design that evaluated 1,4,7, and 10kHz stimulator frequencies. Each patient received each frequency for 2 to 4 weeks at a time and then rated their pain. Patients had no preference, suggesting there was no difference in pain relief by frequency."*

"Nevro has tried to bash the study. Simon has consulted with Boston Scientific, so there's some of that. Boston didn't fund the trial and I believe the PROCO study. ***Nothing has convinced me to date that 10kHz is better than 1kHz."*** ***– KOL and key player in the SENZA-RCT pivotal trial***

Source: Consultation call with expert

3. Trial investigators, KOL's, and ex-employees painted the SENZA pivotal study as a fraud

He concluded his already devastating comments by stating that a UK-based KOL saw no sustained benefit from Nevro's high frequency either and preferred other devices – and that Nevro was now a stale story in which he wouldn't buy stock. Comically, this UK doctor was the lead author on Nevro's key European 24 month HF study – the US equivalent of the SENZA-RCT pivotal trial. His study is the first that Nevro cites on the "Clinical Evidence" page of its site. This European study and the US SENZA-RCT are Nevro's two 24-month outcomes studies - the foundation upon which Nevro's high frequency's claims rest. Deep skepticism of Nevro's study from one and apparent skepticism by the other is telling.

Nevro's key European 24-month HF study

Observational Study › Pain Med. 2014 Mar;15(3):347-54. doi: 10.1111/pme.12294. Epub 2013 Dec 5.

Sustained effectiveness of 10 kHz high-frequency spinal cord stimulation for patients with chronic, low back pain: 24-month results of a prospective multicenter study

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Affiliations + expand

PMID: 24308759 PMCID: PMC4282782 DOI: 10.1111/pme.12294

Comments by key US player in SENZA US pivotal trial

***"Adnan Al-Kaisy said he had switched over to Nevro and then he started seeing what you've noted. He had seen 20 to 30 patients with no sustained benefit. He was seeing explants**. So he started spreading his business around. He didn't bash Nevro completely. But he's gotten to a point where he thinks other devices like Boston Scientific are a better option."*

***"[Doctor name redacted] in my state switched over completely to Nevro. Then he had issues with Nevro**. I think he switched away again."*

*"Nevro came out with something new and got a lot of share in a crowded space. **The sheen is off Nevro**. I've known [Nevro senior executive] for [redacted] years. I don't know that he's the right guy. **I wouldn't buy stock in Nevro right now. Their story is getting stale."** – KOL and key player in the SENZA-RCT pivotal trial*

Source: http://www.ericlinmd.com/back-vas-form.php; consultation call with expert.

3. Trial investigators, KOL's, and ex-employees painted the SENZA pivotal study as a fraud

Our research indicates that disbelief and mistrust of Nevro's SENZA-RCT study is widespread among high volume implanters and leading KOL's - including recipients of payments from Nevro - as well as among the company's former executives and employees. That the study's results were a sham appears to be an open secret in the SCS field. One of the most well-known KOL's stated that "there were so many problems that we just shook our heads…." Others conveyed the view that Nevro has "always played a lot of games" with their trials.

Comments by 5 different KOL's and high volume implanters

"Nevro definitely designed their HF10 trial to make their product look better. There's no question about it."

"I initially had high hopes for Nevro's high frequency. From the very beginning though, ***the trial wasn't a fair fight. They were comparing brand new technology with a 3 year old one. That study was flawed.****"*

"I've read every study from every company. Nevro says it's better but there's no superiority data for HF10 to Burst, or HF10 to 1200 hz or whatever. ***Interestingly, there's nothing comparing these devices to placebo or sham."***

"When Nevro first launched, we looked at this and said, "There could be something to a high rate of stimulation. You're basically flooding the zone. What a great idea." ***And then you start going through the study design, and you start looking at real outcomes, and there were so many problems.*** *Huge problems with their study, the Kapural study.* ***There were so many problems that we just shook our heads*** *in some of our doctor groups."*

"The Hawthorne effect is well documented in science. If a person knows they're getting the experimental product or treatment they tend to have more of a placebo effect. ***Every patient in Nevro's study knew which device they got. Doctors believe the Hawthorne effect completely skewed Nevro's results. It happens in all their studies.*** *Everybody knows which device they're getting.* ***Nevro's always played a lot of games****."*

Source: Consultation calls with experts

3. Trial investigators, KOL's, and ex-employees painted the SENZA pivotal study as a fraud

KOL's and former employees elaborated on the reasons for their skepticism, beginning with the center and the physicians who led the trial, offering opinions which implied that they were corrupt and paid to deliver only certain kinds of study results.

Comments by 4 different KOL's and high volume implanters

"[Doctor name redacted] has a factory. *His center just does tons of studies. I only know of one negative study they've produced. I didn't even interpret it as negative, though the manufacturer did.* ***Their whole thing is to design studies to win. I do study design on a regular basis. The guys involved like [name redacted] – he knows where the money is. I wouldn't trust any data from him.*** *I wouldn't trust a lot of the places in the multicenter study. It's an industry what [name redacted] and [name redacted] do. [Name redacted] and [name redacted] get so hot on things and then they peter out.* ***It's just business."***

"The way Nevro compared themselves to Boston Scientific in the study was bogus. It's all about study design. ***[Name redacted] and [name redacted] give you a study that's designed to win. That's why you get the data.*** *You have to understand the study design."*

"[Investigator name redacted] got launched into stardom with Nevro. ***They couldn't go to the usual considered experts, the guys who were real because eventually the cat would be out of the bag. They would know that what Nevro was selling was bullshit.*** *That's why they tended to develop their own new breed of experts, KOL's and so forth."*

"The [name redacted]-led study - they were paid to do that. ***If you're paid to do a study, there's a significant amount of bias. That's why you have to have the investigator blinding. There are so many reasons why it's a wishy washy study****."*

Source: Consultation calls with experts

3. Trial investigators, KOL's, and ex-employees painted the SENZA pivotal study as a fraud

The opinions that KOL's and former employees shared of the SENZA-RCT's lead investigator appear consistent with patient reviews – with one patient warning "Please beware this clinic and this man." We caution that these reviews are from a public doctor review site, that we have not verified their accuracy or authenticity, and that they therefore may be neither.

"I was seen by this clinic several times, a different person each time, and only on the last visit did I get to see the lauded Dr. [redacted]. He stormed into the room, introduced himself, and told me, without hearing a word from me, what he had determined I needed to do next, which was another procedure. When I told him I was not interested at this point in that procedure, and tried to discuss what I had come to talk about, which was concerns about contraindication with the medicine he had prescribed, he raised his voice and began telling me about how his way is the only way that works, and all my other doctors are incompetent. The longer I tried to get back to what I needed to speak with him about, ***the nastier/louder he got, until he was literally standing in front of me, yelling at me. In the end, he yelled he wouldn't treat me any more, and yelled from down the hall for me to leave****. He absolutely did not care about anything I had to say.* ***Please beware of this clinic and this man."*** *–* ***Patient review, 11/11/2019***

*"****I felt he was trying to SELL me a spinal stimulator, rather than explain what it is. He blatantly lied*** *about the size of battery and the pain level associated with it."****- Patient review 6/26/2018***

"Dr. [redacted] is the greatest doctor in the world, and if you don't believe it just ask him. *His explanations are poor, doesn't seem to want to listen to the patient."* ***– Patient review 11/1/17***

Source: Healthgrades.com

3. Trial investigators, KOL's, and ex-employees painted the SENZA pivotal study as a fraud

Of the various games used to manipulate the pivotal trial, KOL's and other experts repeatedly pointed to the cherry-picking of patients. Physicians slammed Nevro for constructing a study cohort that was wildly unrepresentative of "real world" stimulator patients. Skeptics include some of Nevro's highest volume implanters, one of whom we quote below, who we believe continues to use the product only because he receives payments from the company.

"Nevro cherry-picked patients. *The criteria to be in the HF10 study was one or less back surgeries. If you talk to any pain doctor who implants stimulators, the national average is almost three back surgeries. Every patient also requires a psychiatric evaluation before a trial implant. Nevro controlled the psych evaluation. They were much more stringent than doctors in the real world, who'll pass the patient through. The trial did standardization of lead placement. When you work with doctors in the field, there are some excellent doctors who meticulously place leads. Others just thrown them out there.* ***It wasn't a real world study****."* ***– Longtime head of one of Medtronic's largest territories***

"I mean, they ruled out workers comp patients. They ruled out a significant opioid use. They ruled out even prior spinal cord stimulation. *Once they started liberalizing the use of the device in cases beyond the Senza study and people started applying it broadly, you're going to have a more difficult population than the study."* ***– KOL and one of Nevro's highest volume KOL"s/accounts***

"They programmed the Boston Scientific patients the same as they had always been done. ***But in the Nevro arm, we'll pick our patients, like virgin patients with only one back surgery. They didn't choose people with questionable psychological evaluations, spinal stenosis, arthritis in conjunction with back pain. They did a good job in cherry-picking patients."*** ***– Longtime head of one of Medtronic's largest territories***

"The biggest problem with their study was the exclusion criteria. They committed the cardinal sin, which is to cherry-pick. *If you look at the Boston Scientific LUMINA study, they took every garbage patient that walked into the clinic. It was sequential enrollment, so if a patient had high pain scores or other diagnoses, everything that would confound a perfect study, the study said this is the real world. If you look at the exclusion criteria of not only the Senza study but Nevro's new study for diabetic peripheral neuropathy, they cherry-picked. There's something like 24 points that would exclude diabetics from participating."* ***– KOL and high volume implanter***

Source: Consultation calls with experts

3. Trial investigators, KOL's, and ex-employees painted the SENZA pivotal study as a fraud

In addition to cherry-picking and bias from lack of blinding, some of the most troubling allegations about the conduct of the trial came from former executives of Nevro, who described Nevro's approach to studies at "highly unethical" and suggested Nevro's skill at manipulating study patients. The most damning comments below are by a former executive who we believe to maintain relationships with the CEO and management team, who suggested that Nevro suppresses data which contradicts their high frequency trial.

Comments by two former Nevro executives

*"**What assisted Nevro with the Kapural study was interaction bias. It's all about how the study was designed and how the study team interacted with patients** in the Boston Scientific arm versus the Nevro arm. The Boston patients' stimulators were re-programmed the same as always. But the Nevro arm had a team come in. **The patient knows it's a new stimulator. The study team is excited to see you. You have 5 to 6 people at your programming session. They were methodical with patients in between sessions as well. Patients were managed differently.** Nevro's PDN study would have managed patients exactly the same way, I'm sure. They compared Nevro to CMM [conservative medical management], and CMM is a very low bar." – **Former executive***

I have concerns and issues with how Nevro manages data especially around clinical research**. If a study didn't produce results congruent with their high frequency trial, they wouldn't publish it. **I feel that's highly unethical**. They'd pay the study out and close it. I had a huge problem with that. – **Former executive

"Another factor is how Nevro managed patients post-implant is create their own placebo effect**. Nevro has a management system that sees when to call a patient, what questions to ask. Pain patients have psychological comorbidities. It creates a crutch. Nevro is commercially savvy in the interaction cycle with the patient. **My concern is that they do this during clinical trials."** - **Former executive

"The RCT patients were so closely followed up, so closely managed and optimized with full time field clinical engineers dedicated to them**, that then going to a general population and not having that same support infrastructure, yeah, of course you're going to see some fall off [in efficacy versus the pivotal trial]. – **Former Nevro executive

Source: Consultation calls with experts

3. Trial investigators, KOL's, and ex-employees painted the SENZA pivotal study as a fraud

KOL's corroborated these comments by Nevro's former executives. One influential KOL – who interacted extensively with Nevro and its management - bluntly stated that the company systematically manipulated study patients to engineer a favorable pivotal study. Another prominent KOL stated that the study was "rigged," not reproducible, and that Nevro's approach in general was to "rig their studies."

Comments by 3 different KOL's and high volume implanters

"Nevro manipulated the patients in the pivotal study to show the results they wanted. They ask leading questions. They have a whole algorithm of leading questions to get the patient to say the magic word, 50% pain relief. As soon as they say 50%, bang, they're out of there*. They couldn't give a shit about anything else and they really did many patients a disservice along the way because they would just leave them hanging.* ***It was clear to me that they were trying to sell the company and looking for data to show 50% pain relief."*** *-* ***Former high volume Nevro implanter***

"My international colleagues, the ones in the original Nevro study that got them the IPO, showed great data. ***What they didn't tell you is how much time the rep was spending in the doctor's office to make the results good****."* ***–High volume implanter***

"I know Al-Kaisy. He and [names redacted] headed Nevro's advisory board at the beginning. ***I think Nevro's high frequency study was rigged. I've stated that no one would be able to repeat the those results.*** *Nevro kept giving me the run-around when I wanted to be a site for one of their studies, because they wanted to make sure that they kept their numbers high. They specifically chose [name redacted, a top 5 recipient of payments from Nevro].* ***They only pick sites so that they can rig their studies. I'm convinced of it."*** ***–High volume implanter***

Source: Consultation call with experts

3. Trial investigators, KOL's, and ex-employees painted the SENZA pivotal study as a fraud

Another KOL indicated that Nevro reps who were involved in the pivotal trial admitted that patients were manipulated into providing the answers that Nevro wanted. He indicated that other KOL's confirmed this in their own discussions with reps. We note that this KOL was one of Nevro's highest volume and most enthusiastic implanters, in addition to being a consultant and speaker for Nevro. He stopped using Nevro completely after having to surgically remove the vast majority of their devices due to failure – we discuss his experience in depth in the section on Nevro's explants crisis.

"We subsequently found out, as we spoke to former Nevro reps who were involved in the Senza study, that the manipulation in statements from the patients was crazy*. They had very leading questions like, "in certain times of the day do you feel that your pain is this much better, that much better?" It wasn't an overall global pain assessment scale.* ***These were very, very specific questions to manipulate the answer that they wanted.***

I wasn't the only one who found this out*. Other doctors who I respect greatly in the field also got the same input from other reps who were formally working for Nevro.* ***So, it was a big scam. The way that they manipulated the data was criminal. I would say that the bigger names in neuromodulation who weren't getting paid by them, think of Nevro with disgust."*** ***–KOL and former Nevro implanter***

Source: Consultation calls with expert

4. HF10 is a phony premise and mechanism of action

KOL interviews indicate widespread skepticism that 10kHz stimulation is any more efficacious than stimulation at lower frequencies. Even Nevro's most ardent loyalists and highest volume implanters – consultants, speakers, and/or trial investigators - were at best ambivalent in their support of high frequency as a mechanism of action. The comments below by a high volume KOL and Nevro user are representative: that high frequency was nothing more than a marketing ruse, that even Nevro knows that high frequency is a dud, and that 10kHz results are no better than traditional stimulators operating at 70-90% lower frequency – in other words, that Nevro basically has no IP.

"Chronic pain is such a unique and idiosyncratic thing that for a company to claim that this one method will work and be good for everyone - ***really, I'm surprised that Nevro was able to essentially fool the world.***

I'm not a believer that 10kHz is so much better than 1 or 3kHz*. High frequency is just sort of keeping them afloat, and if they had not done this, the company would not have survived. But they had to do this because* ***they realized that their initial predictions, their initial claims were just simply not true.***

The science showing that 10kHz is so much better than 3kHz is weak, and I don't believe that it is so much better than even something in the 1kHz range or a little bit higher. *I don't believe 10kHz is a holy number. I just don't believe that.* ***I haven't seen any better efficacy with 10kHz versus other frequencies."*** ***– High volume implanter/KOL and Nevro user***

"You don't need 10kHz like they claim*. Once you reach 2-3kHz it works better than old systems which had 3-500Hz. You don't need the magic 10kz high frequency.* ***Clinically, less is ok and you don't need Nevro".*** ***- High volume implanter/KOL***

Source: Consultation calls with experts

4. HF10 is a phony premise and mechanism of action

Numerous KOL's pointed to tolerization as a reason for high frequency's failure, suggesting that Nevro's device overwhelms the spinal cord with current, which backfires by resulting in a faster adaptive response than traditional stimulators. While we note strong evidence indicating little efficacy and high failure rates of stimulators in general (p.___), KOL's indicated that high frequency led to faster tolerization and degradation of efficacy than traditional stimulators.

***"People get used to high frequency**. My hypothesis is that the neurons may re-learn and then the pain can come back". – KOL in Europe*

***"I've observed, when I and other doctors get together and talk about this, that patients tune out of high frequency faster than traditional stimulators**. In one year the devices are all the same and the curves converge. **There's no difference in efficacy**. Maybe a little bit on the front end but it disappears by 12 months. – High volume implanter/KOL and Nevro user*

***"You can only beat on the spinal cord so long before a refractory response happens. Look at drugs – ones that effect the nervous system lead to tolerance**. If you take two Vicodin a day you need four a day after 6 months to get the same effect […] I believe, and a lot of other doctors believe, that you can only pound on the spinal cord so much. You're seeing a shift now, where other companies are pulsing the energy where it's on for 30 seconds, off for a couple of minutes, repeat, as a potential way to mitigate the tolerance that occurs in the nervous system. **I'm saying it's just too much energy and you have to back off. Either the cells are down-regulating and can't hear the noise anymore, or there's an inflammatory response to high frequency and you get cell formation that's impeding the electrical signal."** - KOL and former high volume Nevro implanter*

Source: Consultation calls with experts

4. HF10 is a phony premise and mechanism of action

An influential study presented in 2018 at the key annual NANS conference (North American Neuromodulation Society) corroborated what physicians were seeing in clinical practice – that high frequency provided no benefit over lower ones. The PROCO study was a major event in the neuromodulation space. It showed that 1, 4, 7, and 10kHz frequencies all "provided equivalent pain relief." The study utilized a far more credible design than Nevro's 10kHz pivotal SENZA-RCT, double-blinding patients and doctors, for example.

Neuromodulation: Technology at the Neural Interface

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Effects of Rate on Analgesia in Kilohertz Frequency Spinal Cord Stimulation: Results of the PROCO Randomized Controlled Trial

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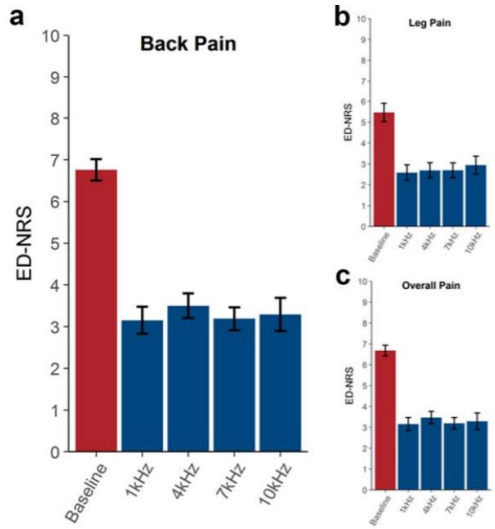
Objective: The PROCO RCT is a multicenter, double-blind, crossover, randomized controlled trial (RCT) that investigated the effects of rate on analgesia in kilohertz frequency (1–10 kHz) spinal cord stimulation (SCS).

Materials and Methods: Patients were implanted with SCS systems and underwent an eight-week search to identify the best location ("sweet spot") of stimulation at 10 kHz within the searched region (T8–T11). An electronic diary (e-diary) prompted patients for pain scores three times per day. Patients who responded to 10 kHz per e-diary numeric rating scale (ED-NRS) pain scores proceeded to double-blind rate randomization. Patients received 1, 4, 7, and 10 kHz SCS at the same sweet spot found for 10 kHz in randomized order (four weeks at each frequency). For each frequency, pulse width and amplitude were titrated to optimize therapy.

Results: All frequencies provided equivalent pain relief as measured by ED-NRS ($p \leq 0.002$). However, mean charge per second differed across frequencies, with 1 kHz SCS requiring 60–70% less charge than higher frequencies ($p \leq 0.0002$).

Conclusions: The PROCO RCT provides Level I evidence for equivalent pain relief from 1 to 10 kHz with appropriate titration of pulse width and amplitude. 1 kHz required significantly less charge than higher frequencies.

"Conclusions: The PROCO RCT provides Level I evidence for equivalent pain relief from 1 to 10 kHz with appropriate titration of pulse width and amplitude."



Source: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5814855/pdf/NER-21-67.pdf

4. HF10 is a phony premise and mechanism of action

Although Nevro has tried to trash the PROCO study, our interviews indicate widespread belief in its results, even by a key investigator who is close to Nevro management and played a critical role in their pivotal trial. Interviews with KOL's as well as former executives and employees of Nevro indicate that it is no coincidence that the PROCO study was presented the same year – 2018 - that the company's sales and stock hit the wall. Nevro had already been undermined by doctors fleeing the device, and now a study verified what they were seeing in practice: that 10kHz stimulation provided no benefit.

"Nevro took 10kHz as a frequency and threw a dart at the wall. They chose it because they could get IP on it. ***10kHz is not a magic number. The PROCO study by Simon Thompson shows that.*** *It was a crossover study design that evaluated 1,4,7, and 10kHz stimulator frequencies. Each patient received each frequency for 2 to 4 weeks at a time and then rated their pain. Patients had no preference, suggesting there was no difference in pain relief by frequency. Nevro has tried to bash the study. Simon has consulted with Boston Scientific, so there's some of that. Boston didn't fund the trial and* ***I believe the PROCO study. Nothing has convinced me to date that 10kHz is better than 1kHz."*** ***– KOL and key player in Nevro's pivotal SENZA-RCT trial***

"The Boston Scientific data throws a monkey wrench in Nevro's data. It creates reasonable doubt even for someone like me who likes Nevro." ***– High volume implanter and significant Nevro customer***

"There was a revolution with Nevro's HF10. It was very attractive initially. Then Boston Scientific showed there's nothing magical with 10kHz*. Nevro was the first kid on block with their paresthesia-free, kind of like Tesla with the first electric vehicle. Now everyone has electric vehicles.* ***The advance Nevro had is now outweighed by the compromises of it****. It's the biggest device by far. It requires way, way more recharging. It needs a lot more reprogramming than any other device. If reps spend a lot of time reprogramming in your office, they need a lot more reps to support docs. It's a business model issue."* ***– KOL and high volume implanter***

Source: Consultation calls with experts

4. HF10 is a phony premise and mechanism of action

In addition to the PROCO study, KOL's pointed to the DeAndre study published in 2017. The study compared high frequency head to head versus stimulators operating at conventional frequencies, reaching the same conclusion: that results do "not differ according to whether the frequency of stimulation is conventional or high." We note that unlike Nevro's SENZA-RCT, the DeAndre study took pains to standardize programming across treatment arms and was not manufacturer-sponsored.

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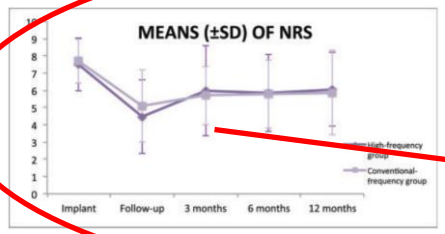
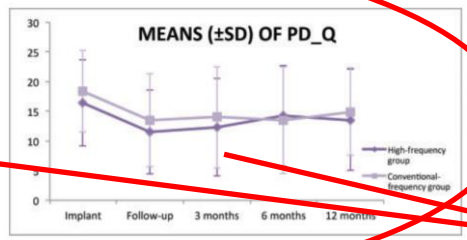
OXFORD

NEUROMODULATION & INTERVENTION SECTION

Original Research Article

Prospective, Randomized Blind Effect-on-Outcome Study of Conventional vs High-Frequency Spinal Cord Stimulation in Patients with Pain and Disability Due to Failed Back Surgery Syndrome





"De Andres did a blinded outcomes assessment with Nevro to Medtronic. In other words, they blinded the outcomes assessors, like you're supposed to do in medicine to eliminate investigator bias**. They also made sure that the programming time was equal for each system so that there wasn't bias. Nevro, in their Senza and other studies, doesn't do that. Nevro biased patients by talking about [the comparator device with] paresthesia as evil, while the De Andres study showed that there was no difference between Nevro and Medtronic." **– West coast-based high volume implanter

Two lines are HF and conventional stimulation, showing no meaningful difference at various intervals up to a year, on several endpoints measuring pain.

Source: https://academic.oup.com/painmedicine/article/18/12/2401/4591682

4. HF10 is a phony premise and mechanism of action

We find a third study, published the year before Nevro's SENZA-RCT, even more devastating. The study compared high frequency stimulation to a sham: one arm received high frequency stimulation while in the other arm the device was turned off. Shockingly, the study found no statistically significant difference in endpoints including VAS pain scores. We repeat: the study found no difference whether the patient had a HF stimulator turned on or off. We note that this study was double-blinded, unlike Nevro's pivotal trial, and remains – as far as we can tell – the sole study to date comparing high frequency to a sham device.

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Analgesic Efficacy of High-Frequency Spinal Cord Stimulation: A Randomized Double-Blind Placebo-Controlled Study

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Introduction: Spinal cord stimulation is a recognized treatment of chronic neuropathic and vascular pain. Recent data suggest that the use of very high-frequency (HF) stimulation modes does produce analgesia without paresthesia.

Aim of the Study: To compare the efficacy of HF stimulation (HF spinal cord stimulation [HFSCS]) and sham stimulation on the patient's global impression of change (PGIC), pain intensity, and quality of life.

Patients and Methods: Forty patients who have achieved stable pain relief with conventional SCS have been recruited. After randomization, HFSCS and sham are initiated in a double-blind randomized two-period-crossover design.

Results: Complete data were available from 33 patients. The primary outcome was a minimal improvement in the PGIC. The proportion of patients responding under HFSCS was 42.4% (14/33 patients) vs. 30.3% (10/33 patients) in the sham condition. The mean benefit of HF vs. sham was not statistically significant with a proportion of 11.2% in favor of HFSCS ($p = 0.30$). There was a highly statistically significant "period effect," irrespective of treatment received, with 51.5% of patients ($N = 17$) improving at visit 3 vs. 21.2% ($N = 7$) at visit 5 ($p = 0.006$). The mean pain visual analog scale (VAS) on sham was 4.26 vs. 4.35 on HFSCS ($p = 0.82$) and the mean EuroQol five-dimensional (EQ-5D) index with HFSCS was 0.480 vs. 0.463 with sham ($p = 0.78$).

Conclusion: This is the first randomized double-blind study on SCS. HFSCS was equivalent to sham for the primary outcome (improvement of PGIC) as well as for both the secondary outcomes (VAS and EQ-5D index). There was a highly statistically significant "period effect" ($p = 0.006$) with improved PGIC scores in the first study period regardless of the treatment. The same trend was seen for VAS and EQ-5D. It appears that the effect of HFSCS and sham is equal and only the order in the sequence, not the nature of the treatment, seems to dictate the effect.

"It's amazing how much mindshare Nevro got. ***They didn't invent 10kHz high frequency. Medtronic did high frequency studies and they were no better than placebo.*** *It's just a stimulator like everything else. It's not a panacea."* ***– Former Medtronic neuromodulation employee***

"Conclusion: This is the first randomized double-blind study on SCS. HFSCS was equivalent to sham *for the primary outcome (improvement of PGIC) as well as for both the secondary outcomes (VAS and EQ-5D index) […]* ***It appears that the effect of HFSCS and sham is equal****…"*

Source: https://pubmed.ncbi.nlm.nih.gov/23425338/

4. HF10 is a phony premise and mechanism of action

It is therefore no wonder that even Nevro loyalists state bluntly that all stimulators are a commodity. We quote three implanters below. The first doctor is a longtime Nevro whale and consultant in one of the largest metro's in the northeast. OpenPayments lists him as a recipient of significant payments from the company. The second and third doctors are heavy and moderate-volume Nevro implanters, respectively, on the west coast and east coast. Our research indicates that their dismissiveness toward Nevro's purported differentiation is now the norm in the SCS field.

Comments by 3 different implanters

"If somebody came in today and had traditional back and leg pain from spinal surgery, ***you can achieve meaningful and significant results with any of the devices. That's for sure and that includes even some outdated systems that are still on the market."*** ***– High volume Nevro loyalist and KOL in the northeast***

"There's not much of a difference between the devices. ***They're all the same. It's like buying a car."*** ***– High volume Nevro implanter on west coast***

"All these devices are similar*. It just depends on the puts and takes with a patient."* ***– Moderate volume Nevro implanter on east coast***

Source: https://pubmed.ncbi.nlm.nih.gov/23425338/

5. High frequency is Nevro's fatal flaw and dooms any turnaround

Unlike conventional stimulators, high frequency devices impose a number of significant tradeoffs on patients and doctors. By definition, they consume large amounts of power and rapidly drain the battery implanted inside the patient, requiring the patient to be next to a charging paddle for long periods of time on a daily basis. On Facebook groups some patients report charging times that can approach an hour. The patient burden and resulting non-compliance and dissatisfaction were a recurring theme of our KOL interviews.

Comments by 5 different KOL's and high volume implanters

"There were a couple of other problems with Nevro besides loss of efficacy. One, the size of battery*. When you put in a huge generator like Nevro's original device, you can't hide it well.* ***The other is charging it every day.*** *It's a burden and now you see Abbott going huge into non-rechargeable devices. Their device lasts 5-7 years. When I switch people out of Nevro or whatever into an Abbott they're like, "I don't have to charge it? Are you kidding me, why didn't we do this in the first place?"* ***Patients don't understand the burden of charging every day until they actually have to charge it every day.*** *Initially people don't mind, but after 6 months it becomes a problem."* ***–KOL and former high volume Nevro implanter and consultant***

"The problem with a 10kHz device is that battery is going to be gone in a day. *You have to recharge it like your iPhone.* ***You don't need to do that. You can have 1kHz, and you have the same outcome****. That's been shown."* ***–KOL and high volume implanter***

*"****The average duration between recharges is one of the biggest detriments for high frequency****. Patients are charging daily. For the older folks who struggle with technology, it's a significant detriment. I won't implant Nevro in folks over 60.* ***It's a big turn off for me and my patients."*** ***–KOL and high volume implanter***

"I haven't seen any better efficacy with 10kHz versus other frequencies. ***I would also say that one of the downsides of Nevro is that because of the high energy requirements, patients need to recharge very frequently*** *and there are patient populations who may not be compliant and there's data on that, that patients don't charge them, that the devices don't last as long and that the patients just don't use the device as much."* ***– High volume implanter***

"Nevro has to be charged every couple of days or every day ***versus others every 1 or 2 weeks."*** ***–High volume implanter***

Source: Consultation calls with experts

5. High frequency is Nevro's fatal flaw and dooms any turnaround

The core of the high frequency premise – and Nevro's entire reason for existence – is based on the notion of "paresthesia-free". Traditional, lower frequency stimulators cause tingling, known as paresthesia, in an attempt to mask the pain. The entire point of conventional stimulators is to create a "paresthesia-field" that covers the pain area. Nevro's clinical and marketing narrative is so intimately tied to "paresthesia-free" that the term is used interchangeably with "high-frequency" by employees and doctors. Nevro's main "innovation" is that paresthesia is imperceptible to patients at a high frequency, and that paresthesia is something that patients and doctors wish to avoid.

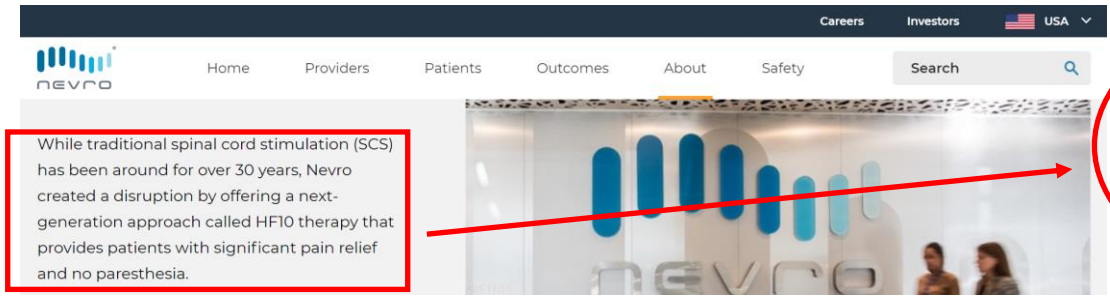
Opening paragraph of Nevro's 2020 10K

"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."*

Excerpt from 10K, which mentions "paresthesia" 36 times across various sections

*"**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."*

Nevro's "About" page



*"While traditional spinal cord stimulation (SCS) has been around for over 30 years, **Nevro created a disruption by offering a next-generation approach called HF10 therapy that provides patients with significant pain relief and no paresthesia."***

Source: Nevro 10K; https://www.nevro.com/English/us/about/overview/default.aspx

5. High frequency is Nevro's fatal flaw and dooms any turnaround

Nevro had supposedly found the holy grail: eliminating pain versus masking it with paresthesia. Traditional stimulators are implanted with the patients awake to enable paresthesia-mapping: the physician adjusts the placement of stimulator leads along the spine in a trial-and-error process until the patient reports tingling that overlaps with the area of pain. Nevro touted that it eliminated the need for "paresthesia-mapping," but quickly discovered upon launch that a large percentage of doctors and patients strongly preferred paresthesia. Comments from a KOL and two former employees are representative.

Patients "crave" paresthesia

"Nevro didn't want the patient to feel paresthesia, but ***what you'll find is that they crave the paresthesia. Once they feel it, they think that that's the indication of whether the device is working or not. You can't just get rid of paresthesia unilaterally*** *and say it's a great thing because there are definitely reasons for it."* - ***High volume implanter/KOL***

Half of doctors even at launch asked for paresthesia, with Nevro stubbornly refusing to accommodate

"The HF10 results don't pan out over time, correct. Again, that's my personal opinion*. It's the reason Omnia is out. A lot of people wanted the paresthesia.* ***Even right from the start, probably 50% of the doctors that I came across wanted paresthesia as an option for patients****.They were saying, what if a patient wants it? We'd say, no, no, we have to follow the evidence and we can only do it this way."* - ***Former Nevro territory manager, member of launch team, and one of the most tenured stimulator reps in the industry***

In the absence of feedback from paresthesia, Nevro's device became difficult to program and target to the area of pain

"If the leads move even a little bit ***the Nevro reps get lost and they don't know where to program because there's no buzzing or tingling, no paresthesia. So they don't know what to do. They're programming blind****."* - ***High volume implanter/KOL***

Source: Consultation calls with experts

5. High frequency is Nevro's fatal flaw and dooms any turnaround

A former Nevro executive, who oversaw a key function, elaborated on the programming difficulties unique to high frequency and explained how the lack of paresthesia undermined the company's value proposition and backfired. Reps in the field couldn't program stimulators, patients failed to get relief, and Nevro tried to stem the crisis by creating a centralized call center that played whack-a-mole in an attempt to get devices working. The executive described the resulting patient support burden as a driver of Nevro's broken business model.

"High frequency comes with challenges. The patient doesn't get feedback from paresthesia*. They either feel pain or don't. That's where the challenge comes in for Nevro. There's a whole psychological issue with paresthesia that plays into it. The patients are dependent on opioids. The device could be working, but patients say it's not working, and then the patients want opioids. Patients have to be in a mindset to be patient to be cooperative. If they had a low frequency device, they're used to making programming changes on the fly, which you can't with high frequency. Some patients are compliant. A good number are not.* ***They just crank the device up and have more pain."*** ***– Former Nevro executive***

"Nevro put together a brand new patient support and programming team*. It's role was to work with patients, call the patient on a daily basis, and advise the patient to turn the stimulator on or off.* ***It was a big organization****. They would have a list of patients they were in charge of. They would call them daily during the trial, right after, after the procedure, to make sure the stim is set correctly.* ***No other neuromodulation company had that. It was unique to HF10.*** *A lot of times the patient had to be patient. We'd lower or increase the stimulation. We'd start at a low frequency, would wait 24 to 48 hours, would increase it by 1, then wait, then increase it again.* ***For one algorithm, you'd spend a week and a half just on that algorithm.*** *The reps would ask on the phone if you're getting pain coverage, take notes, then add 3 milliamps. They'd have to go through this over the next 3 to 4 weeks to get correct coverage.* ***If they didn't get correct pain coverage, they'd have to bring the patient back in for reprogramming to see which programs work or don't work****.* ***– Former Nevro executive***

Source: Consultation calls with experts

5. High frequency is Nevro's fatal flaw and dooms any turnaround

A former regional sales director, who oversaw one of Nevro's largest territories and now runs the region for a competitor, stated that "paresthesia-free" created chaos in Nevro's field sales organization. Reps spent all their time trying to get devices programmed properly, creating salesforce attrition and other challenges for Nevro's business model. He stated that programming a high frequency device took "twice as long if not longer" than competing devices.

*"**Nevro's salesforce attrition was due to unique challenges for the sales team in managing patient outcomes. It's a derivative of the fact that Nevro touts a paresthesia-free experience for the patient**. This is unlike traditional stimulator companies who offer a paresthesia-based therapy where the patient can describe the coverage of paresthesia to where the pain is. **With Nevro, there's no clear way of mapping out the stimulator's coverage."***

*"Since its launch, Nevro was completely against paresthesia mapping of any form. **This created unique challenges for the field staff**. It consumed significantly more time and would require significantly more programming, plus added corporate resources and support."*

***"More than 50% of patients required interventions for more than one re-programming session within the first 90-120 days.** For new field reps, a session could take 45 to 90 mins. What I found working at [competitor name redacted] and Nevro is that programming took twice as long if not longer at Nevro. With a [competitor] device, when a patient describes where the pain is, the rep can program right to that site. With Nevro, a patient goes through an algorithm being asked does it feel better now, does it feel better now, does it feel better."*

*"**Reps could be there all day trying to make the patient happy. Paresthesia-free led to a mess in the field. The Omnia launch was an acknowledgement that they needed to change course because the novelty of high frequency has worn off.** Nevro launched when there had been no new innovation in SCS in three decades. Their timing couldn't have been better then." **– Former Nevro regional sales director, now at a key competitor***

Source: Consultation calls with experts

5. High frequency is Nevro's fatal flaw and dooms any turnaround

Given the size of his territory and the volume of patient outcomes that he witnessed, we find his comments on Nevro's lack of efficacy to be illuminating. He stated that "less than 20% of patients" experienced results consistent with Nevro's pivotal trial and that almost all suffered periods with no efficacy at all. He offered a pithy explanation for why "paresthesia-free" is a fatally flawed concept: paresthesia-based devices only need to provide some masking for the patient to feel relief, but without a compensatory tingling sensation to substitute for the pain, Nevro's device has to provide 100% pain relief, which is impossible.

"The lack of therapeutic efficacy affected significantly more than 50% of patients at some point. 100% of patients experienced it at some point."

"With high frequency, patients are waiting for pain relief versus pain masking. Paresthesia has an immediate effect on leg pain because it masks it. ***High frequency requires going from painful to no pain. It requires 100% pain relief which never happens. The patient still feels pain. The patient wants zero pain."***

"The disconnect between the clinical data and actual results is that the data said you get 70-75% pain reduction with high frequency. Probably less than 20% of patients in my region got that*. 25% of patients were non-responders. They weren't responsive to high frequency at all. 50% had pain relief but not to RCT-reported levels. For those 50% of patients, competitor devices fared better."* ***– Former Nevro regional sales director and now at a competitor***

Source: Consultation calls with experts

5. High frequency is Nevro's fatal flaw and dooms any turnaround

He explained what happened next: Nevro found itself "in a bind" with the CEO and management refusing to accept that high frequency is a dud that never lived up to the hyped-up "data," which led to conflict with the field organization and sales reps leaving "in droves" despite the best compensation and benefits in the space. He added that Nevro's message no longer resonates and that the space has moved on.

"The real world results that Nevro had in the field didn't live up to the clinical data they were purporting. They found themselves in a bind*. The initial response was to try and re-educate doctors on why it would work because the data says it would and they just need to keep believing."*

"Nevro refused to acknowledge the product was responsible. The product didn't work as well as senior leadership would say. This led to conflict with the CEO and a disconnect between headquarters and the field*. It led to significant attrition, despite how generously they compensated the field and benefits which are unmatched in medical device sales. Candidates would fall over in their chairs when they heard the benefits, but reps still left in droves."*

"Nevro's paresthesia-free message doesn't resonate anymore. Competitors have waveforms that mimic paresthesia-free pretty closely. *Boston Scientific and Abbot for sure. Or they have paresthesia-light. Abbott brought out paresthesia-light with the Burst DR platform. It's been out for a few years now. Boston Scientific has Wavewriter."* ***– Former Nevro regional sales director now at a key competitor***

Source: Consultation calls with experts

6. A covered-up device failure and explants crisis

Having run a sham pivotal study and with its sole product based on a flawed theory, reality dawned on Nevro as doctors and patients began to see the device fail. Nevro took the space by storm at launch in 2015, on the heels of exciting "data" that led doctors to try the device. Our research indicates that doctors soon began to notice problems with the device, which caused them to abandon Nevro in droves and explant (surgically remove) its stimulators. We begin by noting Nevro's absurd claim of having the lowest explant rate in the industry.

Nevro claims that only 1.2% of Wave writer devices are explanted because of failure, and that only 3.7% are explanted overall

HF10 MATTERS

HF10 Therapy: Lowest Explant Rate in SCS

Explant Rates in SENZA-RCT

Less than h
the explant
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Source: Senza RCT

HF10 MATTERS

Real World Results

High-Volume HF10 Centers Analysis

Design

- Eight global, high-volume HF10 centers
- 1660 patients enrolled (2014-2018)

Long Term Efficacy (n=1100*)

- 78% responder rates
  - 74% responder rates in prior SCS patients
- 90% satisfaction
- 32% of patients reduced medication intake
- 3.7% reported explant rate
  - 1.2% due to loss off efficacy


A multicenter real-world review of 10 kHz SCS outcomes for treatment of chronic trunk and/or limb pain

Stauss, Thomas et al. A Multicenter Real-World Review of 10kHz SCS Outcomes for Treatment of Chronic Trunk &/or Limb Pain. Annals of Clinical and Translational Neurology. January 2019 (Currently in Press).
Among the 1,290 patients with safety data available, 48 had their devices explanted (3.7%). Of these, 22 were removed sequela to infection (1.7%), 15 due to loss of efficacy (1.2%), and 11 for other reasons (0.9%).
*The mean time between implantation and the last visit was 8.9 months (range 0.1–33.2).

Source: Nevro Q1 2019 investor slides https://s24.q4cdn.com/932612397/files/doc_presentations/Nevro-IR-Presentation_Q12019_050919.pdf

Scorpion Capital | Nevro (NYSE: NVRO)

6. A covered-up device failure and explants crisis

This claim of a low single-digit explant rate is based on a 2018 "study" that analyzed outcomes at a mere 8 cherry-picked clinics. The study – which appears to be written by a Nevro medical writer with 3 employees as authors - is a barely-disguised marketing brochure masquerading as a legitimate paper. The 8 sites are not detailed, but apparent from the list of authors as strictly those of paid Nevro consultants. Given that the study looked at only 3, 6, and 12 month outcomes, we presume the trumpeted explant rates are based on these absurdly short intervals and clinically irrelevant.

ANNALS of Clinical and Translational Neurology — Open Access — ANA American Neurological Association

RESEARCH ARTICLE

A multicenter real-world review of 10 kHz SCS outcomes for treatment of chronic trunk and/or limb pain

Thomas Stauss[1], Faycal El Majdoub[2], Dawood Sayed[3], Gernot Surges[4], William S. Rosenberg[5], Leonardo Kapural[6], Richard Bundschu[7], Abdul Lalkhen[8], Nileshkumar Patel[1], Bradford Gliner[9], Jeyakumar Subbaroyan[9], Anand Rotte[9], Deborah R. Edgar[10], Martin Bettag[4] & Mohammad Maarouf[2]

Table 2. Details of device explants in the population.

Reason for explant	*n* (%; 95% confidence range)
	N = 1290
Infection	22 (1.7%; 1.0%–2.4%)
Loss of efficacy	15 (1.2%; 0.6%–1.8%)
Other reasons	11 (0.8%; 0.3%–1.3%)
Total	48 (3.7%; 2.7%–4.7%)

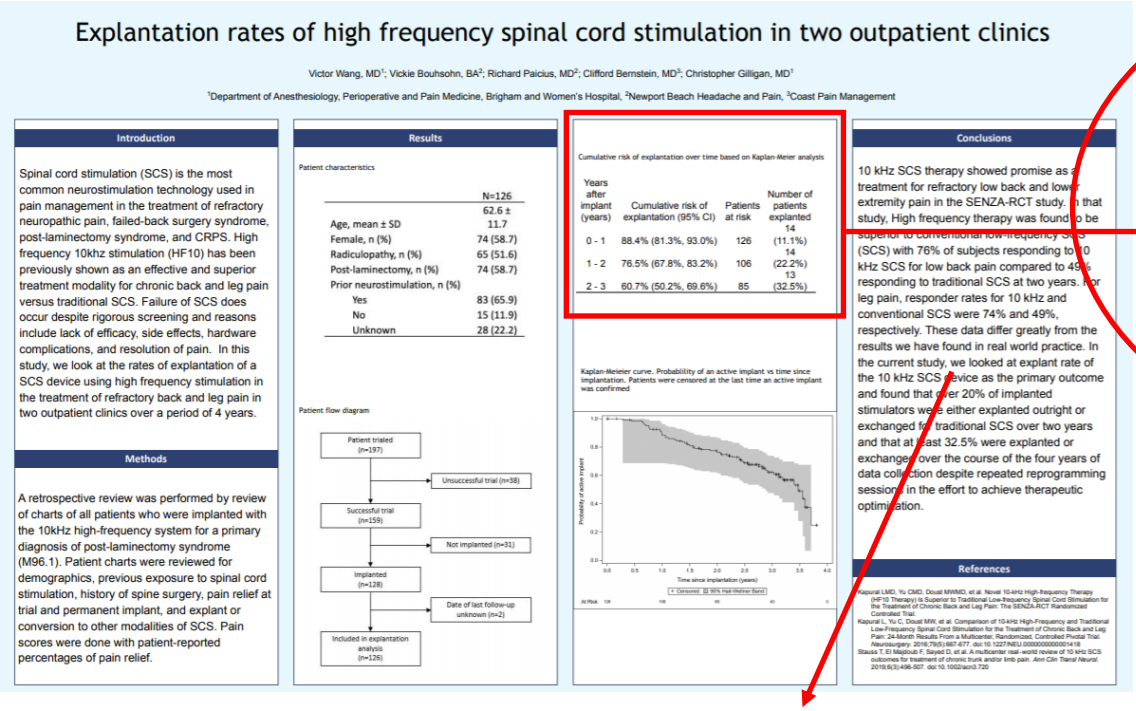
Conflict of Interest

T. Stauss, G. Surges, D. Sayed, F. El Majdoub, W. S. Rosenberg, L. Kapural, R. Bundschu, A. Lalkhen, M. Maarouf and N. Patel are consultants to Nevro Corp., Redwood City, CA, USA. B. Gliner, J. Subbaroyan, and A. Rotte are employees of Nevro Corp., Redwood City, CA, USA. Funding was provided to Dr. Deborah Edgar in her capacity as a medical writer by Nevro Corp., Redwood City, CA, USA, for the preparation of this manuscript.

Source: https://onlinelibrary.wiley.com/doi/epdf/10.1002/acn3.720

6. A covered-up device failure and explants crisis

A paper presented in January 2020 at NANS, the key annual neuromodulation meeting, indicated explant rates of 22% within 2 years and 33% within 4 years for Nevro's product "despite repeated reprogramming sessions in the effort to achieve therapeutic optimization" – dwarfing the 1.2-3.7% rates Nevro's own "paper" claimed by ~10-30x. The study indicated that the purported results in Nevro's pivotal SENZA study "differ greatly from the results we have found in real world practice."



Explantation rates of high frequency spinal cord stimulation in two outpatient clinics

Victor Wang, MD[1]; Vickie Bouhsohn, BA[2]; Richard Paicius, MD[2]; Clifford Bernstein, MD[3]; Christopher Gilligan, MD[1]

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Introduction

Spinal cord stimulation (SCS) is the most common neurostimulation technology used in pain management in the treatment of refractory neuropathic pain, failed-back surgery syndrome, post-laminectomy syndrome, and CRPS. High frequency 10khz stimulation (HF10) has been previously shown as an effective and superior treatment modality for chronic back and leg pain versus traditional SCS. Failure of SCS does occur despite rigorous screening and reasons include lack of efficacy, side effects, hardware complications, and resolution of pain. In this study, we look at the rates of explantation of a SCS device using high frequency stimulation in the treatment of refractory back and leg pain in two outpatient clinics over a period of 4 years.

Methods

A retrospective review was performed by review of charts of all patients who were implanted with the 10kHz high-frequency system for a primary diagnosis of post-laminectomy syndrome (M96.1). Patient charts were reviewed for demographics, previous exposure to spinal cord stimulation, history of spine surgery, pain relief at trial and permanent implant, and explant or conversion to other modalities of SCS. Pain scores were done with patient-reported percentages of pain relief.

Results

Patient characteristics

	N=126
Age, mean ± SD	62.6 ± 11.7
Female, n (%)	74 (58.7)
Radiculopathy, n (%)	65 (51.6)
Post-laminectomy, n (%)	74 (58.7)
Prior neurostimulation, n (%)	
Yes	83 (65.9)
No	15 (11.9)
Unknown	28 (22.2)

Patient flow diagram

Cumulative risk of explantation over time based on Kaplan-Meier analysis

Years after implant (years)	Cumulative risk of explantation (95% CI)	Patients at risk	Number of patients explanted
0 - 1	88.4% (81.3%, 93.0%)	126	14 (11.1%)
1 - 2	76.5% (67.8%, 83.2%)	106	14 (22.2%)
2 - 3	60.7% (50.2%, 69.6%)	85	13 (32.5%)

Kaplan-Meieier curve. Probability of an active implant vs time since implantation. Patients were censored at the last time an active implant was confirmed

Conclusions

10 kHz SCS therapy showed promise as a treatment for refractory low back and lower extremity pain in the SENZA-RCT study. In that study, High frequency therapy was found to be superior to conventional low-frequency SCS (SCS) with 76% of subjects responding to 10 kHz SCS for low back pain compared to 49% responding to traditional SCS at two years. For leg pain, responder rates for 10 kHz and conventional SCS were 74% and 49%, respectively. These data differ greatly from the results we have found in real world practice. In the current study, we looked at explant rate of the 10 kHz SCS device as the primary outcome and found that over 20% of implanted stimulators were either explanted outright or exchanged for traditional SCS over two years and that at least 32.5% were explanted or exchanged over the course of the four years of data collection despite repeated reprogramming sessions in the effort to achieve therapeutic optimization.

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"10 kHz SCS therapy showed promise as a treatment for refractory low back and lower extremity pain in the SENZA-RCT study […] These data differ greatly from the results we have found in real world practice. In the current study, we looked at explant rate of the 10 kHz SCS device as the primary outcome and found that over 20% of implanted stimulators were either explanted outright or exchanged for traditional SCS over two years and that at least 32.5% were explanted or exchanged over the course of the four years of data collection despite repeated reprogramming sessions in the effort to achieve therapeutic optimization."

Source: NANS 2020 poster

6. A covered-up device failure and explants crisis

The paper generated significant buzz at the NANS conference, despite representing early data from only two sites. Our research indicates that other papers and studies on Nevro's explants rate may either be in process or in peer review, to expand upon the initial data and findings, which we expect to further undermine Nevro's credibility with KOL's and its trajectory. We believe it was the first time doctors publicly began to confront the elephant in the room regarding Nevro's explant rates. We spoke to several KOL's who were in attendance or intimately familiar with the research and its authors. The talk attracted an overflow crowd, and numerous doctors in attendance confirmed that they too had seen similarly abnormal rates of explants. Another KOL indicated that Nevro would try to undermine the presenter.

*"**There are doctors that are saying, "I saw [doctor name redacted] speak at NANS**, and I saw [doctor name redacted's] outcomes and other doctors' outcomes, and I dug into it, and **I'm having the same outcomes. I'm not using high-frequency anymore."** **– One of the most senior and plugged in executives in the SCS space***

"The NANS talk was well-attended**. I was surprised. It was at 6AM and a lot of people came. It filled up like three rooms. **They had to take the dividers out. I'd say there were 100 to 150 attendees**" **– KOL

*"**After Nevro's explant rate was publicly presented, several doctors came up to say that more research needs to be done on this because we're seeing a lot of explants as well**. A lot of pain doctors aren't willing to say much about the negative aspects of spinal cord stimulation, but **a lot of them at the conference approached the author about their explant rates. They said we're seeing about the same numbers.** They of course didn't look into their data. When you're a provider, you're noticing trends. It's not a day to day thing, but you're thinking that for some reason in the past few months I'm explanting a lot of high frequency spinal cord stimulators." **– KOL***

*"The most important thing the presenter said was that 5 or 6 implanters came up to him after the talk and said they had the same experience. **Another paper shows that doctors who did big volumes had the same explant rate. This study will be big and show what's going on because right now Nevro is going to try and throw [redacted] under the bus and say [redacted] is getting paid by somebody else to do this."** **– KOL***

Source: Consultation calls with experts

6. A covered-up device failure and explants crisis

Another KOL suggested that Nevro may have tried to retaliate prior to the presentation, and stated his belief that Nevro prevented the explants paper from being listed in the program and tore the data presentation from the wall. The doctor referenced previous retaliatory behavior by Nevro and "disinformation" regarding their explant rates, characterizing the company's conduct as "slimy."

*"I talked to [KOL name redacted]. **One creepy thing – the paper that had been posted got torn down after the first day. Somebody tore it down. And then the talk wasn't listed in the program, which is weird. The first thing we all thought was that it sounds like Nevro**. We all said, yup that sounds like a Nevro deal…[KOL name redacted] called me and said, do you think it's weird that [name redacted's] talk was not in the program? So I picked up the program and was like, wow it's not. It's weird. As this had to do with Nevro, it doesn't surprise me."*

*"**They have a good disinformation approach**. They nationally vilified [name redacted, doctor who was critical of Nevro's explant rates]. They actually sent a rebuttal to all their implanters talking about how [redacted] had some vendetta. They've done that before historically. **It's a slimy company, hands down."** **–KOL and former Nevro consultant***

Source: Consultation calls with experts

6. A covered-up device failure and explants crisis

The 33% explant rate found in the NANS paper was corroborated by one KOL after another during our 20+ research interviews with doctors – across countries and a broad sample of US states, among doctors in private practice and those in academia, whether they still selectively use Nevro or now refuse to use it. We believe Nevro sales hit the wall because of a covered-up explants crisis, and that fatal flaws specific to its high frequency mechanism of action are an albatross that dooms its trajectory. The following pages shall substantiate the broadly shared, remarkably consistent, and damning feedback from doctors.

- A KOL in Europe, with extensive experience implanting Nevro's devices, stated that **the company's device failure rate is common knowledge in Europe**, where Nevro launched several years before the US.

  "***A lot of doctors in Germany are saying that Nevro's device only works for 2 to 2 ½ years and then the patient comes back with more pain. They say it fails*** *and then they have to put in an Abbott or Boston Scientific device.* ***It's a big issue here in Germany. These are credible people****. People who do a lot of surgeries and are involved with the society. Every time there's a spinal cord stim meeting, this is an issue that colleagues talk about.* ***People have become nervous and become afraid to use Nevro.***" ***– High volume European implanter***

- US KOL's stated that **Nevro was lying about it explant rate, that "everyone" thinks its high**, and that the rate was "**talked about at every meeting."**

  "The Nevro marketing materials that state a ***2% explant rate are just a flat out lie."*** ***– High volume KOL***

  "Everyone thinks Nevro has a high explant rate." ***– High volume implanter***

  "***The Nevro explant rate was known all over. At every meeting, colleagues talked about the explant rate being high. [****KOL name redacted] explants a bunch of Nevro a week.* ***He was a big Nevro advocate*** *and has a lot of explants. Everyone was drinking the Nevro kool-aid at the beginning."* ***–KOL, high volume implanter***

Source: Consultation calls with experts

6. A covered-up device failure and explants crisis

The 33% explant rate (cont'd)

- **Doctors confirmed the ~33% explant rates in the NANS paper**. Some provided figures a bit lower based on their own experience, while others (as we shall detail) said their personal explant rates for Nevro were 80%+.

  ***"The explant rate was more than 25%. It was a lot**. A lot of time I'd replace Nevro with a Medtronic unit because it was so tiny." –High volume KOL*

  *"**For every 100 Nevro devices implanted, 30% of them will be explanted within a year or two.** What Nevro has done hurts the rest of us because then people are less likely to use any company's devices. What one greaseball does affects the rest of us. It's flawed. Nevro's research is deeply flawed." –High volume KOL*

- KOL's stated that Nevro's **explant rate was the highest in the industry and an outlier, and questioned why the company won't publish proper explant data**

  *"I had stopped using Nevro. I know so many of their devices that were explanted because patients couldn't stand the size and programs that drain battery life. **The explant rate is higher for Nevro than anyone else. I'm so frustrated with how I put it in.** I've had zero results with Nevro in trials and it's so unusual. **I've had more failed Nevro trials than with any other device**. I don't have an explant rate with other devices. Maybe some three to fours years out. Maybe once a year I explant out of someone. **Colleagues tell me Nevro's explant rates are higher than anything else. I hear that from other doctors. Walk around the next NANS meeting and ask people about explant rates**." –High volume KOL*

  ***"What is the explant data? Nevro will not publish it**. They have to keep information on every patient that gets explanted. With Nevro's high frequency device, **I have never seen so many explants from one company.** Every once in a while, I'll see a crap Medtronic or Abbott device and I need to put in something else. But just **in terms of lack of efficacy and explants, Nevro is clearly number one."** –High volume KOL*

Source: Consultation calls with experts

6. A covered-up device failure and explants crisis

The 33% explant rate (cont'd)

- Doctors indicated that **Nevro's devices begin to fail fast**, requiring explantation as soon as 6 months out

  *"It's rare to see a device not working at all, but **I've seen with Nevro at 6 months that it's not helping patients."** -KOL*

  ***"The biggest reason for Nevro explants is device failure**. That's probably the biggest reason, over 80-90%. And then infection rates. But it's almost always failure. **Anecdotally and from the data there's a range, but it seems to be within about a year.** But some of them fail later, within three years." -KOL*

- KOL's who didn't provide exact explant percentages nonetheless provided **qualitative color that was similar**

  *"High frequency seemed to have a lot of traction when it first started off. We're trying to figure out if the initial pain improvement is still there, a year out, two years out, five years out. **It seems like a lot of the high frequency implants have been explanted, or exchanged for something else."** -KOL*

- Another high volume KOL provided **a separate data point substantiating Nevro's abnormal explant rate**

  *"Abbott is currently doing a study called Prolong. The study's not specifically going up against Nevro. It's just using the Abbott device as a salvage therapy for failed spinal cord stimulation patients. But, **most of the salvage appears to be for Nevro patients. I think almost 50% of the enrollment so far in the study has been Nevro patients**. Abbott's study was never meant to be a superiority study. The study wasn't meant to bash Nevro. But **Nevro didn't like that the overwhelming majority of patients that needed to be salvaged in the study were all theirs."** –KOL*

Source: Consultation calls with experts

6. A covered-up device failure and explants crisis

The 33% explant rate (cont'd)

- KOL's provided other reasons for explants beyond device failure and lack of efficacy, such as **"intolerable" patient discomfort, "untenable" recharging requirements, adverse effects, and improper indications**.

> *"Senza had a **very high explant rate because of patient discomfort. The frequency of recharging was untenable. Some patients got sore skin from the charging coil**. Having to do it every day could make the skin sore. **It became intolerable to some patients. I have a friend who explanted 3 Nevro devices in one day. He's not a big Nevro guy anymore."** -KOL*

> *"**I've explanted a lot of Nevro because of lot of my colleagues started implanting it for indications I didn't agree with**. You need some form of neuropathic pain like a previous surgery or trauma. **It won't work for regular back pain** like if it's your joints or a disc." -KOL*

Source: Consultation calls with experts

6. A covered-up device failure and explants crisis

A number of KOL's indicated why the 33% explants rate in the NANS paper actually underestimates how often Nevro's device fails: many patients just turn the device off and don't bother to have it surgically removed because "they don't want to go back to their doctor because he sold them on the idea." It's therefore not technically an explant, but still a device failure.

"The explant rate is also ***underestimated because the device would stop working and the patient doesn't want it pulled out.*** *'* ***– High volume KOL***

*"****You have to include another population of patients when you talk about explants, something which happens a lot. You ask patients how it's going and they say "I don't use the stimulator."*** *I ask why and they say, I just don't feel like it's working that well." There are people that aren't explants. They just leave it in, and they don't even use it but they don't want to explant it. They don't want to go back to their doctor because he sold them on the idea.'* ***–High volume KOL***

Source: Consultation calls with experts

6. A covered-up device failure and explants crisis

Aside from both KOL's and former employees indicating rampant device failures and explants, we provide confirmatory color from territory managers at key competitors, for whom Nevro's explants problem appear to be common knowledge. One indicated that the largest clinic he sells to had an 80% explant rate with Nevro's device and "won't let Nevro back in."

"I've heard upwards of an 80% explant rate, at the biggest clinic that we sell to. ***They won't let Nevro back in. They said about 80% of their Nevro devices have come out."*** ***– Longtime Medtronic territory manager, running a large midwestern region***

"*Nevro defines explants differently. Their study on explant rates said it's just 1%. The Europe study [that indicated high explant rates] looked at the real world.* ***I had a doctor in my territory who put in 25 Nevro devices and explanted all of them."*** ***–Longtime Medtronic territory manager, running a larges multi-state region on the east coast***

Source: Consultation calls with experts

7. Nevro's explants crisis is pervasive yet unknown to most investors: case studies of 5 KOL's

As additional corroboration, we share five detailed case studies of KOL's, each of whom was initially excited by Nevro's device only to experience an explant crisis, and who provided remarkably consistent and damning feedback about Nevro's technology and conduct. We begin with case study #1: a high volume implanter who described his initial experience with Nevro as "almost miraculous," only to sour after seeing rampant failures within 3-6 months. He states that the 33% explant rate in the NANS paper is massively underreported and that the actual rate is "tremendous" and possibly 50-60%; that Nevro's reps couldn't get the devices to work again; that the device harms patients; that Nevro "just lies"; and that's he's never seen anything like this with other stimulators. He bluntly stated that "patients hate the Nevro device" and that it's a "piece of shit."

*"**I worked with Nevro for a while, but I had a bad experience with them**. When they first released [in the US] they had a study from Australia that showed that they were head over heels better than the other stimulators. I started implanting them, and it was almost miraculous. Patients loved it. **Everything was great for a few months. But then I noticed that for a lot of the patients, the device stopped working after three to six months."***

*"The reps would then come out and go through their very rigid algorithm. **And most of them couldn't get the implants working again. And then I noticed that the high frequency started hurting patients**.. It went from being great to not working to irritating."*

*"**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."***

*"I've worked with others to study their explant rate, because it's tremendous. **I've been implanting for a long time and I rarely explant**. Sure, sometimes stimulators don't work. But rarely do they stop working and irritate a patient. I mean, it's happened but not at the numbers we saw with Nevro. I would rarely explant people. I would say 1 or 2%, if that."* ***–High volume implanter and KOL***

Source: Consultation calls with experts

7. Nevro's explants crisis is pervasive yet unknown to most investors: case studies of 5 KOL's

Case study #2: A high volume implanter and KOL who was also initially impressed with Nevro's data, only to see patients fail "like clockwork" within 3-6 months. He states that he didn't have a single back/leg pain patient who made it past a year, and that only 2 out of 90 patients he implanted with Nevro still have the device – an explant rate approaching 100%. He added that "a lot, a lot of doctors" have had the same experience with a "70-80% explant rate." Similar to the first case study, the KOL emphasized that his explant rate with other companies' stimulators is negligible.

*"**When Nevro launched in 2015, I was really interested in the data and how much better it worked** than regular spinal cord stimulation. So I used it and I was very impressed with it in the beginning."*

***"But then the failures just kept coming. People just kept getting explanted or the pain just kept coming back**. I used to use Nevro for just about everything, like low back pain, leg pain, and neck pain. **But after three to six months it was like clockwork that patients just started shitting the bed. So I just stopped using it**. In 2016 and 2017 Nevro was 40% of my implant volume and then a drop in 2018 and 2019. I've only used two Nevro devices this year."*

*"The patients' pain just came back. It was pretty consistent. **It was between three to six months almost across the board**, or if not then by 8 months. **I didn't have a single patient that made it past a year** except for the ones with abdominal pain. Every other patient - like every one of them - **I might have 2 back patients that still have it out of 90** I implanted with Nevro. That's not unheard of. **There are a lot, a lot, of doctors who have had that experience. I know of a lot of doctors who had a 70-80% explant rate.** My overall explant rate is very low. No one can say that my Nevro explants were due to my patient selection"*

***"A third of my explants were because the device sucks. The device stops working** - call that the reason a third or fifty percent of the time. The vast majority of my explants were because the device stopped working. **The remainder were because of the rep not being able to program it. If the leads move even a little bit the Nevro reps get lost and they don't know where to program** because there's no buzzing or tingling, no paresthesia. So they don't know what to do. **They're programming blind."** – High volume implanter and KOL*

Source: Consultation calls with experts

7. Nevro's explants crisis is pervasive yet unknown to most investors: case studies of 5 KOL's

Case study #3: One of the most prominent KOL's in the field – a former Nevro consultant and speaker – described his initial enthusiasm for Nevro's device, implanting 80 within the first 18 months. He stated that patients started off well, only to experience a quick collapse in efficacy. As a well-known figure, he regularly conducts group sessions with other "busy implanters," whose experience with high frequency failure was similar to the point that they also became "hesitant to use the product."

"I've consulted at length for Boston Scientific, Abbott, Nuvectra, and of course Nevro over the course of my career. I have been doing implants for 20 years. I've put in probably several thousand over the years *and probably do about 5 or more per month. I actually am [role redacted] at [medical journal name redacted] which is kind of the bible for neuromodulation.* ***I would review papers on stimulation every month as a peer-reviewer so I'm quite versed with the field."***

"When Nevro first came out I was using primarily Boston Scientific. At the time I thought it was the best product on the market but I was convinced to try Nevro. I had a couple of patients that weren't getting relief with Boston, so we hooked them up to a Nevro device and it did very well. ***So that precipitated my journey from Boston Scientific to Nevro several years ago. And probably the first 18 months I put in close to 80 Nevro implants and did 100 trial implants which is a fair amount."***

*"****What I noticed is that initially almost everybody did really well and subsequently there was a big fall off****. **We would hold round tables** where we would have 15 implanter leaders and I and two other moderators would talk about the space in general and **I found that I was not alone and that other busy implanters also had the same experience**, where initially things looked good and then there was a significant drop off **to where many doctors were hesitant to use the product."*** ***–Ex-Nevro consultant/speaker and one of the most prominent KOL's in the space***

Source: Consultation calls with experts

7. Nevro's explants crisis is pervasive yet unknown to most investors: case studies of 5 KOL's

Case study #3 (cont'd): He elaborated that 75% of Nevro patients experienced a collapse in efficacy, with explants beginning within 6 months and then accelerating. This KOL was familiar with the NANS paper which reported a 33% explant rate, and stated that the rate would have actually been ~50% if not for methodology constraints. Notably, he added that other papers on Nevro's alarming explant rates are in peer review "to be published shortly."

"I would say overall probably 25% of the patients are satisfied with Nevro, maybe less. ***We first started seeing a diminution at about 6 months, and it really became prevalent at close to a year.*** *I would say on average, towards the end of the first year of the implant, we saw a huge drop off in efficacy."*

"I noticed that 50% of patients were not getting relief by end of one year, and within 18 months, 75%*. I think the efficacy drop off was present at a year, but it may have taken us 18 months to really delve into how many patients weren't getting relief."*

"If all the patients were included, the explant rate in the study would have been closer to 50% [versus the 33% in the paper]. Including the patients he wasn't able to follow, the explants would have been worse. *There was another doctor [name redacted] who had a high implanting volume. Exact same story.* ***Other papers on explant rates are in peer review to be published shortly."*** ***—Ex-Nevro consultant/speaker and one of the most prominent KOL's in the space***

Source: Consultation calls with experts

7. Nevro's explants crisis is pervasive yet unknown to most investors: case studies of 5 KOL's

Case study #3 (cont'd): He stated that he was initially excited by Nevro's SENZA pivotal study data, which at first appeared miraculous compared to all previous stimulators – only to realize in hindsight that it was too good to be true and fraudulent. He referenced conversations with Nevro reps who admitted as much, leading him to label it "a big scam" with "criminal" data manipulation. He added that other KOL's came to a similar conclusion and viewed Nevro with "disgust."

***"If a doctor says I use Medtronic, Boston Scientific, or Abbot, the outcomes would be relatively similar**. Each has its bells and whistles, but if my hospital forced me to use one manufacturer, I might do 10% better without it, or 10% with Boston Scientific but **the reality is they are so similar** that it's not that different."*

"But with Nevro, two things made them the big bang success at the beginning**. They came out with the Senza study which showed **just amazing outcomes. Better stimulation results than we had ever seen** and this is including back pain. Stimulation historically has been great for radiculopathy, pain that is going in your arm or down your legs. But for axial pain, cervical, low back, stimulation has never been that great. You might get a success, you might get some benefits, but it wasn't a home run - ever. With Nevro, they came out and said they got 75, 80% relief for two years with back pain and leg pain. **Now, I have been involved in the space. I publish. I'm involved in neuromodulation publications, probably three or four papers a year. I know how this works, and in everything we did we would augment [the data] a little bit to get manipulation of statistics and so forth, but for this kind of number, this was like…what??"

***"We subsequently found out, as we spoke to former Nevro reps who were involved in the Senza study, that the manipulation in statements from the patients was crazy**. They had very leading questions like, "in certain times of the day do you feel that your pain is this much better, that much better?" It wasn't an overall global pain assessment scale. These were very, very specific questions to manipulate the answer that they wanted. **I wasn't the only one who found this out. Other doctors who I respect greatly in the field also got the same input from other reps who were formally working for Nevro. So, it was a big scam. The way that they manipulated the data was criminal**. I would say that the bigger names in neuromodulation who weren't getting paid by them, **think of Nevro with disgust."** –Ex-Nevro consultant/speaker and one of the most prominent KOL's in the space*

Source: Consultation calls with experts

7. Nevro's explants crisis is pervasive yet unknown to most investors: case studies of 5 KOL's

Case study #3 (cont'd): The KOL described visiting Nevro's headquarters to address rampant device failure and explant rates. The company sent their top experts who spent 4 months flailing in their attempts to get the therapy working again, at which point the KOL ceased using Nevro. He said he had a strong relationship with Nevro; that they "paid me a lot of money" as a consultant/speaker; but concluded the technology just "doesn't work" despite working "hard with them to try to accomplish this." He expressed dismay at Nevro's ethics and ongoing "smoke and mirrors" – calling it "crazy."

"We went to Nevro's headquarters to discuss the high explant rates and for four months they had their top couple of programmers come down to my office *to see a bunch of my patients and "optimize their therapy." It got to the point where I was like, we can't do this anymore.* ***After 18 months I stopped implanting Nevro. I realized this shit doesn't work****. I'm not beholden to a company. Whichever device I'm using now, if I think there's a better mousetrap I'm jumping to it. I don't have any brand loyalty."*

"I had a good relationship with Nevro. They took really good care of me*. They flew me all over the country to speak, paid me a lot of money, put me in first class which is unusual for consultants, so I didn't have any animosity towards them.* ***It was just that the patient outcomes never showed up****. I worked with them thinking their device was good stuff. I know how to do neuromodulation, so when Nevro's devices didn't work, I thought maybe there's a different way to change the program, change the location, do something different. I worked hard with them to try to accomplish this and I was beating my head against the wall because it just wasn't happening.* ***I tried everything to make the devices work****, as a scientist. I wanted to see where the problem was. When I looked at their data I was like, ok that's not what I got, am I doing something wrong?* ***So I worked hard with them to rectify it, but there was nothing to rectify."***

*"I don't understand how these people can…I worked my ass off to make Nevro's device work and spent days and days in my office trying to figure out this stuff and nothing was working and it wasn't because I was a shitty implanter..****I don't understand how Nevro can continue to keep the smoke and mirrors going, I really don't. I mean, it's crazy. It's a cult, for sure."*** ***-- Ex-Nevro consultant/speaker and one of the most prominent KOL's in the space***

Source: Consultation calls with experts

7. Nevro's explants crisis is pervasive yet unknown to most investors: case studies of 5 KOL's

Case study #3 (cont'd): The KOL offered detail on why he and "a lot of other doctors" believe Nevro's technology fails and is actually harmful to the spinal cord. Similar to other KOL's, he stated that high frequency overwhelms the spinal cord, inducing tolerization. He indicated an emerging consensus in the field against high frequency approaches, with key players now shifting to lower energy devices. He noted that "the pathological changes" caused by Nevro's device – such as inflammation and cell formation – are currently being actively studied. We presume that any such papers, on top of new ones in peer review regarding Nevro's explant rate, would be devastating for the company's "turnaround."

*"**You can only beat on the spinal cord so long before a refractory response happens. Look at drugs –** ones that effect the nervous system lead to tolerance. If you take two Vicodin a day you need four a day after 6 months to get the same effect because your nervous system is plastic. It accommodates when you put in that much energy. **The pathological changes that may have occurred in patients with Nevro's HF10 therapy are being studied."***

*"**I believe, and a lot of other doctors believe, that you can only pound on the spinal cord so much. You're seeing a shift now**, where other companies are pulsing the energy where it's on for 30 seconds, off for a couple of minutes, repeat, as a potential way **to mitigate the tolerance that occurs in the nervous system."***

*"I'm saying it's just too much energy and you have to back off. **Either the cells are down-regulating and can't hear the noise anymore, or there's an inflammatory response to high frequency and you are get cell formation that's impeding the electrical signal**. I don't know, but there's definitely something happening neurologically. **We've seen this in people who have had chronic stimulation at very high frequencies**. If you crank it up to 8 millivolts, which is a lot, that works but the patient will burn out in a few years. There's only so much you can hit the cord with. It's either downregulation, tolerance which is similar but not the same, or an inflammatory response that's impeding the signal."* **-- Ex-Nevro consultant/speaker and one of the most prominent KOL's in the space**

Source: Consultation calls with experts

7. Nevro's explants crisis is pervasive yet unknown to most investors: case studies of 5 KOL's

Case study #3 (cont'd): The KOL concluded with comments we found particularly withering given his previous role as a Nevro consultant/speaker/advocate – that there is "no question" that anyone not influenced by Nevro payments "has the exact same clinical experience with explants that I had" and that the company is viewed by the most credible and ethical KOL's in the field as "slimy people" with "falsification of data."

"***No question, no question, that anybody who's not in the Nevro cult has the exact same clinical experience that I had with explants. Not a question***. *Additionally, you should talk to [KOL name redacted]. He is the former chairman of [redacted] at [redacted] University and then former chairman of [redacted] at the University of [redacted]. He was the editor in chief of [redacted] and President of [society name redacted]. He knows every inside story about everything.* ***His take on Nevro is slimy people, falsification of data. Everything we have talked about but amplified. He can't stand them. He's a real ethical guy."*** ***-- Ex-Nevro consultant/speaker and one of the most prominent KOL's in the space***

Source: Consultation calls with experts

7. Nevro's explants crisis is pervasive yet unknown to most investors: case studies of 5 KOL's

Case study #4: A fourth high-volume implanter and KOL corroborated the accuracy of the previous case studies in detail. He stated he is friendly with some of Nevro's top engineers, and that his conversations with "hundreds of physicians across the US and internationally" – in his capacity as a speaker/educator – underscored the widespread nature of Nevro's device failure and explants crisis. He personally came to the conclusion that Nevro simply "can't be used, based on the problems we're seeing," and questioned Nevro's refusal to publish real explant data.

"I use Boston Scientific, but I'm not hard-core. I haven't done slideshows for them in three years, maybe more, so it's not like I'm a sheltered animal, I just wound-up evolving to use them. I implant maybe 75 stimulators per year, sometimes 100."

*"**Some of the engineers at Boston Scientific went to Nevro. I know a couple of them very well. There was a pretty significant falloff in Nevro usage after the honeymoon** period of something new and sexy hitting the market. There were significant problems, including in evaluating their studies. We saw this before with St. Jude. Based on Nevro's study design and based on the number of explants that I and other doctors have had to do, **I made the decision that Nevro can't really be used, based on the problems we're seeing**. So, the percentage of my implants that are Nevro is zero. None."*

*"**I can tell you from talking to hundreds of physicians across the United States and internationally, because I did speaking programs internationally, it's about explants**. The number of explants that you see…you can do the math. **Why doesn't Nevro publish its explant data? We've asked them to do that, and they refused**. You put a stimulator in, life is good for a little while. Then the honeymoon's over. Nevro doesn't talk about explant data long-term, and you need that because that's real life." **– High volume implanter/speaker/KOL***

Source: Consultation calls with experts

7. Nevro's explants crisis is pervasive yet unknown to most investors: case studies of 5 KOL's

Case study #4 (cont'd): The KOL – identical to the other case studies – said he was initially excited by Nevro's data only to become disillusioned by "huge problems" at which "we just shook our heads" during peer meetings. He stated that Nevro's product was designed for "lazy" or "greaseball" implanters who don't care about patient outcomes.

"When Nevro first launched, we looked at this and said, "There could be something to a high rate of stimulation. You're basically flooding the zone. What a great idea." ***And then you start going through the study design, and you start looking at real outcomes, and there were so many problems****. Huge problems with their study, the Kapural study in 2015. There were* ***so many problems that we just shook our heads in some of our small doctor groups."***

"If you're a lazy implanter and you don't want to look for the right spot to implant and actually program patients, Nevro is perfect for you*. You put the leads in exactly the same spot every single time, don't have to do any work, the rep turns it on and there you go.* ***This requires physicians that don't care what the outcomes are, that are greaseballs, or that are just lazy."***

"Some people use statistics to bend the truth. We catch Nevro on the little things*, but the overall gestalt is that their the device needs to work for a long period of time. We know from the Kumar study that stimulating with one modality, one waveform, fails as time goes on. You need to come up with something else that the body doesn't get used to. We've known that for years. Nevro is just starting to figure that out. They're behind on the eight-ball."* ***– High volume implanter/speaker/KOL***

Source: Consultation calls with experts

7. Nevro's explants crisis is pervasive yet unknown to most investors: case studies of 5 KOL's

Case study #5: We include detailed color from a fifth KOL – who spent time with Nevro's CEO - whose experience implanting Nevro is a carbon copy of the previous four doctors: initial enthusiasm as "a 100% Nevro believer," followed by rapid device failures and explants the likes of which he "had never had before." He stated that 6 to 7 doctors he compares notes with had the same experience, and expressed skepticism of doctors who claim otherwise, saying their purported lack of explants is not credible. He described widespread disillusionment among implanters, said Nevro's clinical claims are false, and that it's a "one-trick pony."

"I started using Nevro in late 2015. Before that I split my volume between Abbott and Medtronic. ***I got excited by Nevro. I thought it was the Tesla of spinal cord stimulators****. It got a lot of interest among implanters. Now everyone is doing high energy stimulation.* ***I stopped using Nevro toward the end of 2018. I became increasingly frustrated as I began to see a lot of failures with the device.*** *I had dinner with the CEO."*

"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."***

"A local doctor [name redacted] says he's done 450 Nevro implants without any explants and none of us other implanters in the area believe his data."

"I compare notes with 6 to 7 other doctors in the area. Nevro gets one guy to try their device and be excited, and then the initial excitement wears off. ***Surgeons who used to only use Nevro have all gone back to Medtronic or St. Jude."***

"I used to be a 100% Nevro believer in the beginning. They can say or claim whatever they want but it's not true in clinical practice*. It's absolutely not true that it can handle back and leg pain. Nevro is a* ***one trick pony."*** ***- High volume implanter***

Source: Consultation calls with experts

8. Nevro's response to its explants crisis appears to be marked by denial, cover-up, retaliation, and patient/doc manipulation

In striking contrast to some of the most prominent implanters/KOL's in the field, the Nevro loyalists we spoke to stridently denied the existence of explants. We spoke to two of Nevro's key "KOL's," both among their highest volume implanters and widely known as go-to doctors for their studies. We believe they are near the top of the leaderboard for speaking/consulting fees. The first melodramatically claimed that he has personally never seen, nor is aware of anyone else who has ever seen, a Nevro device fail. Then he falsely claimed he has no financial connection with Nevro, contradicting his own conflict-of-interest disclosures in multiple papers. Comically, we learned from his colleague that he's dismayed with Nevro after experiencing pervasive explants himself. The second Nevro adherent claimed he has only one Nevro explant out of hundreds – logarithmic magnitudes below Nevro's own purported rates. We found him belligerent at the slightest question, emphasizing his awards and accusing us of working for a Nevro competitor.

Nevro loyalist KOL #1

"I have never seen a person who used Nevro and say it didn't work. I haven't seen one….I have no financial connection with Nevro *or any other company…Ask people who use Nevro and* ***find one who says it doesn't work…*** *There are doctors who are really against Nevro despite using only one implant but opposing it from beginning. They complain it's not working. It's just their opinion. It's never backed up with quality studies. We produce a lot of papers based on science."*

Nevro loyalist KOL #2

"I like Nevro because of its efficacy and long term outcomes. ***We've removed one device. That's a great achievement out of the hundreds of devices implanted****…I got a lot of accolades for the study. I got 7 awards for the publication."*

Our question: How confident are you of the Senza pivotal study?

"Of course it's not a blinded study. Are you aware of any blinded studies? How can it be blinded? Are you a consultant for Boston Scientific??"

Source: Consultation calls with experts

8. Nevro's response to its explants crisis appears to be marked by denial, cover-up, retaliation, and patient/doc manipulation

KOL's stated their belief that the company is aware of its explant problem but "couldn't care less" and made a "conscious decision" to ignore it, but that doctors were nonetheless starting to 'pick up on it." A former Nevro regional sales director – in charge of one of the largest regions and sales teams – indicated that Nevro kept explant rates "very well hidden from the field reps." He described a widespread "don't ask, don't tell" culture regarding explants, which he said were "a hell of a lot higher" than the company stated – "I didn't want to know. Don't ask questions you don't want to know the answers to."

"I don't get it because Nevro's device is a piece of crap. I think people are picking up on it*, especially when they start reading papers. Most doctors don't read those papers. It's just like the Mueller report. The best way to hide something is to put it in the literature.* ***But you know, sooner or later, doctors are going to pick up on it. The company couldn't care less about explant rates. They know. It's obvious. They don't want to hear from doctors because they already know this stuff. They've made a conscious decision. They don't give a shit. They just want to sell the company."*** ***– High volume implanter and KOL***

*"****Nevro keeps explant rates very well hidden from the field reps****. I don't know if area VP's had access to them. As regional sales director I didn't.* ***The explant rate was a hell of a lot higher than [the stated] 2%. I don't know that people asked for it, because ignorance is bliss. I didn't want to know. Don't ask questions you don't want to know the answer to. My peers in the field felt the same way****. Nevro was data focused but they weren't dispersing it for success rates."* ***– Former Nevro regional sales director***

Source: Consultation calls with experts

8. Nevro's response to its explants crisis appears to be marked by denial, cover-up, retaliation, and patient/doc manipulation

A KOL and former Nevro consultant reported other tactics beyond simply denying explants, describing behavior which sounds potentially retaliatory in trying to "discredit" doctors who criticize the company's device, using the words "cult," "Scientology," "crazy," and "fanatical" – labels identical or similar to those used by a number of other KOL's. In particular, he detailed Nevro's reaction to a paper which he stated showed that high frequency stimulation was degrading neurons and burning the myelin sheath. Another KOL alleged that Nevro planted doctors in conference audiences and gave them talking points.

*"**I was a consultant and speaker for Nevro** from [redacted] to [redacted]. I was on the board of [society name redacted]. I just got tired of the company. **I'm really well published in the field and it's nothing personal against Nevro. Their devices just stopped working.** Nevro is like a cult, like **us versus them**. It's crazy. It's like Scientology. **They'll cut you out, jump all over you. They'll ostracize you and they're very intense about it**. There was a publication that [name redacted] did showing that high frequency stimulation was causing degradation of neurons. It was burning the sheath that goes around the axon, the myelin. People heard about this publication for a year or two before it came out."* **–– Former Nevro consultant and KOL**

*"Someone mentioned this article to someone else and next thing you know Nevro's Chief Medical Officer quickly sent an email to Nevro's entire sales force and to every one of their key opinion leaders **accusing a doctor having written the article, just because the doctor happened to mention the article to somebody else. So they're very fanatical. They're very intense and anytime there's the slightest bit of negative press** they send out these massive press releases to all their doctors basically **discrediting it and anybody who doesn't believe** it is not part of our camp and that's it. They're very intense."* **– Former Nevro consultant and KOL**

*"The doctors that use Nevro are very quick to raise their hands at conferences. **It seems like Nevro gives them talking points. They train them on how to speak and what to bring up if someone says anything negative about Nevro."*** **- KOL and high volume implanter**

Source: Consultation calls with experts

8. Nevro's response to its explants crisis appears to be marked by denial, cover-up, retaliation, and patient/doc manipulation

High volume KOL's who met with Nevro management regarding explant rates described a disinterested CEO and a company strategy of denial, deflection, and disingenuously blaming the patient or the implanter – which keeps low procedure volume doctors in line as they are easily manipulated by aggressive sales reps. One of the KOL's said Nevro had "excuses for everything," blaming him and other doctors who raised the issue for having poor patient selection. The KOL methodically explained why Nevro's attempts to blame others were simply a deflection tactic.

"Most doctors that do stimulators only implant six a year. They don't do that many, so they're nervous. They're insecure about it. And the reps are knowledgeable and very aggressive They can run the show. So when you're doing half a dozen a year and they're not all with Nevro and you've had a couple of bad outcomes, ***the reps blame you, and the doctor accepts it."***

"But I've been doing hundreds of these per year over my career and [doctor name redacted] is the same way. And we told Nevro, no, we do not have bad patient selection. Your stimulator outcomes just suck. *Then Nevro would say, well you have more workers comp patients. And I'd say, yeah I've always had more workers comp patients and they've always done great on other stimulators.* ***Nevro complained about [doctor name redacted, who criticized Nevro's explant rates], saying he had bad patient selection. He had the same patient selection he had for years****. Same types of patients. He would switch them over to Nevro, when they needed a new one or the battery died."*

*"****We had dinner with higher ups at Nevro to talk about explant rates. We didn't go to Rami [previous CEO]. He didn't want to hear about it. They have excuses for everything****. They were just - whatever they could think of as an excuse. You have bad patient selection, you have more workers comp patients. I'd say all I've ever done are workers comp patients and they've always done great with other stimulators. My stats have always been comparable to regular patients.* ***Nevro would make a bunch of excuses for explants by blaming the patients or blaming the doctors."*** ***– High volume implanter and KOL***

Source: Consultation calls with experts

8. Nevro's response to its explants crisis appears to be marked by denial, cover-up, retaliation, and patient/doc manipulation

Another KOL described in detail how Nevro denies the existence of explants and attempted to manipulate him into thinking that his device failure and explant rate wasn't high. He indicated that Nevro tried the same tactics on "a lot of other doctors."

Question: Did ever try talking to Nevro about these explant rates or were they just not receptive?

*"**They deny it. When Nevro saw my volumes drop off so substantially, they flew in a VP** I had a relationship with. After bullshitting for an hour at dinner he says "So what's going on, are you not with us anymore" and I said "Guys, I'm having all these explants." **And they came prepared with ammunition to try and say "Oh, here all the patients that are succeeding. The explants aren't as high as you think they are."***

"So I printed out an entire list of every patient I had ever implanted with them and I said "You left this person out. You left this person out.** You left this person out." I went down the list and said "Of those that you say still have it, half of those don't. And you left off all the patients that got explanted". **Nevro had given him talking points to convince me to come back. So they admitted, yes, you're getting explants, but they wanted to convince me I wasn't getting that many. I've heard they've done this with a lot of other doctors** as well."* ***- KOL, former Nevro implanter

Source: Consultation calls with experts

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Nevro may produce doctors, perhaps via sell-side reports, who attest that they haven't seen abnormal explant rates. KOL's advised us to be skeptical, dismissing them as inexperienced, willfully ignorant, or being paid by Nevro. One KOL stated that these Nevro loyalists were on the fringe, as reputable implanters and thought leaders wouldn't work with the company. The KOL implied Nevro was similar to a "Scientology cult," a characterization we heard several times during our research. A second KOL indicated that Nevro's device was tailor-made for "unethical, corrupt doctors" who "couldn't care less if there's a high explant rate."

"When Nevro first started, if you look at the doctors in the forefront, true thought leaders, key opinion leaders, the white shoe reputable people – that's not who they got*. They brought in a bunch of guys - I wouldn't say they were outcasts, but…* ***it was like a Scientology thing. They did these retreats at some huge mansion, like crazy stuff****, and I remember coming back and telling my rep, "What the heck was that?" There are a few guys like [name redacted, one of Nevro's highest volume implanters and key study authors] who got in with them right away and they pumped him up. He went from 0 to 90 mph because of Nevro. He was on every committee and pumped it up at NANS.* ***Nevro is not science. It's a cult and I am blown away because every doctor I know that does a lot of implant volume doesn't use Nevro except for a small cult."*** ***–KOL, former high volume Nevro implanter***

*"****If you put doctors into boxes, Money Mike couldn't care less if there's a high explant rate****. It's just about the price you give him for the device.* ***He could care less about whether it works or not. Yes, there are unethical, corrupt doctors. In that population, Nevro is the best thing since sliced bread."*** ***–KOL, former high volume Nevro implanter***

Source: Consultation calls with experts

8. Nevro's response to its explants crisis appears to be marked by denial, cover-up, retaliation, and patient/doc manipulation

Several KOL's indicated that doctors who deny the existence of explants do too few implants per year to notice or care that they're failing.

"Then you have Kaiser docs like one who said to me that he thinks patients like Nevro. I said, "You think patients like it because you do 10 implants a year and you really don't know." ***So there are a lot of Nevro doctors that don't do many implants, and then you have higher volumes ones at these surgery centers where it's a financial decision because of the price."*** ***–KOL, former high volume Nevro implanter***

"For the low volume implanters, Nevro said, hey you don't have to test*, you don't have to elicit paresthesias, you just put it in this one place T9/10 and that's all you have to do.* ***The ease of implanting took the whole thought process out****. When we used to teach neuromodulation 10-15 years ago, there were all kinds of algorithms. So that was incredibly attractive to implanters who didn't really do many - this is easy. You just put it in.* ***And initially those few implants did really well****. You thought things are good.* ***After a while it didn't do so good, but you weren't doing enough neuromodulation to really pay attention to it."*** ***–KOL, former high volume Nevro implanter***

Source: Consultation calls with experts

8. Nevro's response to its explants crisis appears to be marked by denial, cover-up, retaliation, and patient/doc manipulation

A KOL implied that doctors who deny Nevro's device failure and explants problems are consultants and speakers for the company who are being "bribed" to "say whatever you want." He compared Nevro's practices to those of Insys, the notorious fentanyl vendor which went bankrupt after executives went to prison for a speaker and consulting program-driven pay-to-play scheme. Two other KOL's stated bluntly that doctors who deny Nevro's explants are "really lying," "not following" up with their patients, or financially conflicted.

Comments by 3 different KOL's or high volume implanters

"Doctors that implanted a lot of devices, they hated Nevro. I don't know doctors who were high volume Nevro implanters that liked it and continued with their device*. The high volume Nevro implanters today who are involved with Nevro's studies – I saw the guys who went to jail for prescribing the Insys fentanyl drug. An Insys VP was saying how he hired hookers and strippers. You have to remember the doctor runs the show. And the only way I know to change that doctor's practice paradigm is* ***bribing. It works. You give a doctor some money and they will say whatever you want****. I would imagine Nevro probably doesn't give them money. They just hire them as consultants, pay them to give lectures and to teach classes. Doctors are whores."* ***–KOL, former high volume Nevro implanter***

"Nevro has an almost cult-like following saying that this is really the best thing since sliced bread and no one's explanted. ***It's just not true. If you say that, then you're probably either really lying or not following your patients."*** ***–High volume implanter***

"I could give you two real strong advocates you can call on Nevro. ***They're very positive on it. But they've done studies with Nevro and work with them. Patients would say the opposite."*** ***–KOL and high volume implanter***

Source: Consultation calls with experts

8. Nevro's response to its explants crisis appears to be marked by denial, cover-up, retaliation, and patient/doc manipulation

Interviews with KOL's and industry experts revealed an under-appreciated but astonishing dynamic behind some Nevro implanters claiming they don't have explants: they're simply unaware, as doctors outsource all patient follow-up to Nevro reps, who feed them misinformation about how their patients are actually doing. A longtime executive - one of the most tenured in the space – indicated that Nevro "did a very good job of managing and buffering the patient from the physician." He repeatedly emphasized the significance of this dynamic and stated that this ignorance – willful or otherwise - was "unequivocally" responsible for doctors who refuse to acknowledge explants. He provided examples of KOL's who discovered explants crises in their practices only after bypassing reps.

"Here's the reason that [the doctor who stopped using Nevro because of explants] started to look at his patients. ***Physicians would say, "I'm getting phenomenal results with Nevro." And I would say, "Okay. How do you know that?"*** *And they would say, "Well the trial was phenomenal. The patients love it. The patient is saying that the results they're getting are, I've got 90% pain relief." "How do you know that?"* ***"Well, the rep tells me." "When was the last time a patient told you?" And physicians would have an aha moment, and Nevro did a very good job of managing and buffering the patient from the physician."***

*"****If a doctor says, my explant ratio is the same as Nevro's as it is with everybody else, you should ask "Okay, how often do you meet with your Nevro patients? Are you there for the actual programming?*** *When the rep re-programs a Nevro patient, are you there for the re-programming?"* ***I'll bet you 9 out of 10 of them or 10 out of 10 of them aren't there; they don't know. I've challenged physicians****. Your first 10 Nevro implants, call those patients yourself and ask them how they're doing.* ***Don't ask the rep; call the actual patient. So, a bunch of them did, and that's how [doctor name redacted] found out [the device wasn't working****].*

Our question: So, you're saying that the doctors who say that they don't have huge explant rates are just checked out after they implant, and outsource everything to the rep?

"Yes, unequivocally." – Longtime executive in the SCS space

Source: Consultation calls with experts

8. Nevro's response to its explants crisis appears to be marked by denial, cover-up, retaliation, and patient/doc manipulation

We caution investors to be mindful of this dynamic, if Nevro parades doctors who deny they have an explants problem. Several KOL's described a related driver: when a Nevro device fails, that patient goes to a different doctor for explantation, and the original implanter remains blissfully ignorant that his/her Nevro patients are being removed. One KOL had a third of his Nevro devices explants, but didn't realize it for 1-2 years.

"One of Nevro's biggest implanters had about 300 Nevro devices implanted and he didn't know that they were all failing because the reps were fielding all the patient calls*. Patients were told, if you have any problems just call Nevro or call your rep. Don't call the doctor.* ***He didn't know until a year or two later that a third of his patients had gotten explanted at other practices****. So, a lot of Nevro's high volume implanters split."* ***– High volume implanter and KOL***

"There's dispersion in Nevro feedback, because ***one of the biggest challenges with explants is that the guy who implants the stimulator is not the guy who explants it****. The patient says I don't want to see the doctor who implanted this again."* ***– High volume implanter and KOL***

Source: Consultation calls with experts

8. Nevro's response to its explants crisis appears to be marked by denial, cover-up, retaliation, and patient/doc manipulation

A KOL who experienced high rates of explants described in detail how Nevro reps manipulated and pressured patients into saying the device worked, when the same patients were telling the doctor that it didn't. The KOL indicated he was upset at being lied to by the company's reps. As the process of coaxing patients to say "I have 50% pain relief" appears systematic, we wonder if Nevro reps are proactively trained in this tactic. Note that Nevro can only sell a permanent implant if the patient achieved 50% pain relief during the temporary trial period that lasts a few days, creating a powerful incentive for sales reps to bulldoze the patient into uttering the magic phrase, and creating a patient base in whom the device never worked and will eventually need to be explanted.

"What really upset me was I'd get two different stories, one from the patient and a different one from the rep. I would talk to a patient and they'd be like, get this piece of shit out of me. Then I'd send a rep to see them who'd say the patients had 50% pain relief. *That was Nevro's big thing. 50% pain relief. I had various discussions with them. I'd go to dinner with the higher ups. And they're all talking 50% pain relief, and I'm like don't you ever want to try getting better than 50%?"*

"Patients complain and tell me they want this piece of crap device out and the Nevro rep then goes and talks to them. One of my patients described to me in detail how the reps then manipulate them. *She actually had a Medtronic stimulator implanted and then became a rep. She later had the Nevro implanted. She knows the technology and how all the stimulator companies market."*

*"**She explained what Nevro reps would say to patients**. They'd say, as you know, stimulators work much better for nerve pain than axial back pain and the patient would be like, ok. And then the rep says, so you can't expect the stimulator to work very well for your back, but on your leg, it should work much better. And then, of course, you know, you're going to have good days and bad days. So, would you say on a good day, looking at your legs, would you say it's 50% pain relief? **And that's how the reps would coax the patient to say they got 50% pain relief. I confirmed with other patients that this is how Nevro reps get the patient to say they're getting relief."** –*
Prominent KOL and high volume implanter

Source: Consultation calls with experts

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Numerous KOL's confirmed similar experiences. A second characterized Nevro's conduct as falsifying patient outcomes and potentially illegal. A third described reps using "leading questions" as "patient manipulation" and catching reps who were telling patients what to say. He indicated that reps are "very very incentivized" to push patients into an implant. Aside from the entire high frequency premise being a flop, we believe that a key driver of Nevro's explants crisis is patients being bulldozed into devices that never worked for them during the trial phase.

Our question: So what specifically have you seen Nevro reps do that crosses the line into illegality?

*"**Falsify outcomes**. A lot of times patients won't report back to the doctor about how the stimulator trial went. They talk to the rep, and the rep says, "Oh my gosh, I talked to the patient who's at home now, enjoying their trial. The patient is getting 90% relief." **So, they falsify the actual outcome from the patient and they persuade the patient irrespective of the patient's opinion. I've heard it.** The rep will say, "Isn't this great? Aren't you doing well?" **You can hear the back and forth and that that's not what the patient said. There are a lot of unethical things."*** ***– High volume implanter and KOL***

"Leading questions are one area of patient manipulation. I've caught reps specifically telling patients what they have to say. It's an incentive-based thing for reps. Reps are very very incentivized *to want the permanent implant and they'll tell patients what to say. The rep will ask, what's your pain relief? A patient comes in and their pain is an eight, and after the trial implant the patients says well now it's a five. The rep says, "If you want this device you'll have to say you have 50% pain relief, and you want the device right?" And the patient says, "Well I guess so, I mean, I guess it helped me a little bit."* ***– High volume implanter and KOL***

Source: Consultation calls with experts

8. Nevro's response to its explants crisis appears to be marked by denial, cover-up, retaliation, and patient/doc manipulation

A fourth KOL - a current Nevro consultant, recipient of significant payments from the company, and one of their highest volume KOL's - was nonetheless candid about reps being "an extension of your practice" and "steering" and "pushing" patients into stimulators. He stated that the physician often doesn't pay attention and receives "misinformation" about patients. Shockingly, he described a rep cozying up to his surgery scheduler, in order to switch the devices that he planned to implant. A fifth KOL described the psychological pressure exerted by a rep's presence at the patient follow-up, with patients being "too embarrassed" to say the trial device wasn't working. He called it "co-opting" that prevented him from discovering Nevro's device failure problem sooner.

"The rep is kind of an extension of your practice. I've seen some really egregious things where the feedback is really negative about what the rep did in terms of steering a patient that was unsure and pushing them towards implant*. The reps will certainly try to be there every time because that's their opportunity to steer the conversation.* ***My concern is that they're potentially doing things that I don't like, on the phone with the patient****. Sometimes practices don't have a bandwidth to engage with their patients every day for a week. The rep gives text message updates saying "Hey Mr. Jones is going great" and then you call Mr. Jones and he's like "Oh no I am doing terrible. I don't like this".* ***Sometimes the doctor is not really paying attention. They start to get misinformation****. One time really early in my career I had a stim rep that was too social with my booking person. I wouldn't remember which therapy I chose for which patient, because you don't necessarily put that in your notes. So she was switching therapies around and probably driving my schedule.* ***That's the kind of nonsense*** *that can go on."* ***- Nevro consultant and KOL***

*"****What I noted psychologically is that the rep would often be present at the patient's follow-up*** *and when I would talk to patients with the rep, they'd say they were having some issues, it wasn't going great, and they were going to try another parameter for programming, using different electrical wavelengths and so forth. What I noticed is that compared to when they were alone,* ***patients were embarrassed to say anything in front of the rep so there was this co-opting of the patient that I think, had they not been there, we would probably have found out sooner than later [that the device wasn't working]."*** ***- Nevro consultant and KOL***

Source: Consultation calls with experts

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A sixth KOL elaborated on the "tremendous potential for abuse in the role the rep plays with the patient," describing reps who were "full of crap," "acted unethically, and were "just very sleazy." He described a toxic dynamic of quid pro's quo's between stimulator reps and doctors. Another KOL illustrated how the paresthesia-free nature of high frequency is tailor made for patient manipulation. Because patients feel no tingling – and therefore can't even feel whether the device is on or off – they are particularly susceptible to the rep convincing them it's working. He added that Nevro was "very sneaky" at launch in hiring reps who were good at handling patients.

"There's tremendous potential for abuse in the role the rep plays with the patient**. I have refused to work with reps who have **acted unethically and that I knew were full of crap. There's no question that they influence the patient during the trial**. There's no question about it, that there's the ability to influence. It just depends on your judgment. It's more common with younger implanters and people who work in private practice, who are trying to get a business out there. The reps are saying I'll do this for you, I'll do that for you, I'll introduce you to doctors. It's natural. No question, I've seen over the years reps that are just very sleazy. I have told companies straight out: I will not work with these people." **– KOL and high volume implanter

*"You bring a patient in for a trial implant and then you turn it on. The patient is like, when are you going to turn it on? Especially if they're used to the feeling of paresthesia. And I'd say, no, the device is already on. **Patients never felt the device being on. It was always just a leap of faith that the thing was working. So when it stopped working, Nevro's reps could use that tactic against the patient. You're not doing this, you're not doing that. How do you even know when the battery is dead?** The whole time, the patient just has to believe that the device is on and that it's working. **You could probably get a placebo effect**. Whether it's on or off, they just always think it's on. **Nevro did another thing which was very sneaky**. When they first launched, they hired all the best reps in the country. The ones who did the best because they are very good with the patients. **A patient who likes their rep will be happy and report a successful stimulator. Even if the device is turned off. I'm telling you, it is all about the reps**." **– KOL and high volume implanter***

Source: Consultation calls with experts

9. Nevro's current predicament – a one-tick pony stuck in a ditch – and drivers of its ongoing growth collapse

KOL's and former Nevro executives outlined where the company finds itself now: after the hype from its pivotal study and 2015 launch wore off by 2018, sales growth went to zero. With the honeymoon period now over, Nevro's "turnaround" finds itself stuck in a ditch: high volume implanters – who drive 90% of industry volume – have soured on the company; KOL's now believe the initial data was dubious and that the technology doesn't work; and even Nevro loyalists have migrated back to Medtronic/Abbott/Boston Scientific devices.

- One of the most well-known KOL's in the space stated that 10% of doctors drive 90% of industry volume, and that these **high-volume implanters are the ones "souring on Nevro."** He stated that **Nevro's sole innovation – paresthesia-free stimulation – is now widely offered by competitors.**

> *"There are 10 to 20 doctors like me in the country, maybe a little more, that implant stimulators at these high volumes. People like me are the majority of the implants. It's a 90/10 rule. By and large,* ***it's the high volume doctors souring on Nevro. It's a big deal that other companies can give you paresthesia-free stimulation.*** *And Medtronic's Intelis came on like gangbusters. It' really tiny. I was really excited by it."*
> ***– One of the most well-known KOL's in the stimulator space***

- One of **Nevro's highest volume implanters stated his usage is down, that the honeymoon is over,** and that **doctors are skeptical the device works**. A second user said **the pool of Nevro die-hards "has shrunk" with "not much more growth to be captured" in Nevro's base.**

> *"****Nevro is down to 50% of my share. Two years ago I used two-thirds Nevro****. Nevro is overused. The honeymoon phase, that Nevro will solve all, is over. You'll find doctors that tell you Nevro doesn't work.-*
> ***KOL and one of Nevro's highest volume implanters***

> *"When we poll at conferences, initially doctors who were doing Nevro were all or nothing. They had a very dedicated following.* ***That pool has shrunk. Now more us are finding that we like to spread it around****.* ***Of the 15 to 20 implanters in New York like me, all of us are doing some Nevro and there's not much more growth to be captured among this circle."*** ***– High volume Nevro implanter***

Source: Consultation calls with experts

9. Nevro's current predicament – a one-tick pony stuck in a ditch – and drivers of its ongoing growth collapse

A senior Nevro ex-executive provided a key reason why growth hit a wall: the legacy SCS incumbents – Medtronic, Boston Scientific, and Abbott – who were asleep at the wheel when Nevro launched in 2015, have quickly caught up, while Nevro "still feels like a boutique" one-trick pony that's "not really as sophisticated as they say they are." A KOL provided identical feedback: Nevro is a "one-trick pony" and that everyone now offers paresthesia-free stimulation.

- The ex-executive pointed to the **"amazing amount of new technology" coming out annually in the space**

> ***"We embarrassed the legacy competition but over time that forced them to create new platforms, software, better technology****, better interfaces, quicker trial times. They've done a lot more for their customers.* ***Nevro still feels like a boutique company. They're not really as sophisticated as they say they are.*** *When you go to North American Neuromodulation Society meeting every January, you're seeing* ***an amazing amount of new technology****. All the other companies create different types of platforms for different patients. They have optionality, which is a superior sales tactic with the patient saying, "Hey, this didn't work, but I have other frequencies and waveforms for you and I have this and this and this."" –* ***Senior Nevro ex-executive***

- **KOL's indicated that everyone now has paresthesia-free,** that Nevro is a **"one-trick pony,"** and that there's **no clinical difference.**

> *"Nevro disrupted the industry with high frequency.* ***Then everyone developed sub-threshold paresthesia-free waveforms. Now companies who don't even have high frequency have these waveforms. There are lots of competitor pipelines. They're a one-trick pony. They're not versatile.*** *That I truly believe. It's hard to tell a difference clinically." –* ***High volume KOL***

Source: Consultation calls with experts

9. Nevro's current predicament – a one-tick pony stuck in a ditch – and drivers of its ongoing growth collapse

One KOL after another labeled Nevro a "one-trick pony" and pointed to the influx of paresthesia-free waveforms from key competitors as eliminating Nevro's sole selling point. A former Nevro loyalist stated that "they were the first kid on the block" but doctors who "were enthralled with Nevro are not as enthralled" now. A key investigator in Nevro's pivotal trial said the "sheen is off," that the story is "stale," and that he wouldn't buy the stock.

- A KOL and **former Nevro loyalist stated that doctors are no longer "as enthralled,"** and that Nevro's **differentiation has evaporated as everyone introduced paresthesia-free stimulation**.

  *"Colleagues who were enthralled with Nevro are **not as enthralled with it now**. They were the first kid on the block. **Now it's 4 companies. Abbot doesn't call their device high frequency, just Burst but it ramps up and down. Same with Medtronic. Then Wavewriter** from Boston Scientific The uniqueness of paresthesia-free isn't there anymore and that was the main selling point for Nevro, and then you have the bulky battery." **- KOL, previously a high-volume Nevro user***

- **A key investigator in Nevro's pivotal trial** said the **"sheen if off,"** the story is **"stale,"** and that he **"wouldn't buy stock."**

  ***"Nevro came out with something new and got a lot of share in a crowded space.** I doubt they can hang on to the IP, and it's not the only IP out there. **The sheen is off Nevro**. I've known [Nevro executive, redacted] for many years. I don't know that he's the right guy. I wouldn't buy stock in Nevro right now. **Their story is getting stale."** – KOL and Nevro trial investigator*

- A KOL explained that **as Abbott and Medtronic caught up, his Nevro usage dropped**

  *"**Abbot's Burst and Medtronic's Intellis are what changed my usage of Nevro the most**. It was a big switch for me was when Burst came out. Then Intellis came out and was smaller than anything anyone has ever been by quite a bit. My average patient doesn't' want a big device sticking out of their ass. And Intellis is one charge a week." – High volume implanter and KOL*

Source: Consultation calls with experts

9. Nevro's current predicament – a one-tick pony stuck in a ditch – and drivers of its ongoing growth collapse

An executive in Medtronic's spinal cord stimulation division explained Nevro's trajectory in great detail, from his vantage point as a competitor monitoring each territory. He admitted that Nevro caught Medtronic asleep and took share from 2015 to 2017, but that by mid-2017 Nevro 's share peaked and began to decelerate. The feedback squares perfectly with Nevro's sales growth, which collapsed shortly thereafter. He stated that going from 0 to 15% share is easy, and then Nevro's share gains and business model collapse. Interestingly, Nevro's SCS market share has remained flat at ~15% since 2017.

"Nevro cherry-picked the lowest hanging fruit at launch. They went to the 25 best places like New York*, Los Angeles, Atlanta. They went to teaching institutions who are receptive to new stuff.* ***It's a lot easier to get from 0% to 15% share than from 15% to 30%****. Zero to 3% is hard, 3% to 10% is easy, and after 15% it's trying to grow in Buffalo versus New York City."*

"When we look at our revenue and where we got beaten, it was in the biggest metro's, A markets, some B markets. ***We saw a deceleration in Nevro's share starting in mid-2017. It went from Medtronic being handed our lunch to our share stabilizing. They've taken as much share as they're going to take in class A cities."***

"A big piece of their wins were all class 1 teaching hospitals. Nevro will say to them to partner with on studies. It's a gray area. If you use our product, you can participate in our study. We observed this in teaching hospitals. We see less of that now."

"So that leaves places like Charleston and Syracuse. You have to invest in places without teaching institutions which is their playbook. And you can't offer participation in trials. Trials are a sugar boost. Doctors like seeing their name. You need a very different playbook to expand from 15% to 20% share than what Nevro has used. We have a pretty good sense of where Nevro's team is and which hospitals they're strong in."

*"****We can see from spreadsheets where our sales have accelerated or decelerated relative to Nevro's presence.*** *We know from data that if you do a clinical trial in a hospital, your sales there accelerate.* ***We definitely saw growth decelerating for Nevro."*** ***– Medtronic SCS executive***

Source: Consultation calls with experts

9. Nevro's current predicament – a one-tick pony stuck in a ditch – and drivers of its ongoing growth collapse

Another Medtronic employee - in charge of one of their largest spinal cord stimulation territories - offered ground level color on Nevro's predicament. At launch in 2015, Nevro poached Medtronic's senior rep and lured most of their "whale implanters" in the region to their device. But the success was fleeting: "almost all Nevro devices" have since been explanted and doctors soured on Nevro. By late 2016/early 2017, Nevro rapidly gave back the market share it gained in the region – mostly back to Medtronic, and some to Abbott.

"In 2015, Nevro hired away the senior partner of our sales territory, which had quite an impact for 2016. Most of the big whale implanters in our territory made a full switch over to Nevro. That lasted, and really hurt us, for about a year."

*"**Since then, almost all Nevro devices have been either explanted**, or they're trying to salvage a little bit with Omnia. But **there really has been a significant decline in our market from their high frequency device. The doctors just didn't see the outcomes the studies were presenting. Their reps in town are trying to discuss the new technology** and new research that they're touting, **but it's been really slow** to get a pickup from the physicians here. They continue to ask for a price premium and the surgeons in town aren't willing to pay for that."*

*"**In 2015/16 they came out with their guns and probably took, just from those two big accounts that I'm referring to, probably $4-million or $5-million. They had the cool new thing** and the data from their pivotal HF10 trial was compelling. They had a good story, and everyone bought into the story. The docs trusted the rep who had been around for 20 years. Everyone was on board and thought it was the sexy new thing to offer their patients. Give or take **the fall of 2016, our numbers started picking back up and then significantly in the spring of 2017**. Medtronic had come out with a new algorithm to try to combat Nevro and we saw some good results, and we made significant changes to how we were talking to patients. It was good timing as **Nevro was starting to see some failures and patients having different outcomes than what their study said."***

"Of the $5-million or $6-million we lost to Nevro at the peak** of their taking share, Abbott took one big chunk of that. They probably got $2-million, and **we probably got back the rest."** **– Medtronic regional manager

Source: Consultation calls with experts

9. Nevro's current predicament – a one-tick pony stuck in a ditch – and drivers of its ongoing growth collapse

The Medtronic regional manager stated that Nevro "lost all of that revenue" from their launch and that "all of [the doctors they poached] are done with Nevro. They won't even listen to them." The primary reason was lack of efficacy and explants, followed by the device's bulkiness and lack of MRI compatibility. He stated that the sales reps Nevro poached have all either returned to Medtronic or left Nevro, adding he was incredulous at Nevro's stock given what he sees in territories across the US: a lack of clinical outcomes; the new Omnia device flopping; and "shrinking" market share. He stated Medtronic now views Nevro as irrelevant.

"Then in 2018, we had a huge rebound year. Medtronic launched a new product called Intellis, and ***we were also getting a lot of Nevro explants.*** *We had a phenomenal year in 2019. Abbott with their non-rechargeable device dinged us a little bit in a couple of different spots. All in all, we've been able to maintain our growth, and hopefully, we'll continue to do so"*

*"****Basically, Nevro lost all of that revenue from docs that came on their initial wave. All of them are done with Nevro. They won't even listen to them. Their number-one complaint was lack of efficacy****. Patients just weren't getting the pain relief that they were promised or presented in the RCT. Number two was the size of their device. They really had a lot of problems with the bulkiness and the size of it. And three, the lack of MRI compatibility. They were running into MRI centers not willing to do MRIs even though they had the full-body MRI label for the percutaneous systems, and* ***it just got to be too much of a headache."***

*"****To be honest, we watch their stock and we're like "What are we missing?" In our market, we don't see a ton of good outcomes. Omnia has really not done anything****. We hear rumbling from Caraway [Nevro's Chief Medical Officer] that they're researching more indications, and we just don't know how a one-trick pony makes any headway.* ***We can't figure it out - they continue to do well on Wall Street, but I do not see any movement or any changes here. If anything, they're shrinking here. Frankly, there's very little discussion of Nevro at this point at Medtronic****, at our national sales meeting. or really any talk about their taking business away.* ***A lot of the reps that they hired away are now either back with Medtronic*** *or have moved on.* ***That's pretty common from what I can tell in territories across the country.*** ***– Medtronic regional manager***

Source: Consultation calls with experts

9. Nevro's current predicament – a one-tick pony stuck in a ditch – and drivers of its ongoing growth collapse

One of Nevro's most tenured district sales managers, one of the first employees hired and part of the launch team – now running one of the largest regions for a key competitor – offered a detailed account of Nevro's trajectory and current plight identical to that shared by the Medtronic regional manager. He began by describing Nevro's launch: "the easiest sale ever because everyone wanted to try this paresthesia-free stimulator", with the company quickly getting to 15% share of the SCS market. Then he explained that "this all worked" because Nevro was selling "biased" data that "wasn't real world."

*"**Nevro changed the entire dynamic of the spinal cord stim industry**. They created excitement. It was the first company to do a head-to-head level one RCT study against the competitor and **their data was remarkable. It was the best data that we've seen and so, that's one of the main reasons I went there.** There were doctors that were reaching out to me—it was the easiest sale ever, because everyone wanted to try this paresthesia-free stimulator that sort of crushed axial, back, and leg pain. The only thing I had to bring in was the stim and it sold itself."*

"So let's go back to 2015. We're growing. The trials always did very well with Nevro and with HF10 and across the board, trials typically do very well in this industry because it's sort of like the patients get this burst of: "Wow! Pain relief." It's remarkable, right? They only have this for seven days and, you know, the representatives, they're reaching out to them, they make sure everything is going well, so the trials always did very, very well at Nevro."

*"We went up to around 15% of the market. **But this all worked because the data they were selling was based on choosing the exact patients they wanted. A lot of it was just biased. It wasn't real-world data."*** ***– Former Nevro district sales manager, now at a key competitor***

Source: Consultation calls with experts

9. Nevro's current predicament – a one-tick pony stuck in a ditch – and drivers of its ongoing growth collapse

Within 6 months of Nevro's launch, he began to notice that clinical outcomes failed to match the results purported in the pivotal trial. He stated that Nevro started seeing this as well and "started freaking out" 18 months after launch. He stated the Nevro's sales reps in Europe, where Nevro had launched a few years earlier and achieved some modest sales, had already experienced the same disillusionment: "I realized that high frequency therapy wasn't what Nevro said it was." The company attempted to manage the crisis by building a team of "Therapy Support Specialists" to "hound these patients" to the say magic phrase "50% pain relief."

*"**But then, six months in, I started to notice that the implants were not comparing to the outcomes we were getting from the trials. I started seeing it and then, the company started seeing it.** We weren't getting the results that we thought we were going to get."*

*"So, you have the RCT and then you have real world. Once you start to funnel thousands of patients in the real world, **you start to notice that, "Hmm, it's not working as well…"***

*"**Before I realized that high frequency therapy wasn't what Nevro** said it was, I trained in Europe because HF10 was on the market there for two and a half years prior to launching in the U.S. **In Europe the reps weren't super gung-ho about it**, so I think they've always known that it was very patient-specific from the very beginning. **I started seeing within the first twelve months that it wasn't the therapy that everyone thought it was going to be and I think the company realized that at the 18 month mark and they started freaking out."***

*"So, we put a team in place called Therapy Support Specialists TSS, where they would call the patients every single week, the implanted patients, they'd call the implanted patients every single week until they got at least 50% pain reduction, so then they said, " All right, **we're just going to hound these patients** so they know that they're supported at home and hopefully, we can turn this around that way." **– Former Nevro district sales manager, now at a key competitor***

Source: Consultation calls with experts

9. Nevro's current predicament – a one-tick pony stuck in a ditch – and drivers of its ongoing growth collapse

The ex-Nevro district manager's comments reveal the severity of what we believe the company has covered up: that "sort of every KOL was saying the device isn't working"; that sales reps across the country came to the same conclusion; the company refused to acknowledge the situation and blamed the reps instead; and that he personally couldn't look customers "in the eye and ask them for visits anymore, because I didn't believe in the therapy."

"Sort of every KOL was saying the device isn't working. We had this one doctor in New York who implanted 13 Nevro systems. He removed 10 of them within a year. *Nevro saw that a lot of these doctors were going away. They saw that their sales reps, like me, were leaving and the number one reason was because the therapy wasn't living up to expectations."*

"They hired a really experienced sales force and they relied heavily on the field to let them know what was going on. Upper level management never wanted to say this. They'd tell the field that they missed a step in the algorithm, to go back and start over. ***No matter what we did in the field, it didn't work. But the company was like, "You guys missed something. We have the level one evidence. It has to work."***

"The field reps were always communicating across the nation. ***The discussions among the reps were, "We're in a tough situation here."*** *The company treated us very, very well. They paid us well. I appreciated everyone I worked with there, but it was—****as months went on, it became very - I would have a hard time selling this device when I didn't believe that it's right."***

"I've been in the spine field for a long time, and ***a lot of these customers are my friends. I couldn't look them in the eye and ask them for visits anymore, because I didn't believe in the therapy."***

"One reason for explants is that patients get sick of recharging, which can cause heating at the site and cause infections*. Patients just get pissed off because they have to recharge. The higher the frequency, the more energy it uses. Patients had to charge once a day for 30 to 45 minutes.* ***A second reason is that the therapy wasn't working*** *so patients would just get fed up. So they didn't want to charge anymore, and then, they would just have the device explanted, so loss of therapy and just, burden and the burden of recharging every day." –*
Former Nevro district sales manager, now at a key competitor

Source: Consultation calls with experts

9. Nevro's current predicament – a one-tick pony stuck in a ditch – and drivers of its ongoing growth collapse

A second former Nevro territory manager, also part of the launch team as one of the company's earliest reps and a long-tenured rep in the SCS field, echoed these comments and added that Nevro is pushing stimulators onto patients who simply aren't appropriate candidates. He expressed dismay toward Nevro's conduct and stated that stimulators will never work for the patients the company's physicians are selecting.

"The indications that are approved for spinal cord stimulation are chronic pain of the trunk and limbs. ***You can't treat mechanical pain with a spinal cord stimulator****, meaning for example they have a herniated disc putting pressure on a sciatic nerve with pain traveling down the leg.* ***A stimulator is not going to help that patient****. The problem can be when you put a stimulator into somebody that has a mechanical issue when their issue is related to the nerve. They may go through a trial period and do fairly well for a little bit. However, the mechanical pain isn't going away because you're still going to be doing activity."*

"A lot of patients that you see in the spinal cord stimulator market are patients that have had three, four, five surgeries*, meaning discectomy, laminectomy, fusion, adjacent fusion, redo of the fusion. Now, they're not a surgical candidate.* ***Is a stimulator appropriate for that patient? Possibly. You can come to your own conclusion on how I painted that picture."***

Question: So it sounds like that's the target market - last line patients, but it's so chronic and nothing has worked, so what's the point of a stimulator? Is that the point you're getting at?

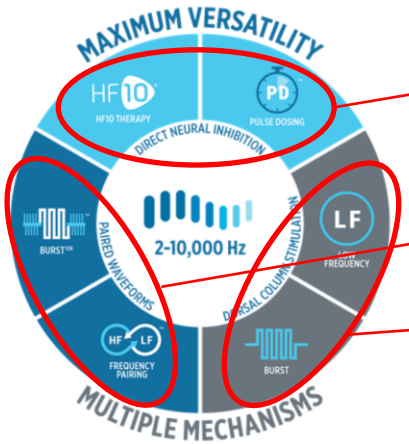
*"****That is exactly what I'm getting at****. Of 10 patients coming into the doctor's office, I would say 3-4 have neuropathic pain that does very well with a stimulator. Patients 5,6,7, are questionable. They are multi-surgical, with no more surgery available, on medications and a challenge for long-term success. And the other three or four, they don't know exactly what to do with them, and a last resort is the stimulator, and that's somebody that had the discectomy, the laminectomy, the fusion, the adjacent level fusion, the revision of the fusion, and now they've had 3, 4, 5, or 6 surgeries, and then they show up at the pain doctor."* ***– Former Nevro territory manager***

Source: Consultation calls with experts

10. The new Omnia stimulator, the centerpiece of Nevro's turnaround hopes, is a Hail Mary and colossal flop

On November 5, 2020 Keith Grossman announced the launch of the new Omnia spinal cord stimulator - the centerpiece of his plan to turn Nevro around. The company's previous Senza stimulators offered only high frequency stimulation, Nevro's sole claim to fame. The Omnia signaled a 180 degree turn in strategy versus the positioning of the past decade: the company would now offer every frequency and waveform under the sun and throw the kitchen sink at doctors and patients.

"Other SCS systems on the market are limited to a frequency below 1500 hertz. ***Omnia delivers the widest range of frequencies of any SCS system, between 2 and 10,000 hertz. In addition to HF10, Omnia offers the most waveforms in a single product*** *and can be programmed to provide waveforms independently or paired with HF10."* ***– Press release 11/5/2019***



More Frequency and Waveform Versatility

Treating pain requires flexibility and persistence. Omnia offers the most waveforms in a single product and can be programmed to provide waveforms independently or pair HF10 with other waveforms, enabling dual mechanisms of action that no other system can offer.

"Direct Neural Inhibition"
-HF10 high frequency therapy
-"Pulse dosing"

"Paired Waveforms"
-"Burst"
-"High/low frequency pairing

"Dorsal Column Stimulation'
-"Burst"
-"Low frequency"

**Red ours for emphasis*

Source: https://s24.q4cdn.com/932612397/files/doc_news/archive/383ad665-1d67-4ea5-88aa-f4321006b014.pdf;; https://www.nevro.com/English/us/providers/omnia/default.aspx

10. The new Omnia stimulator, the centerpiece of Nevro's turnaround hopes, is a Hail Mary and colossal flop

We find Nevro's about-face and embrace of low-frequency stimulation interesting and suggestive of desperation, given that the company has spent the last decade disparaging it as useless and dangerous: ***"unpleasant," "uncomfortable," "causes a shocking or jolting sensation," "a continuous reminder of the patient's chronic condition," "limited clinical evidence," "lack of evidence supporting efficacy," "71% of patients" with low-frequency stimulation "experienced discomfort," "variability in the procedure" impacts "the physician's schedule and patient comfort" and requires "a cumbersome process of paresthesia-mapping," and restricts "driving a motor vehicle or sleeping…."***

Nevro S-1 filing

"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."*

Limitations of Traditional SCS Therapy

- **Limited clinical evidence:** To date, we believe there are only two published prospective randomized SCS studies that provide long-term (one year or longer) data, both of which focused on leg pain. Neither of these studies was done to support initial regulatory approval of an SCS system.
- **Lack of evidence supporting efficacy in back pain:** We believe predominant back pain is more difficult to treat with traditional SCS therapy than leg pain due to the reduced ability to achieve and maintain pain coverage in the back. We are not aware of a prospective, randomized clinical trial supporting the efficacy of traditional SCS therapy in treating back pain. As a result, back pain patients are usually not recommended for treatment with traditional SCS therapy.
- **Paresthesia:** Traditional SCS therapy relies on paresthesia to mask pain with a constant tingling sensation. Paresthesia is often considered unpleasant or uncomfortable and is a continuous reminder of the patient's chronic condition. Medtronic, a current leader in neuromodulation, released a survey showing that 71% of patients with implantable neuromodulators experienced discomfort when changing position.
- **Paresthesia mapping:** A crucial part of the traditional SCS procedure is called paresthesia mapping. This mapping process requires a patient to be sedated for the lead placement, then awakened and repeatedly questioned in order to assess paresthesia coverage over the patient's area of pain and reposition and reprogram the leads to redirect the paresthesia. This process creates variability in the procedure and a complicated anesthesia management process, impacting the physician's schedule and patient comfort.

Source: Nevro S-1 and 10K; transcript of management comments at JMP conference 6/24/15

10. The new Omnia stimulator, the centerpiece of Nevro's turnaround hopes, is a Hail Mary and colossal flop

Omnia is Nevro's Hail Mary to re-invent itself now that high frequency has come and gone as a one-trick pony. Both the CEO and the sell-side have emphasized Omnia's centrality to Nevro's story going forward. We shall shortly provide color from Nevro's own loyalist doctors, KOL's, the company's former executives, and competitors indicating that Omnia is a flop. However, the clearest indication that Omnia has bombed comes from the CEO directly: he admits that Omnia is still programmed for high frequency stimulation 85-90% of the time, rendering the new frequencies and waveforms irrelevant. One year into launch, Omnia has failed to alter how Nevro is perceived and used.

Keith Grossman, Nevro CEO, comments on May 5, 2020 earnings call that only 10-15% of Omnia patients are augmenting high frequency stimulation with lower frequency or other waveforms.

"In terms of how patients are actually being treated, ***we expected this to take a little bit of time****. Given the certainty we had that the early adoption of Omnia would be among our existing customers and our existing customers skew to those customers who have a heavy belief in high frequency as a standalone therapy.* ***So we knew that over time the use of paired waveforms, the use of lower frequencies standalone or combined would increase over time. But I think as we sit here today we look out over our very early patient population, I think it's something in the range of 10% to 15% of our patients are already using particularly paired waveforms with high frequency and other lower frequencies.*** *And I think that's probably right about where we thought it would be at this point in time."*

On an August 26, 2020 group call during an investor conference, we asked the CEO what percentage of Omnia patients are currently using lower-frequency and other waveforms., and reminded him of his May comments. He repeated the same figure as above. Contrary to his May comments that "the use of lower frequencies standalone or combined would increase over time," it is abundantly clear that Omnia remains just another high frequency stimulator – even about a year after launch.

Source: Earnings call transcript 5/5/20; group call with CEO 8/26/20.

10. The new Omnia stimulator, the centerpiece of Nevro's turnaround hopes, is a Hail Mary and colossal flop

Grossman's tentative and artful choice of words on the August 5th and November 4th earnings calls suggest all is not well with the Omnia launch , which he stated is "doing as well as we could have hoped on a relative basis" and "again, from a relative standpoint, we think we continue to do well with Omnia" – not exactly the tenor one would expect for the launch at the center of his turnaround hopes. We note the ongoing lack of metrics to help investors assess the launch.

Keith Grossman, Nevro CEO, comments on August 5, 2020 earnings call

"So the -- I think the response to the Omnia launch has been very good. And as I mentioned in my remarks, we've now just launched Omnia in Europe and Australia following approvals there, respectively. I think the Omnia launch is ***doing as well as we could have hoped on a relative basis****, obviously the COVID interruption aside, we felt extremely good about what Omnia was doing in the U.S. in the first quarter coming into COVID.* ***And again, from a relative standpoint, we think we continue to do well with Omnia."***

Source: Earnings call transcript 8/5/20.

10. The new Omnia stimulator, the centerpiece of Nevro's turnaround hopes, is a Hail Mary and colossal flop

Over the course of 20+ interviews with KOL's and interviews, including Nevro loyalists, one doctor after another slammed Omnia as a me-too, irrelevant, late to the game product that muddles Nevro's message, with several suggesting that the only people who thought differently were on Wall Street. Even Nevro's most ardent users – KOL's who receive significant payments from the company and play key roles in its trials – offered reactions that ranged from an utter lack of enthusiasm to outright mockery and disparagement. The only positive comments we heard indicated that Omnia may help retain some share among Nevro loyalists who have soured on the company and are spreading their business around.

- Most doctors, even **loyal Nevro users, view Omnia as "a joke"**

> ***"Omnia is a joke I think to most doctors****. Nevro's tried to make you forget about six years of marketing where they said paresthesia is the enemy, and now they're trying to make you forget they said that by launching a paresthesia-based device.* ***Most people thought it was a joke, even the doctors that were loyal Nevro users. Doctor's don't talk about it as a game-changer or anything."*** ***– KOL and former high volume Nevro implanter***

- **One of Nevro's highest volume implanters** – closely aligned with the company and involved with their studies - **has disparaged Omnia as "nothing"**, according to a KOL who's friends with him

> *"Doctors who are implanting the Omnia, like my friend in [state name redacted] who's* ***one of Nevro's highest volume implanters in the world - even he doesn't think it's as great as they are making it out to be****. He says the device is a little bit smaller and the programmer is a little bit different. But it's not like patients are raving about it.* ***There's no wow. It's nothing. It's nothing that changes the space."*** ***– KOL and former high volume Nevro implanter***

- Another of **Nevro's highest volume implanters belittled Omnia as just "a marketing move"** that **won't "move the needle much"**

> *"I think that that Omnia was* ***more of a marketing move than anything else.*** *I've been in this field for a long time. In my practice it wasn't a game changer.* ***I don't think it will move the needle much*** *in Florida."* ***– High volume Nevro implanter***

Source: Consultation calls with experts

10. The new Omnia stimulator, the centerpiece of Nevro's turnaround hopes, is a Hail Mary and colossal flop

Comments from one KOL after another were consistent and devastating in their assessment of Omnia.

- Omnia is **irrelevant, a me-too device, and not "a game changer"**

  ***"I don't think Omnia matters**. All of the other manufacturers are pretty much doing the same thing with their batteries. **It's not a game changer."** – KOL in the SCS field with prominent papers published*

- Omnia is **"an attempt to save market share with beleaguered cohort of doctors that are sick of explanting the device"** when high frequency fails

  *"So Nevro had a good idea but they failed to maintain programming options having thrown their entire emphasis behind 10,000Hz. When it was proven that 1,000Hz was equal in efficacy, **Nevro quaked in their boots. The Omnia is an attempt to save market share with a beleaguered cohort of doctors that are sick of explanting the device** when the 10,000 Hz programming fails to work." –KOL, former high volume Nevro user*

- Even the most positive comments indicate Omnia is **merely no better and no worse than other stimulators**

  *"Omnia has burst, tonic, HF10, intermediate frequencies, and you can use multiple programs. When it came out, if one program doesn't work, I can change to another. **I've started using it. It hasn't been any better than Boston Scientific but it works**." –KOL and high volume implanter*

- Omnia is **an admission of high frequency's problems** and a forced **move to prevent the company from going out of business**

  *"If HF10 was as groovy as they thought it was, they wouldn't have had to change the device to do paresthesia. **They were forced into Omnia or they would have gone out of business."** – KOL and former high volume Nevro implanter*

Source: Consultation calls with experts

Scorpion Capital | Nevro (NYSE: NVRO)

10. The new Omnia stimulator, the centerpiece of Nevro's turnaround hopes, is a Hail Mary and colossal flop

The feedback was equally devastating whether from current Nevro users, former high volume Nevro implanters, or other KOL's.

- A KOL and former high volume Nevro user **slammed Omnia's claims of special waveforms, deriding it as a me-too device with nothing "brand new or innovative."**

  "They try to call Omnia a high-frequency tonic [low frequency stimulation] ***which is bullshit****. It's the same thing. They try to claim that they have burst which is also like a high-frequency burst.* ***Bullshit. There's no data. They never did a study. Omnia is what everyone else's device can already do, just packaged in a little Nevro box****. If a doctor already left Nevro because their device sucks, there's* ***nothing Omnia does that's brand new or innovative*** *that you can't do with whatever company you already use."* ***–KOL and former high volume Nevro implanter***

- One of the highest volume implanters in New York, who still uses some Nevro, **hasn't bothered to try Omnia, calling it "incremental" with no effect on his share**

  "I haven't implanted the Omnia. It's an incremental benefit*. It will be better than Senza. I don't think it'll be a game changer.* ***It won't bump my Nevro share any more****. Every stim company comes up with a new device every couple of years. It's an incremental, evolutionary advancement. Not revolutionary."* ***– High volume implanter***

- **One of Nevro's highest volume implanters**, and a consultant who receives significant payments from the company, **dismissed Omnia as cannibalizing existing Nevro users without gaining new ones**

  "The impact of Omnia is incremental*. I think it's incremental for the Nevro users that were concerned about Nevro's limitations and therefore gave some cases to other companies.* ***I don't know how much it gains new doctors. By now you've either used Nevro or you haven't. They're not really converting people*** *from other companies all of a sudden because of the Omnia. They've almost exclusively converted over the previous Senza and Senza 2 users to Omnia but at the same time, I don't think that it's a as big of a leap as the first time around with HF10 versus paraesthesia-based stim."* ***- KOL and high volume Nevro implanter and consultant***

Source: Consultation calls with experts

10. The new Omnia stimulator, the centerpiece of Nevro's turnaround hopes, is a Hail Mary and colossal flop

The uniformity of negative comments suggests that an Omnia-fueled turnaround is a delusion.

- **A KOL who still uses Nevro** as 25% of his device mix described Omnia as **"nothing special" and me-too**

  "To tell you the truth, I was always relatively pessimistic on Nevro**. In fact, I had to write an article in one of the journals a few years ago saying that Nevro will not last unless they provide other waveforms and the company wrote nasty letters back to me because I believed even at that time that it's not a one-size-fits-all. What they're doing with Omnia - **what they're doing is nothing special, that's the bottom line. They're coming around to every other company** which says that you need to offer everything. I don't consider this a gamechanger at all. Omnia is nothing dramatic. That Nevro has come out with this is not earth-shattering." **–High volume implanter

- Omnia is just **an attempt to "salvage the company" after doctors began to abandon high frequency**

  *"Omni's not a game-changer. **The rest of the world moved on from Nevro so Omnia is just using the low-frequency therapy Nevro claimed they were better than, to salvage the company**. But you could do low frequency with Abbott, Medtronic, or Boston Scientific, and you have a device that's MRI compatible and one you don't have to recharge." **– KOL and former high volume Nevro user***

- Doctors have **no reason to use Omnia's low-frequency option** versus current low-frequency devices

  *"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."** **– KOL and former high volume Nevro user***

Source: Consultation calls with experts

10. The new Omnia stimulator, the centerpiece of Nevro's turnaround hopes, is a Hail Mary and colossal flop

Although five pages of KOL commentary on Omnia may be overkill, the launch is key to the bull case and a broad sample of real-world doctor feedback may be useful to investors betting on Omnia as Nevro's savior.

- Omnia merely **caters to Nevro users who turned away versus expanding the company's base**

  *"**The Omnia works best for heavy Nevro users who stopped being users**. My share is 10% Nevro, 40% Boston, 25% Medtronic and 25% Abbot. Nevro's share will stay at 10%. I wasn't that happy with the anchor. If takes an extra half hour with the anchor it's a hassle. It's the biggest rechargeable there is. The only bigger stimulator is the Abbot non-rechargeable. **The Nevro device is still big, just not as big as it was. They're just going from zero share to 10% of my share**. These are chronic pain patients and if you give them something uncomfortable they'll complain about it a lot more. It's the population you're dealing with." –* ***KOL, former heavy Nevro user who now uses it sparingly***

- Omnia is an attempt to re-position the company after hitting the wall due to explants, but it's "**old stuff" as Nevro's competitors have offered multiple wave form devices for most of this decade**

  *"Now all of a sudden Nevro realizes that with their explants rate, they're going to have to do something new and sexy with Omnia […] **They've basically turned themselves into Boston Scientific which has offered multiple waveforms ever since Spectrum launched in 2013. This is old stuff.** They're saying "I guess we better be competitive because our differentiation at 10khz failed." -* ***KOL***

Source: Consultation calls with experts

10. The new Omnia stimulator, the centerpiece of Nevro's turnaround hopes, is a Hail Mary and colossal flop

A broad sample of former Nevro executives and sales reps, some still in touch with the CEO and management team, concurred with KOL's and doctors in their scathing assessments of Omnia's potential. We found the level of consensus and conviction among both sets of experts notable. We begin with comments by a senior and plugged-in former Nevro executive: just "window-dressing with Grossman"; "nobody's going to buy Omnia" unless essentially bribed via study participation fees; that it's "just repackaging of an old product"; and that he'd "be shocked" if it drives growth. He described a core business in decline and a company on the precipice.

- **The senior ex-executive described the CEO as engaged in "window-dressing"** and questioned the **lack of "uptake" despite "a hundred more reps."** He bluntly stated that **"nobody's going to buy Omnia" unless they're essentially bribed** via study participation.

  "I think there's a lot of window-dressing with Grossman and that's why you're not seeing this big uptake *in revenue. If Omnia is so good and you've got a hundred more reps out on the field and you're doing all this great selling and all these customers are happy,* ***why is it not going up? They've eroded their price. Nobody's going to buy Omnia****, unless you're getting paid a couple thousand bucks to be put in a study to use it."* ***– Senior Nevro ex-executive***

- He added that **few of their "hardcore customers" are even utilizing Omnia** and described **a declining company that is on the precipice of competitive irrelevance**

  *"****I watch this very, very carefully*** *- out of all those really Nevro hardcore customers, how many are actually utilizing Omnia?* ***Not a lot. So, what does Nevro really have?*** *They have a core group of customers. They're not growing the business. The stock is doing well, so it's providing some stability. Then Saluda comes in, Nalu comes in, and all of a sudden they're going directly after them."* ***– Senior Nevro ex-executive***

Source: Consultation calls with experts

10. The new Omnia stimulator, the centerpiece of Nevro's turnaround hopes, is a Hail Mary and colossal flop

Another former executive, in a key sales role and now at a large competitor, offered an identical assessment that Omnia is a dud. In addition, two territory managers, both part of Nevro's launch team and one now at a key competitor, concurred that they see no market impact.

- The former sales executive stated that Omnia is **"nothing new" and a dud**, noting that Grossman has admitted that it's **still used as a high frequency device 85% of the time**. He stated that Nevro's **employees don't even know how to program Omnia** properly for anything except high frequency stimulation. Damningly, he stated that Nevro actually expects Omnia to remain a high frequency device and that its purpose is simply to create a **marketing "perception."**

  "They think Omnia's going to be a big thing. ***I just don't see it. Grossman even said on the earnings call that non-high frequency is utilized only 15% of the time****. There's nothing new…****Nevro does not feel that a lot of these other waveforms are going to be utilized with Omnia. It is rather to provide physicians with the perception that they have more options****. The utilization of low-frequency and other waveforms besides high frequency will be very low, because one, a lot of Nevro's people don't know how to program those patients well because they've been utilizing the high-frequency algorithm and two, most of the time Senza is what people want."* ***– Senior Nevro ex-sales executive***

- **Two former Nevro territory managers** independently stated that **Nevro's "not going to get more patients because of Omnia."** One is now at a key competitor and sees **no impact from Omnia from his seat.**

  "The market's not changing because of Omnia*. The spinal cord stim market is what the spinal cord stim market is.* ***You're not going to get more patients because of Omnia****. Right now, you're just playing around in the same old market you've always been playing in, the same market I've been playing in my whole career, and the market's not really changing."* ***– Former Nevro territory manager, one of the longest tenured SCS reps***

  *"****I don't hear anything, from my team or anyone in my territory****, that Nevro's adoption with Omnia is now so much better. Some doctors are trying it out but I haven't heard anything revolutionary about it."* ***– Former Nevro territory manager now at a key competitor***

Source: Consultation calls with experts

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We include additional Omnia commentary by former executives and sales reps, which we found as universal and harsh as the feedback from KOL's and doctors.

- A former sales executive still in touch with Nevro's executive team states that **even the CEO describes Omnia as merely marketing spin**, and that he's "**naïve" in his understanding** of the SCS market. He characterized Omnia as **"just a repackaging of an old product."**

  *"**His understanding** of the technology that he's speaking to, and the way that's going to be received by physicians, **is naïve. Grossman describes Omnia as really just the marketing**, like the same marketing spin that was being presented at NANS. **I don't think he understands the way that these physicians work** and their desire to have new and innovative products. Omnia is not a new or innovative product. It's basically **just a repackaging of an old product**." **– Former Nevro sales executive***

- A former regional sales director in charge of one of the largest territories stated that **his doctor and industry contacts indicate that Omnia is a flop** and that he'd be **"shocked if it was a driver of sales growth."**

  "The feedback from my doctor contacts as well as industry contacts is that Omnia is not changing the paradigm at all**. Will it lead to more market share or reversal of sales declines? **I'd be shocked if it was a driver of sales growth**. I don't see it changing. I don't see how it offers a clinician something unique when all other companies are already optimized on low frequency stimulation. **It's a bad look** when you purport something so strongly and then come out with something that flies so strongly against it. How do you justify it?" **– Former Nevro regional sales director

- A former sales rep in one of Nevro's largest metro's characterized Omnia as **mostly an aesthetic upgrade**, stating that it **enables competitors to undermine Nevro for now admitting that high frequency is "a dud."**

  *"Omnia is not a game changer. It's just that the remote and recharger are a **little more aesthetically pleasing**. 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." **– Former sales rep***

Source: Consultation calls with experts

10. The new Omnia stimulator, the centerpiece of Nevro's turnaround hopes, is a Hail Mary and colossal flop

Executives, regional managers, and sales reps at Nevro's competitors - Abbott, Medtronic, Boston Scientific, and smaller ones - offered ground-level color on Omnia, corroborating remarks by doctors and ex-employees that it's a failed launch with little to no market impact.

- **A territory manager with 20 years of SCS experience, overseeing one of the largest multi-state regions for one of Nevro's 3 key competitors**, described a few doctors dabbling with Omnia but **no material market share impact.** He suggested that the only doctors using Nevro are ones being paid by the company to do so.

  "Omni rolled out in Q3 2019. ***We're seeing it all over social media****. Doctors are saying Omnia's a good battery, that it gives them options* ***but that the results are no better than anyone's else****. They got some more play with it. One of our doctors will do a couple of cases with it and see how it goes. You have your Nevro loyalists like [name redacted] and [name redacted] who are being paid. They're on their studies. Every day doctors though have gotten smarter and use everyone's device.* ***Omnia isn't impacting the market by letting them capture market share. Doctors use everyone. They're not loyal. The only loyal ones are ones being paid a lot of money to put in devices****. Everyone gets their piece of the pie."* – ***Territory manager at one of Nevro's 3 key competitors***

- **A longtime C-level executive in the SCS space** stated that a me-too product like Omnia **wouldn't shift any share to Nevro**

  "Are they shifting share from Boston Scientific with Omnia? ***I doubt it because Boston Scientific, their IPG, has those capabilities, and I think their programming is better."*** ***– Longtime executive in the SCS space***

Source: Consultation calls with experts

10. The new Omnia stimulator, the centerpiece of Nevro's turnaround hopes, is a Hail Mary and colossal flop

Competitor color on Omnia's lack of traction was consistent around the country: "a dud." A regional manager explained that Nevro's salesforce isn't even trained in paresthesia-mapping, the method by which low-frequency stimulators are implanted – yet another reason why Omnia, per Grossman's comments, remains almost exclusively a high frequency stimulator.

- **A longtime regional manager** overseeing one of the largest territories for a key competitor expects Omnia to be **"a dud" and that he has seen no material "uptick for Omnia**." He stated that competitors are leveraging Nevro's about-face toward low-frequency stimulation.

  "I have not seen a big uptick for Omnia in our territory. I think it'll be a dud. We've been pushing hard against their being all in on high frequency, and now allowing low-dose *and multiple waveforms even though everything they've done and all their studies are around 10khz. They're trying to get Omnia into some of their old accounts now. If a patient comes in requesting Nevro, that's about the only time that Nevro is getting implanted in other accounts"* ***– Regional sales manager at one of Nevro's largest competitors***

- **He indicated that Omnia undermines Nevro's positioning and credibility**, and that its **field salesforce isn't even trained in the paresthesia-mapping** required to implant a low-frequency stimulator

  "Part of Nevro's messaging is that it's easy to implant. You throw the leads in; you scan T9/T10; there's no in or out testing. It's very simple. But if you need to switch to low-dose and you need to do mapping, you have no idea what you're getting into as a doctor. ***Nevro never trained a lot of their reps on it. Now they're asking their field to retrain on classic spinal cord stimulation. We leverage that. You've done an about-face*** *and now all of a sudden you're trying to do what every other company is doing. At least in our market,* ***high frequency hasn't been the silver bullet*** *you promoted and now you're just like everybody else."* ***– Regional sales manager at one of Nevro's largest competitors***

Source: Consultation calls with experts

10. The new Omnia stimulator, the centerpiece of Nevro's turnaround hopes, is a Hail Mary and colossal flop

Comments by former Nevro executives/reps, competitors, and KOL's/doctors indicate that Omnia is not only a dud, but that it erodes Nevro's credibility and muddles their message. After spending a decade pushing high frequency stimulation and trashing low-frequency as ineffective and dangerous, experts described the company's sudden embrace of low-frequency as an admission of defeat and a sign the company is going "the way of the Dodo."

- KOL's state the **industry has moved on from high-frequency and that Omnia is an admission of failure**

  "Nevro initially tried to blow everybody out of the water with, "Look, we have 10khz frequency" And I know the key engineer over there. When the PROCO study came out, it showed excellent sub-perception outcomes at 1khz. All of a sudden everybody said, "Who needs 10k?" And then they sued and said "Nobody can have 10khz but us," and Boston Scientific and the other companies said, "It's all yours." So, ***Nevro failed with 10k. Now what they have to do is reinvent themselves, so they re-marketed Omnia. Here's a company that said, "Paresthesia is awful." Now they have to give in and offer paresthesia."***
  - KOL and former high volume Nevro user

  "If paresthesia-free was such a good thing, why come out with supposedly new technology? ***Maybe it's marketing."*** ***- KOL***

- Omnia indicates that Nevro's **future is "problematic"** and that it's **going "the way of the Dodo bird" with price pressure and new entrants**

  "I give them a lot of credit that they've been able to survive financially being a one-trick pony*, but the fact that they came out with* ***Omnia does mean the future is problematic****, because now they've realized that they're not anything special, they're just another stimulator company—what is going to distinguish them from the other companies."* ***– High volume implanter and moderate Nevro user***

  "There are going to be more entrants to the market, and that's going to cause price pressure. ***Nevro is going to go the way of the Dodo bird eventually. That's why they had to do Omnia."*** ***– KOL and high volume implanter***

Source: Consultation calls with experts

10. The new Omnia stimulator, the centerpiece of Nevro's turnaround hopes, is a Hail Mary and colossal flop

Omnia erodes Nevro's credibility and muddles the company's message (cont'd)

- The Omnia launch admits that **all of Nevro's previous clinical data is "hogwash."**

  "All of their clinical data that they first gained market share with - they have ***now said through their actions of launching Omnia that it was all hogwash****, because they now offer a product that does lower frequency."* ***– Longtime C-level executive in the SCS space***

- A former Nevro sales executives stated that **Omnia erases Nevro's identity**, and that **Medtronic and Boston Scientific already tried and failed with the same all-things-to-all-people product strategy**

  "Omnia is not going to do it for Nevro. The issue is that they've now lost their identity. They're now the same as everyone else*. The only product in the space that's differentiated is the Abbot IPG. Nevro, Boston Scientific, others are all saying exactly the same thing. They're all saying burst, different, waveforms, etc.* ***Omnia is not differentiated. It has nothing specific that will hit the nail on the head for doctors****. Omnia's burst waveform isn't actually a burst. They're claiming it's something it's not.* ***I just don't see it being an effective strategy. Medtronic and Boston Scientific already went to market saying we can do other waveforms and things and it hasn't worked for them."*** ***– Former sales executive now at a key competitor***

  "The Omnia launch was an acknowledgement that they needed to change course because ***the novelty and newness of high frequency has worn off."*** ***– Former regional sales manager in charge of one of Nevro's largest territories***

  *"****Nevro has lost their identity****. Going toward they're positioning around Omnia which can do everything.* ***They're no longer differentiated*** *which creates a big problem. Being different is one of the key things in the SCS market."* ***– Former sales executive***

Source: Consultation calls with experts

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Interestingly, former employees and KOL's stated that Omnia isn't even a new offering: Nevro's previous stimulators already included the capability to offer low-frequency stimulation, which the company downplayed for fear that it would undermine its claims of high frequency's supposed efficacy. Multiple interviews indicated that Nevro's HQ and field reps long offered it to KOL's who soured on high-frequency. Nevro, in our opinion, has pushed a fraudulent narrative that Omnia represents a new technology or product strategy. If shipping low-frequency with previous devices failed to prevent Nevro's sales crash, we wonder why it would be the company's savior now.

- KOL's stated that **Omnia isn't "anything new," that the devices "could always do low frequency," and that Nevro already offered this capability to doctors, especially those with high explant rates from high frequency.**

> *"If you speak to reps from other stim companies, they'll tell you that Senza had all of that capability in there and just never used it.* ***I met with [a key Nevro engineer] a few weeks ago to have him explain to me what's in the guts of the Omnia and he admitted to me that a lot of its capabilities were there in the previous device*** *but they never marketed it."* ***– KOL and former high volume Nevro implanter***

> ***"Nevro's device could always do low frequency****, but they put restrictors on it because they didn't want the reps doing that. Nevro knew what was always going to happen: a person fails high frequency and it's natural to put them back into low frequency stimulation.* ***Nevro didn't do anything new [with Omnia]. They just used a new case and rebranded it*** *without the restrictor."* ***– KOL***

> ***"Even a few years before Omnia came out, Nevro was allowing doctors in certain segments of the country to shift their devices to low frequency****. Nevro didn't advertise it. But* ***if you had a high explant rate or were deemed an important person, they would fly out one of their head engineers*** *and say "Listen, because you're you, we're going to let you do tonic [low frequency stimulation] for the patients that are failing."* ***- KOL***

Source: Consultation calls with experts

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Although Nevro already bundled low-frequency capability with devices prior to Omnia, KOL's and former employees suggest that the company was paranoid that it would expose its high frequency data as a sham.

- Nevro sales **reps who independently activated low-frequency when high frequency failed** allegedly faced retaliation from the company.

> *"Nevro had a rep in [area redacted] who was* ***reprogramming their devices to use low frequency to try and save failed [high frequency] patients****, and Nevro threatened him with an injunction. Like, if you tell anybody that it worked we're going to sue you and take away your 401k, Stuff like that.* ***Nevro was afraid it would disprove their entire clinical trial. Several of their reps were doing that."*** **– KOL and former high volume Nevro implanter**

> *"In order to grow the business,* ***some reps would do the paresthesia [low-frequency], and some reps were doing high frequency*** *just like the textbook, and then they wouldn't get cases because the docs were asking them, "Can you program the patient, so they feel it? Give them both options." Well, the clinical team of Nevro, if they saw that you were doing that, that would be a reduction in your commission percentage."* **– Former district manager and part of Nevro's launch team**

> ***"Nevro didn't want the patient to feel paresthesia because what you'll find is that they crave the paresthesia.*** *Once they feel it, they think that that's the indication of whether the device is working or not. You can't just get rid of paresthesia unilaterally and say it's a great thing because there are definitely reasons for it."* **- KOL**

Source: Consultation calls with experts

Scorpion Capital | Nevro (NYSE: NVRO)

10. The new Omnia stimulator, the centerpiece of Nevro's turnaround hopes, is a Hail Mary and colossal flop

Our research interviews suggest that Omnia is just a marketing ploy and stock promotion – "lipstick on a pig" according to one KOL. Even Grossman apparently expected the "new" device to remain as mostly a high frequency product, according to former employees. Our research uncovered another reason which confirms that Omnia was never meant to be anything more than a high frequency device: its leads are still placed along specific vertebrae (T9/T10) which Nevro has always stipulated for high frequency stimulation. However, leads for low-frequency stimulation are typically placed at different points on the spine (T7/T8) based on trial-and-error via paresthesia mapping – ie, low frequency requires an entirely different type of surgical procedure, rendering the entire premise of Omnia clinically absurd. We note a paper by members of Nevro's Scientific Advisory Board comparing lead placement for high vs. low frequency, as well as similar color from the publication for Nevro's pivotal trial.

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NEUROMODULATION SECTION

Review Article

10-kHz High-Frequency SCS Therapy: A Clinical Summary

Lead placement comparison for HF10 high frequency (T9/T10) vs. traditional stimulation (T8)

Table 1 Comparison of HF10 SCS with traditional SCS

System	HF10 SCS	Traditional SCS
Typical pulse width (μsec)	30	400
Typical stimulation rate (Hz)	10,000	40
Typical stimulation location for back pain	T9-T10	T8
Typical stimulation location for neck and arm pain	C2-C4	C2-C7
Typical amplitude for back pain (mA)	1–5	4–6
Implant procedure	Leads placed by anatomical landmarks Patient under continual sedation	Leads placed based on verbal patient feedback Patient provides feedback on paresthesia coverage Intraoperative programming and lead repositioning often required

Comparison of 10-kHz High-Frequency and Traditional Low-Frequency Spinal Cord Stimulation for the Treatment of Chronic Back and Leg Pain: 24-Month Results From a Multicenter, Randomized, Controlled Pivotal Trial

imaging and attached to either an external stimulator (during the short-term screening trial) or a subcutaneously implanted IPG. For HF10 therapy, the distal tip of one lead was placed at T8 while a second lead tip was placed at T9, both near anatomical midline. Lead placement for HF10 therapy did not entail confirmation that they were positioned at physiological midline. Lead position for HF10 therapy was based on extensive empirical observation that most patients respond to stimulation application near T9/10, while allowing for patient variation by covering T8-T11.[4-6] For traditional low-frequency SCS, leads were placed at vertebral levels based on intraoperative paresthesia mapping involving patient feedback, typically resulting in parallel lead tip placement at T7-T8.

Source: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4660894/pdf/pme0016-0934.pdf; https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5058646/pdf/neu-79-667.pdf

10. The new Omnia stimulator, the centerpiece of Nevro's turnaround hopes, is a Hail Mary and colossal flop

Toggling a device between high frequency and low frequency – the entire point of Omnia - is clinically unrealistic and reckless. When doctors implant Omnia leads at the vertebrae used for high frequency stimulation, they render it irrelevant and/or dangerous for low-frequency stimulation which requires lead insertion in a different location. Investors should therefore not be surprised at Grossman's comments that Omnia is still used for high frequency 85-90% of the time. One KOL after another highlighted the lead insertion issue and why it renders Omnia's high-plus-low-frequency messaging disingenuous and "a lie." We posed a question and note the reply, which stated that "you're screwed" if you toggle frequencies. A second KOL provided additional detail to underscore the same concern.

Q: How do you use other waveforms with Omnia like low frequency, if the leads are still in the same place as for high frequency?

"You hit the nail on the head. ***That's part of the problem. Nevro is so locked in that their leads have to be at one spot. If there's any variation they get lost. Low frequency doesn't necessarily work at just that T9/10 junction****. A lot of it works at T8/9. You're bound by their restrictions. So if you use high frequency first and the leads have to be over the T9/10j unction,* ***you're screwed if that patient does better with low frequency because that's not where the leads are implanted."*** ***– KOL and high volume implanter***

"Nevro says that you should cover the 9/10 thoracic interspace. That's their thing. Low-frequency stimulation can be anywhere from T8 to L1*. If you want to stimulate the back, you're probably doing T10. That whole science, the art of neuromodulation, was what Nevro said they mitigated. You didn't have to be a neuromodulator. Historically, when you look at [names redacted, the most prominent KOL's in the field] we would look for different ways to get pain relief at different locations within the spinal cord versus what we called "plant and pray." Nevro's electrodes usually cover the top of T9 and the bottom of T10, which may stimulate a certain anatomic region. If you need foot coverage, that location doesn't have a hope. For below the knee, that array is not going to work.* ***Unfortunately if the HF10 doesn't work, you might not be in the right spot with the leads to do tonic [low frequency stimulation].*** ***- KOL***

Source: Consultation calls with experts

10. The new Omnia stimulator, the centerpiece of Nevro's turnaround hopes, is a Hail Mary and colossal flop

KOL's explained why Omnia's "One System, All Frequencies" positioning is clinically illogical and risky, as different frequencies and waveforms require different surgical lead placements. We believe this explains the CEO's admission that Omnia is used almost exclusively as a high frequency device, and it leads us to find alternate explanations for why Omnia is rarely used for lower frequencies as misleading.

- A KOL explained **why Omnia's "all frequencies and waveforms" shtick is absurd and haphazard**. Aside from differences in lead location by frequency, **different waveforms** which Omnia claims to offer, like burst, also **require placement at different vertebrae than Nevro's one-size-fits-all insertion at T8/9.**

  "If you look at true burst, they want you to be about a level up T8/9 which is the sweet spot for burst. So if your electrodes aren't covering that and you try to do burst, you're not going to hit it*. For different frequencies, you need to be at the right place on the spinal cord to get that stimulation. If you're at T9/10 where you put your Nevro, you might get it depending on where the affected problem is. You might get the upper thigh but for lower leg, probably not. And you may get other paresthesias that you don't want. You try to do a tonic, but you're to get all rib simulation. The idea that you put it in at T9/10 and get the other frequencies to work is very 50/50."* ***– KOL and former high volume Nevro implanter***

- A regional manager in one of Medtronic's largest territories stated that **Nevro's no-paresthesia method** causes doctors to be **sloppy with lead insertion, causing "all sorts of problems and unintended consequences" if trying to use Omnia for low-frequency stimulation.**

  "I've seen some cases where Medtronic was implanted after a Nevro device was in there, I think their docs get a little sloppy with their lead placement because there is no paresthesia. They just kind of put the leads up, pretty much midline, and it's good enough. That's was why docs early on were interested - I don't have to wake up the patient during the procedure. ***If Nevro continues to do sloppy lead placement and try to switch to classic low frequency stimulation, they're going to run into all sorts of problems and unintended consequences."*** ***– Medtronic SCS regional manager***

Source: Consultation calls with experts

10. The new Omnia stimulator, the centerpiece of Nevro's turnaround hopes, is a Hail Mary and colossal flop

A KOL bluntly stated that "it's impossible to capture" both low and high frequency fields and that "you can't have it both ways," saying it's not a "real world" scenario and that Nevro's claims make him "shake my head." He detailed worrisome adverse effects from attempting to do so. A Medtronic regional sales manager provided another reason why 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.

"Nevro puts their patients to sleep during the trial. They're the only company that does this. When I do a trial, I put the leads in at vertebrae six, seven, and eight, and ask the patient "How does that feel?" And they say "You got it in the wrong spot. You're in my rib on the side." We use trial and error to get it right. But with Nevro, it's always staggered leads at T9/T10. That's fine for 10,000-Hz but ***you can't have it both ways and insist the leads have to be in a certain spot and then say with Omnia they can do both high frequency and paresthesia. It just makes me shake my head.*** *They're trying to stay afloat with Omnia, but* ***I don't know how in the real world they can do this****. I watched Nevro program one of my patients. They say, "Turn on 10k. Now, turn on paresthesia-based." My patient was pissed-off. The soles of his feet were on fire. And the Nevro rep sitting in my office would hem and haw and go, "Ah, well, let me try something else."* ***It's impossible to capture both fields."***
- KOL

*"****Honestly, one of the biggest restrictions with Omnia is their handheld patient controller*** *- if you want to turn the volume up on your television, you hit the button once, and it turns up one. You hit the button twice; it turns up two. From my understanding of how the patient programming works, if you do a left and a right, with the Nevro controller, you can't just turn your left leg up, and have your right leg stay the same. You're turning them both up. For high frequency, with their components and their design, they don't need that. But when you have* ***the inability to separate out their programming at low frequency, it will be a challenge for the patients, because it is for us.*** ***– Medtronic regional sales manager for one of their largest territories***

Source: Consultation calls with experts

10. The new Omnia stimulator, the centerpiece of Nevro's turnaround hopes, is a Hail Mary and colossal flop

Although we address Nevro's supposed market opportunity in painful diabetic neuropathy in a later section, we note KOL comments indicating that Nevro's one-size-fits-all lead insertion at vertebrae T9/T10 renders Omnia clinically impossible for PDN patients specifically. Getting stimulation to reach an anatomical region as far from the spine as the feet is difficult and requires a complex trial-and-error process via paresthesia mapping along various vertebrae. However, Nevro's entire reason for pushing high frequency is that it *avoids* paresthesia mapping, which its reps don't even know how to do properly. We caution investors to understand the preposterous contradiction at the heard of Nevro's PDN claims: that high frequency is clinically superior for PDN patients, and high frequency is also easier to implant because its leads are always at T9/10 to avoid paresthesia-mapping. Nevro's PDN claims are so prima facie contradictory that we consider them fraudulent, as paresthesia mapping is mandatory to find which vertebrae stimulate the feet – "they're lying," to quote a KOL.

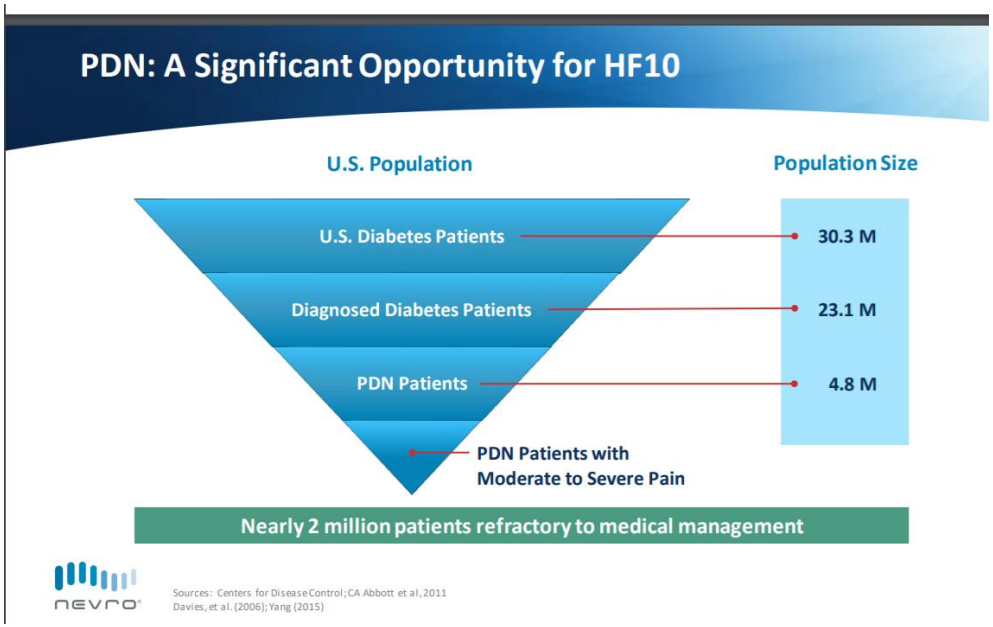
"Nevro has always said you have no choice with lead placement, that everyone has to place the leads at T9/T10. *The beauty of paresthesia-based [low-frequency] stimulation is that* ***if you have foot pain as a diabetic with neuropathy, I would enter with the leads at L2****, and I would put the leads at L1, T12 at what's called the cronus. I'll turn it on and say, "How do you feel?" and you say "This sucks. You're not getting to my feet." Then I push a lead to L5, at the root, at T12, L1 – right in that area of T12, T11. I turn it on there, and I put the leads wide, so we can capture the nerves on the left and the right as they're descending past the lead. And you say, "This is much better." Then the next patient comes in and goes. "What are you trying to do? Kill me? This is all ribs and butt cheek." Then I go back to L1 and that person is happy as a clam.* ***So, each person has a different spinal cord. That's why you've got to do your job, you've got to do paresthesia fishing. You've got to throw your line out there with bait and fish because your spine is different than mine****." – KOL and high volume implanter*

"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 diabetic peripheral neuropathy, you can't be in the T9/T10 spot. You're going to have to be somewhere else, which means now you can't do the high frequency. – KOL and high volume implanter

Source: Consultation calls with experts

11. TAM expansion and growth from painful diabetic neuropathy (PDN) and other new indications are a mirage

A key part of the Nevro bull case hinges on the company expanding its high frequency stimulation into other indications, notably painful diabetic neuropathy (PDN) of the lower limbs. Nevro presented data from its PDN study at the annual neuromodulation meeting in January 2020, and the company has been beating the drum ever since that PDN is the magical, explosive TAM expansion that will reverse its fortunes and get it back to growth. The number of times PDN was hyped by the CEO and sell-side on the recent Q3 earnings call - 19 mentions of PDN - is suggestive of its importance to the story. We excerpt some of the CEO's PDN-focused comments on November 5th -



Keith Grossman, CEO, comments 11/5/20

"...a growing level of excitement among our team and our board about this [PDN] opportunity*. So, I would say we are,* ***with each passing month, we get, the more psyched internally*** *about the ability to enter this market and grow a meaningful and defensible business…"*

"…and the impact of new product in indication ***launches like PDN it should be the beginning of a very attractive period for the company."***

*"…****when we get to the first quarter call, we will almost certainly dedicate a fair portion of that call to talking about the size of the [PDN] market****…*

*"…****Our PDN study continues to move forward****…keeps us on track for a mid-year 2021 approval and a* ***second-half commercial launch****. In next quarter's call, we'll begin to talk a bit more about our market launch plans and expectations for* ***this really exciting opportunity."***

Source: NVRO JPM presentation https://s24.q4cdn.com/932612397/files/doc_presentations/NVRO_JPM-2020_011520_Print_vFINAL.PDF; earnings call transcript.

Scorpion Capital | Nevro (NYSE: NVRO)

11. TAM expansion and growth from painful diabetic neuropathy (PDN) and other new indications are a mirage

We investigated Nevro's PDN study and the claims that it expands the market for their high frequency device. Our research found widespread skepticism and outright ridicule among KOL's and Nevro's former executives and sales reps at the notion that PDN is a meaningful new commercial opportunity. One KOL after another – including some of Nevro's most loyal users – stated that spinal cord stimulation has already been used for decades for PDN and is already approved by Medicare, blasting the company's claims that it's a "new indication" as "so stupid" and "just dopey." One stated that Nevro's PDN study has "value to Wall Street and no one else."

- Stimulators have been **extensively implanted for decades for PDN and the indication is already reimbursed by Medicare**

> *"So here's the deal with diabetic neuropathy. I used to lecture on this in the 90's.* ***I've used stimulators for PDN for 25 years. Nevro's PDN study is not telling us anything new at all.*** *The literature was always there. There were studies in the 90's. Bottom line is, you just call it neuropathic leg of the pain and* ***Medicare pays for it. We were doing that, are doing that, and there's nothing new about it. The study has value to Wall Street and no one else****. Any doctor who knows stimulators already uses them for diabetic neuropathy."* ***– KOL and high volume implanter***
>
> ***"In the 1980's, half of the patients we implanted with stimulators were for PDN."*** ***– High volume Nevro user***

- Nevro **calling PDN a new indication is "so stupid" and "just dopey" according to KOL's, given that it's widely coded today as neuropathy.**

> ***"Nevro saying they have this diabetic peripheral neuropathy indication is so stupid. We've been doing PDN treatment with stimulators forever****. All they did was say, it's off-label. We're going to get it so that it's on-label. But if I have a diabetic that has neuropathy,* ***we just code it as neuropathy****, lower extremity. We don't call it PDN* ***So what Nevro is doing is just dopey****. Here's the thing: everybody is treating diabetics with spinal cord stimulation already yet Nevro's saying "Look what we invented!" We've been using stim forever for diabetics with neuropathy.* ***This has been around forever."*** ***– KOL***

Source: Consultation calls with experts

11. TAM expansion and growth from painful diabetic neuropathy (PDN) and other new indications are a mirage

Nevro's PDN study and claims of a new indication elicited a striking level of derision among KOL's: that it's "putting lipstick on a pig" and won't change anyone's use of stimulators "in any way" and that competitors began pushing stimulators for PDN in 2004. One of Nevro's most loyal and highest volume implanters confirmed he's been using stimulators for diabetic neuropathy "for a long time."

- One KOL called it "**putting lipstick on a pig"** and stated hat "**it won't change my use or anyone else's" use of stimulators "in any way."**

  "The diabetic neuropathy study is an example of putting lipstick on a pig. It really is*. They're saying, wow we have a study that* ***shows us what we already know. I mean, please. It won't change my use or anyone else's*** *of stimulators in any way."* ***– KOL and high volume implanter***

- **Two of Nevro's highest volume implanters, one in the US and one in Europe, disputed that PDN is a new indication** and stated that they've been implanting stimulators for it **"for a long time."**

  "I have been treating idiopathic peripheral neuropathies, diabetic peripheral neuropathies*, complex regional pain syndrome, and other types of painful neuropathies* ***with spinal cord stimulation for a long time."*** ***- High volume Nevro implanter and loyalist***

  "We're the biggest stimulator implant unit in Europe. ***Our experience with Nevro started in 2009 with their EU study. We use it mainly for*** *back pain, back surgery syndrome,* ***and upper/lower neuropathic pain****.* ***– High volume Nevro implanter and consultant***

- A KOL stated that **Nevro's competitors have been offering stimulators for PDN for a decade or more**

  "Boston Scientific has been doing stimulators for neuropathy in diabetics for close to 10 years*, even with Precision-Plus back in 2004. Now all of a sudden, Nevro has some amazing thing?* ***They're trying to hoodwink. I wish they would have gone after something innovative, something new."*** ***- KOL***

Source: Consultation calls with experts

11. TAM expansion and growth from painful diabetic neuropathy (PDN) and other new indications are a mirage

A simple literature search shows why KOL's broadly ridicule Nevro's PDN hype as stock promotion and Wall Street naivete. Far from being a new indication that Nevro pioneered, one can find scores of publications going back over 25 years on the use of stimulators for PDN, leaving only two possibilities: stimulation is already widely used for PDN, and/or it doesn't work well despite what manufacturer-funded studies purport. Although our research indicates both are true, two examples demonstrate that companies have been publishing supposedly spectacular efficacy for this indication for decades. We note that the ~70% pain reductions claimed *in the 90's* with ancient devices are similar to Nevro's recent PDN study.

Study published *in 1996* claimed a 70% reduction in VAS pain score and 86% narcotics reduction – we note this paper is cited by 310 others per PubMed

THE LANCET

Electrical spinal-cord stimulation for painful diabetic peripheral neuropathy

Solomon Tesfaye, Jonathan Watt, Susan J Benbow, Kiang A Pang, John Miles, Ian A MacFarlane

Patient	Baseline		3 months				6 months				End of study				
	Background pain	Peak pain	Background pain		Peak pain		Background pain		Peak pain		Months since implant	Background pain		Peak pain	
			Off	On	Off	On	Off	On	Off	On		Off	On	Off	On
1	3	53	5	4	58	8	13	0	75	0	20	2	2	83	9
2	63	69	55	30	73	64	26	10	41	31	19	72	33	82	42
3	22	54	48	17	85	26	69	68	68	23	18	80	11	81	15
4*	31	46	..	..	..	..	..	..	..	..	..	..	..	..	..
5	71	79	75	62	79	65	88	88	90	90	6	88	88	90	90
6	62	65	90	50	90	53	70	45	80	60	14	73	32	71	23
7	77	73	76	49	84	52	55	29	80	45	11	77	23	81	17
8	34	77	70	10	78	10	73	0	72	0	9	84	23	79	10
Median	..	..	70	30	79	52	69	29	75	31	14	77	23	81	20
IQR	..	..	48-76	10-50	73-85	10-64	26-73	0-68	68-80	0-60	9-19	72-84	11-33	79-83	14-54
Signed-rank test			p=0·016		p=0·016		p=0·03		p=0·03			p=0·06		p=0·03	

*Patient 4 died 2 months after implant of unrelated cause. Patient 5 ceased to respond 4 months after implant.

Table: **VAS background and peak pain scores (mm) with ESCS turned off and on**

20 year literature review of SCS – published *in 2004* – lists 4 PDN studies with 67% success rate

Safety and efficacy of spinal cord stimulation for the treatment of chronic pain: a 20-year literature review

TRACY CAMERON, PH.D.

Department of Biomedical Engineering, University of Texas Southwestern Medical School, Dallas; and ANS, Inc., Plano, Texas

Summary of values after grouping studies according to diagnosis

Diagnosis	Overall Number			
	Studies	Patients	Patient Months	% Success
FBSS/low-back & leg pain	21	747	27,200	62
ischemic limb pain	14	629	24,394	77
CRPS I and II	13	224	7,237	84
peripheral neuropathy	4	36	1,620	67
SCI	5	21	615	57
postherpetic neuralgia	3	11	349	82
stump (phantom limb) pain	2	8	498	62
mixed	8	683	27,295	57

Source: https://stjudepaincenters.com/wp-content/uploads/2018/12/Spinal-cord-stimulation-painful-diabetic-neuropathy-Tesfaye.pdf; https://stjudepaincenters.com/wp-content/uploads/2018/12/Safety-efficacy-spinal-cord-stimulation-chronic-pain-20-year-review-Cameron-1.pdf

11. TAM expansion and growth from painful diabetic neuropathy (PDN) and other new indications are a mirage

One can easily search online for insurance authorization forms, which already include PDN as a typical indication and reimbursement category for spinal cord stimulation. Examples -

Aetna

D. Last resort treatment of moderate to severe (5 or more on a 10-point VAS scale) chronic neuropathic pain of certain origins (i.e., lumbosacral arachnoiditis, phantom limb/stump pain, peripheral neuropathy, post-herpetic neuralgia, intercostal neuralgia, cauda equina injury, incomplete spinal cord injury, or plexopathy) that is refractory to 12 or more months of standard therapy (including non-steroidal anti-inflammatory drugs, tricyclic antidepressants, and anticonvulsants).

Health Partners

For SCS Trial Insertion:

1. Diagnosis of failed back surgery syndrome, complex regional pain syndrome (including upper or lower extremity pain), or diabetic peripheral neuropathy.

One of many state BCBS plans

MEDICAL APPROPRIATENESS

- Spinal cord stimulation (SCS) is considered **medically appropriate** if **ALL** of the following are met:
  - Indicated for **ANY ONE** of the following:
    - A trial treatment with temporarily implanted epidural spinal cord stimulator or dorsal root ganglion stimulator when **ALL** of the following are met:
      - Neuropathic pain, including but not limited to, failed back surgery syndrome, complex regional pain syndrome (i.e., reflex sympathetic dystrophy), arachnoiditis, radiculopathies, phantom limb/stump pain, peripheral neuropathy
      - Chronic intractable pain of the trunk or limbs

PEHP

8.	Is SCS being indicated for any of the following conditions? *Please check.* ☐ Complex regional pain syndrome type I or II ☐ Failed lumbar back surgery syndrome ☐ Severe diabetic neuropathy with stable glycemic control	☐	☐
9.	If SCS is for severe diabetic neuropathy has the patient failed the following? *Please check.* ☐ Anticonvulsants ☐ Opioid/Opioid-like drugs ☐ Tricyclic drugs	☐	☐

Source: http://www.aetna.com/cpb/medical/data/100_199/0194.html; https://www.pehp.org/mango/pdf/pehp/pdc/spinalcordstim_fe3203a6.pdf; https://www.healthpartners.com/ucm/groups/public/@hp/@public/@cc/documents/documents/dev_058770.pdf; https://www.bcbst.com/mpmanual/spinal_cord_stimulation_for_treatment_of_pain.htm

11. TAM expansion and growth from painful diabetic neuropathy (PDN) and other new indications are a mirage

Comments by KOL's that PDN is an established, longstanding indication for spinal cord stimulators were also repeated by Nevro's former executives, sales reps, as well as its main competitors. Nevro may argue that PDN is an off-label indication and that getting it on-label is meaningful, but doctors and former employees forcefully stated that PDN is so widely coded and accepted as regular neuropathy that Nevro's claims are commercially irrelevant and "smoke and mirrors."

- Stimulation **"has always been approved or used" for PDN** and Nevro's claims are **"smoke and mirrors"**

  *"Spinal cord stim has **always been approved or used for neuropathy. PDN is just another smoke and mirrors** way for Nevro to position their device."* ***– Medtronic regional manager in charge of a large multi-state territory***

- Former Nevro sales executive now at a key competitor states **doctors can freely "use stimulators for PDN today."**

  "Doctors can use stimulators for PDN today**. What you're hearing from the Medtronic rep is completely true. The doctor can just say something is neuropathy."* ***– Former Nevro sales executive

- A former Nevro regional sales director, also now at a key competitor confirmed that **stimulators have been used for PDN "for forever" and that it's not "going to be a game changer."**

  "We've been stimulating for diabetic neuropathy for forever, and no, I don't think it's going to be a game changer.** I think you will have guys that live by the indication law and they're going to use Nevro because they have an indication for it, but I don't think it's a game changer […] **And then, you have to look at the data and ask if it's really skewed** like their Senza data was. Like, **is this really real-world data? So, I think there's going to be some skepticism, with the clinical side." ***– Former regional sales director***

Source: Consultation calls with experts

11. TAM expansion and growth from painful diabetic neuropathy (PDN) and other new indications are a mirage

Skepticism of PDN opportunity by Nevro's former executives and competitors (continued)

- **A longtime C-level executive** in the SCS space **echoed the widespread skepticism regarding PDN's potential revenue** contribution for Nevro

  "It's a bit of a quagmire *because they announced a PDN study with the potential for a new indication.* ***Well, the physician community is using it for that anyhow****. Okay, maybe if the physician community is reimbursed for it, but they're coding funky anyhow.* ***I don't know how much of an uptick it's going to give them in revenue."*** ***– C-level executive in the SCS space***

- A territory manager for a key Nevro SCS competitor said he **does plenty of PDN cases today**, and provided granular reimbursement color to explain why he **doesn't "see how a PDN indication changes the market"** and why **PDN is "nothing new or different."** He said he's been dealing with endocrinologists and podiatrists "for years for PDN" and that **any "doctors who want to use stimulation for PDN are already using it."**

  "I did twenty PDN cases in my territory in 2019. ***Stimulation is already approved for PDN. With Medicare, you need a primary and secondary pain indication. You just put in foot and the second as PDN and it will get approved****. You can say today that the secondary indication is neuropathic pain.* ***I don't see how a PDN indication changes the market. I've been walling to podiatrists and endocrinologists for years on PDN****. It's the same indication as regular stimulation. Foot pain is the same codes, same delivery system, same placement of leads.* ***It's nothing new or different. Doctors who want to use stimulation for PDN are already using it.*** *If you have tingling in your hands and feet, they already use it. Off label, on label, they use it. A new PDN indication just allows you to have more of a conversation." –* ***Territory manager at one of Nevro's 3 key SCS competitors***

Source: Consultation calls with experts

11. TAM expansion and growth from painful diabetic neuropathy (PDN) and other new indications are a mirage

While many KOL's indicate that they already use stimulators for PDN today, others stated that diabetics who have deteriorated to the point of neuropathy are too risky as stimulator patients and suffer far higher complications when implanted. Our research suggests that the PDN opportunity is already played out with doctors firmly entrenched in two camps: those who already code it and it implant it today, and those who are wary because of higher complication rates and are unlikely to be swayed by label and reimbursement tweaking. A KOL who occasionally uses stimulators for PDN explained the conundrum: "the ones with the worst pain are the ones with worst diabetes" and therefore the riskiest, adding that "a PDN label won't help Nevro's market share" and that most doctors he knows "feel similarly." A second KOL, a moderate Nevro user, expressed skepticism of Nevro's PDN study and corroborated why a PDN label won't be "a gamechanger": a small, suspect market of high-risk patients whose comorbidities make it less likely they'll even be referred.

"PDN would give Nevro an opportunity to have an extra condition on their label but ***it doesn't move the needle. I'm already using stimulators for PDN but in general diabetic patients are very sick and I don't like to use a stimulator.*** *They're much more likely to get a side effect.* ***They have four times the infection rate with an implant****. When one of these devices gets infected it ruins my month and makes me miserable. I really try to avoid diabetic patients. If their diabetes is under decent control I'll do them.* ***But the ones with the worst pain are the ones with the worst diabetes. A PDN label won't help Nevro's market share with me. When I talk to other implanters at my hospital, most feel similarly to me."*** ***– KOL and high volume implanter***

*"****I wasn't so impressed with the PDN study****. I'm a little bit leery because it's* ***a market of primarily elderly sick people with a lot of comorbidities, and I am not sure that it is such a big market for them, number one****. The patient population is* ***a suspect category for referral to a pain doctor or surgeon****. A lot of them are more elderly, sick with other comorbidities, risks of infection, so it's less common that they'll be referred. I think that the patient population is suspect in terms of surgical candidates.* ***I don't think it's going to be a gamechanger."*** *–* ***KOL, high volume implanter with moderate use of Nevro***

Source: Consultation calls with experts

11. TAM expansion and growth from painful diabetic neuropathy (PDN) and other new indications are a mirage

In chapter 3 we detailed widespread skepticism of Nevro's pivotal SENZA-RCT study, among former executives, trial investigators and Nevro consultants, KOL's and others. We encountered similar mistrust of Nevro's PDN study, which the company used to generate buzz at NANS in January 2020. The study compared a high frequency stimulator plus Conventional Medical Management ("CMM") to CMM alone and is the foundation of the PDN narrative embedded in Nevro's stock. KOL's and former executives blasted the study for using the same tricks and gimmicks as the SENZA trial: an open-label design (i.e., no blinding), a loosy-goosy comparator arm guaranteed to produce a "successful" trial, cherry-picked patients, and patient manipulation. KOL's indicated that the PDN study was the latest example of Nevro's suspect pattern of clinical trial conduct and making up new indications:

- Nevro has a **history of playing "games"** with trials, is "just a lot of **smoke and mirrors,"** and now **"no one buys their data."**

  *"**Nevro's always played a lot of games**. Rami, their previous CEO, was a notorious [redacted]. He just wasn't very on the up-and-up….**It's just a lot of smoke and mirrors. There's not a lot there**. There's a joke going around that we're one annual NANS meeting away from proving that Nevro's high frequency cures Covid. No matter what it is, Nevro says their device treats that, **They put this data out that people don't even read anymore. It always shows these ridiculous numbers. They'll come up with numbers to show that high frequency treats cancer. No one buys their data."*** ***– KOL and high volume implanter***

- A KOL states "**I don't believe anything they say"** and **doubts "their PDN claims"**

  *"Nevro has one size fits all. **I don't believe anything they say and I doubt that their PDN claims are going to be any better. Every Nevro study is the same. It's a bunch of shit** and you might get some initial improvement and **then the same problems a year later."*** ***– KOL and former high volume Nevro implanter***

Source: Consultation calls with experts

11. TAM expansion and growth from painful diabetic neuropathy (PDN) and other new indications are a mirage

PDN study as the latest example of Nevro's suspect pattern of clinical trial conduct and making up new indications (continued)

- Another KOL states that **Nevro is defined by "the flawed design of their studies"** and reflects a desperation to survive

  "Nevro tried to innovate, and I give them credit for that, but ***they're struggling and trying to survive****. So they're trying to come up with these studies demonstrating superiority.* ***The flawed design of their studies defines them as a company and they're failing."*** ***– KOL and high volume implanter***

- The PDN study is the **latest example of Nevro claiming that high frequency cures everything**

  "There's no Rosetta Stone in medicine. ***There's no one thing that can treat everything but Nevro will have you believe that one therapy can treat every type of pain and all you have to do is put it in the same spot****. They would have you believe that the same spot treats phantom limb pain and pelvic pain, that they can treat everything known to man, even though no one can replicate these studies with results in real life. Nevro's publications say you can use the same treatment for back and leg pain, the same spot for diabetic foot pain, for pelvic pain, for CRPS.* ***Every single thing is the same thing for them and it's just it doesn't make sense. It goes against everything in science and medicine."*** ***– KOL and high volume implanter***

- Nevro studies are **not blinded and are skewed by well-known placebo effects**

  "The Hawthorne effect is well documented in science. If a person knows they're getting the experimental product or treatment they tend to have more of a placebo effect. ***Every patient in Nevro's study knew which device they got. Doctors believe the Hawthorne effect completely skewed Nevro's results. It happens in all their studies. Everybody knows which device they're getting. Nevro's always played a lot of games."*** ***- KOL***

Source: Consultation calls with experts

11. TAM expansion and growth from painful diabetic neuropathy (PDN) and other new indications are a mirage

Specifically, KOL's slammed the PDN study's cherry-picking of diabetic patients, implying the exclusion criteria reflected an unethical study design. The criticism was identical to that of the SENZA pivotal trial: enrolling patients that are not representative of the real world. One indicated the PDN study "is just as bad as their original SENZA" trial and "lacks robustness."

- A KOL and speaker who teaches/meets with scores of implanters states that **"everyone again" thinks Nevro cherry-picked study patients**

  "Everyone again feels that Nevro just cherry-picked their PDN study *because diabetics are notoriously not compliant. That's why they have diabetes to begin with. And Nevro cherry-picks* ***picture-perfect diabetic patients*** *that always take the medication, their A1C was always below 7 and* ***that's not realistic****. That's not the average American that eats hoagies in Philadelphia."* ***– KOL and speaker***

- Another KOL stated that **Nevro's exclusion criteria would cause him to reject 85-90% of diabetic stimulator candidates** he sees

  "If I used these exclusion criteria in my own population of diabetic patients, I could maybe enroll 10% or 15% of them. It was a vast list of exclusion criteria. That study doesn't reflect real-world outcomes*. It used the best of the best of the best patients."* ***– KOL and high volume implanter***

- A KOL stated that the **ethics of the study design and exclusion criteria were "questionable"** and thar the study "**lacks robustness."**

  "Nevro's trying to put a sexy spin on a therapy that we've already been using forever. ***The ethics of their study design is questionable, like their exclusion criteria.*** *They're going to have a lot of explants. They don't have the waveform capabilities that other companies have.* ***The diabetic peripheral neuropathy study is just as bad as their original Senza study. It lacks robustness. It's not a level-one study."*** ***- KOL***

Source: Consultation calls with experts

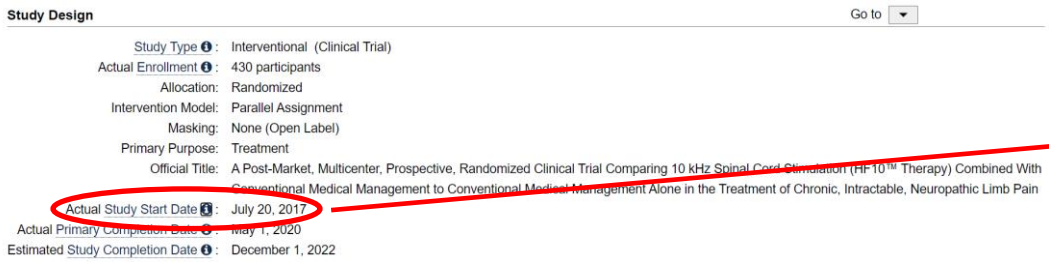
Scorpion Capital | Nevro (NYSE: NVRO)

11. TAM expansion and growth from painful diabetic neuropathy (PDN) and other new indications are a mirage

KOL's indicated that it took Nevro years to complete enrollment for the PDN study, which should have been instantaneous given the vast number of diabetics in the US. Indeed, Nevro's own PDN addressable market slide indicates 2-5MM target patients. KOL's attributed the delays to Nevro's alleged attempts to cherry-pick unrealistic patients, and stated that the company was guilty of the "cardinal sin" of study design, for which it has been "called out" by doctors "a bunch of times" in its studies.

"Nevro's diabetic foot study should have taken them four months to fully recruit*. Diabetes is one of the leading causes of everything in the United States. Every time you look out your window you'll see someone over 50 with diabetes.* ***Yet it took them years to recruit that study. They used rigid inclusion/exclusion criteria and basically have a medical monitor to pluck patients out*** *saying, "Well, that's not outside the study but I just don't have a good feeling about [this patient]" Doctors have called out Nevro a bunch of times for cherry-picking patients in studies."* ***– KOL and high volume implanter***

"The biggest problem with their study was the exclusion criteria. They committed the cardinal sin, which is to cherry-pick. *If you look at the Boston Scientific LUMINA study, they took every garbage patient that walked into the clinic. It was sequential enrollment. So, if a patient had all kinds of secondary problems or they had Medicare disability or really high pain scores or other diagnoses like severe stenosis, everything that would confound a perfect study, the study said this is the real world.* ***If you look at the exclusion criteria of not only the Senza study but Nevro's new study for diabetic peripheral neuropathy, they cherry-picked. There's something like 24 points that would exclude diabetics from participating."*** ***– KOL and high volume implanter***



SENZA-PDN study began enrollment in July 2017 per ClinicalTrials.gov, but didn't complete enrollment until Aug 2019 per Nevro press release on 8/28/19.

Source: https://clinicaltrials.gov/ct2/show/NCT03228420; https://www.nevro.com/English/us/investors/investor-news/investor-news-details/2019/Nevro-Announces-Completion-of-Patient-Enrollment-in-Largest-Multicenter-Randomized-Controlled-Trial-of-High-Frequency-Spinal-Cord-Stimulation-for-Painful-Diabetic-Neuropathy/default.aspx

Scorpion Capital | Nevro (NYSE: NVRO)

11. TAM expansion and growth from painful diabetic neuropathy (PDN) and other new indications are a mirage

The SENZA-PDN study's exclusion criteria are sweeping and aggressive, illustrating the cherry-picking and absurdity KOL's pointed out. The criteria bend over backward to exclude bread-and-butter diabetics, such as those with pain anywhere but the lower limbs, severe obesity, recipients of Social Security disability, anyone with a worker's comp claim, and various restrictions on opioid use or ulcers.

SENZA-PDN exclusion criteria per ClinicalTrials.gov

Exclusion Criteria:

1. Have a diagnosis of a lower limb mononeuropathy, have had a lower limb amputation, or have large (≥3 cm) and/or gangrenous ulcers of the lower limbs.
2. Have a BMI ≥ 40.
3. Currently prescribed a daily opioid dosage > 120 mg morphine equivalents.
4. Have a medical condition or pain in other area(s), not intended to be treated in this study.
5. Have a current diagnosis of a progressive neurological disease such a multiple sclerosis, chronic inflammatory demyelinating polyneuropathy, rapidly progressive arachnoiditis, brain or spinal cord tumor, central deafferentation syndrome, Complex Regional Pain Syndrome, acute herniating disc, severe spinal stenosis and brachial plexus injury.
6. Have a current diagnosis or condition such as a coagulation disorder, bleeding diathesis, platelet dysfunction, low platelet count, severely diminished functional capacity due to underlying cardiac/pulmonary disease, symptomatic uncontrolled hypertension, progressive peripheral vascular disease or uncontrolled diabetes mellitus that presents excess risk for performing the procedure.
7. Have failed prior SCS, dorsal root ganglion (DRG) stimulation, or peripheral nerve stimulation (PNS) trials for chronic intractable pain.
8. Have significant spinal stenosis, objective evidence of epidural scarring and/or any signs or symptoms of myelopathy.
9. Any previous history of surgery on the posterior elements (laminectomy, posterior fusion) resulting in a compromised epidural space.
10. Be benefitting from an interventional procedure and/or surgery to treat lower limb pain.
11. Have an existing drug pump and/or another active implantable device such as a pacemaker.
12. Have a condition currently requiring or likely to require the use of diathermy or MRI that is inconsistent with Senza system guidelines in the Physician's Manual.
13. Have either a metastatic malignant neoplasm or untreated local malignant neoplasm.
14. Have a life expectancy of less than one year.
15. Have a local infection at the anticipated surgical entry site or an active systemic infection.
16. Be pregnant or plan to become pregnant during the study. Women of childbearing potential who are sexually active must use a reliable form of birth control, be surgically sterile, or be at least 2 years post-menopausal.
17. Have within 6 months of enrollment a significant untreated addiction to dependency producing medications, alcohol or illicit drugs.
18. Be concomitantly participating in another clinical study.
19. Be involved in an injury claim under current litigation.
20. Be a recipient of Social Security Disability Insurance (SSDI).
21. Have a pending or approved worker's compensation claim.
22. Have evidence of an active disruptive psychological or psychiatric disorder or other known condition significant enough to impact perception of pain, compliance with intervention and/or ability to evaluate treatment outcome.

Source: https://clinicaltrials.gov/ct2/show/NCT03228420

11. TAM expansion and growth from painful diabetic neuropathy (PDN) and other new indications are a mirage

KOL's – as well as Nevro's former executives – expressed disdain at other flaws in the PDN study beyond cherry-picked patients. One KOL called it "the dumbest study design" and "greaseball," lamenting why Nevro doesn't "just come out with a normal study?" The concerns include the use of CMM ("Conservative Medical Management") as a low-bar comparator arm that ensures "a layup" study; interaction bias and patient manipulation during the trial; and placebo effect from lack of blinding.

- A former executive as well a KOL **strongly criticized the use of CMM as a comparator arm**

  "One thing that concerns me is the huge amount of Nevro's valuation associated with PDN. It seem like half the valuation is linked to their PDN study. ***That study shows amazing results, but if you look at their control it's always CMM [conservative medical management] so these studies are always a layup."*** *–* ***Former Nevro executive***

  "And then the study also doesn't compare a Lamborghini to a Ferrari. ***They compared a stimulator to not another stimulator, but against just medication management. It is the dumbest study design. It's greaseball.*** *And as doctors we just shake our heads and say, "Why doesn't Nevro just come out with a normal study?"* ***– KOL and speaker***

- The former executive described **patient manipulation and "interaction bias" as typical Nevro conduct** curing trials

  "What assisted Nevro with the Kapural study was interaction bias*. It's all about how the study was designed and how the study team interacted with patients in the Boston Scientific arm versus the Nevro arm. The Boston patients' stimulators were programmed the same as always. But the Nevro arm had a team come in. The patient knows it's a new stimulator. The study team is excited to see you. You have 5 to 6 people at your programming session. They were methodical with patients in between sessions as well. Patients were managed differently.* ***Nevro's PDN study would have managed patients exactly the same way, I'm sure. They compared Nevro to CMM [conservative medical management], and CMM is a very low bar."*** ***– Former Nevro executive***

Source: Consultation calls with experts

11. TAM expansion and growth from painful diabetic neuropathy (PDN) and other new indications are a mirage

KOL's stated that although spinal cord stimulation has long been used for PDN, it doesn't work well given difficulties in reaching the extremities and is in fact "notoriously very bad for the foot," , reinforcing doctors' concern that PDN patients are already vulnerable with other comorbidities. Doctors explained why Nevro's high frequency mechanism will backfire if used for the foot. We note that doctors more amenable to using stimulators for PDN – including Nevro loyalists - were vocal in stating that Abbott's DRG is the best waveform for PDN versus high frequency: "without question"; "it's not even a question"; "100 times better than any other neuromodulation system."

"Doctors have been using spinal cord stimulation for PDN for a while, but notoriously it's very bad for the foot*. It doesn't get to the foot.* ***You can't get spinal stimulation into the foot without having to stimulate everything along the way,*** *Stimulation doesn't change the plumbing. Diabetic neuropathy causes pain because there's shitty blood flow which affects the nerves, which get rewired and interpret it as pain.* ***What's going to happen with Nevro is*** *what happens with every other spinal cord stimulator for the foot. You can't get to the foot, so* ***you have to jack up the current, and then you get tolerance and [any pain relief] goes away."*** ***– KOL and high volume implanter***

"For diabetic neuropathy, 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.* ***– KOL and former high volume Nevro implanter***

"The other thing is that a lot of patients with diabetic neuropathy have pain in their feet, the actual feet themselves, and ***I personally don't believe Nevro is the best for the feet as the Abbott DRG is better."*** ***– KOL and high volume implanter, who still uses Nevro moderately***

Source: Consultation calls with experts

11. TAM expansion and growth from painful diabetic neuropathy (PDN) and other new indications are a mirage

On p.148-151 we detailed a fatal flaw that renders Nevro's new Omnia device essentially unusable for low frequency stimulation: leads for high frequency and low frequency are surgically implanted at different vertebrae, making the notion of toggling between low and high frequency so absurd that we consider the claim to be fraudulent. This issue is even more problematic for PDN: high frequency leads are placed at the T9/10 vertebrae, which is NOT the correct spot on the spine for PDN. For Nevro to say its doing both high frequency and PDN is so contradictory that one KOL bluntly stated: "I think they're lying." We note a second closely related discrepancy: pushing stimulation into the foot is notoriously difficult, making paresthesia-based mapping via trial and error essential in finding the correct lead insertion points along the spine. However, Nevro's entire differentiation is that high frequency eliminates paresthesia – which eliminates the tingling/feedback a patient and doctor need to map stimulation to the foot. These two issues – lead placement and inability to do paresthesia-based targeting into the foot – render Nevro's device a non-starter for PDN.

"So 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 diabetic peripheral neuropathy, you can't be in the T9/T10 spot. You're going to have to be somewhere else, which means now you can't do the high frequency." *- KOL*

"In some PDN patients, the leads need to be at T11, T12, L1. If that doesn't work, you can go up to T9, T10, T11*. And it's not just where the leads are - it's also laterality. Do they have to be at the midline? With certain devices, it has to be at midline because it hurts too much to go out to the left and the right. With Boston Scientific and the other one, you can push the stimulation out, off of the lead. You can stimulate off the lead virtually using current. It's amazing. The leads can talk to each other.* ***With Nevro, you can't do that****. There are 32 contacts, say with a Boston Scientific lead.* ***With Nevro, they only activate two of them."*** *- KOL*

Source: Consultation calls with experts

11. TAM expansion and growth from painful diabetic neuropathy (PDN) and other new indications are a mirage

In addition to stimulators already being used today for PDN, skepticism of Nevro's study, a small market of high-risk patients, and high frequency lead placement being incompatible with PDN, the opportunity is commercially dead-on-arrival due to referral patterns with PDN patients. Nevro's former executives and KOL's emphatically repeated that the primary care doctors and endocrinologists who manage PDN patients are gatekeepers who simply will not refer them to doctors who implant stimulators.

- A KOL and moderate Nevro implanter described the **importance of referral patterns and why PDN won't "move the needle"**

  "I have trouble getting PDN patients away from vascular surgeons. They hold on to these patients*. Those are the ones that would have benefit.* ***The PDN opportunity is not going to move the needle. The thing to realize is that referral patterns are really important****. Vascular surgeons hold on to these patients. That's the realty. You don't get the diabetologist referring patient to the pain doctor."* ***- KOL***

- A former Nevro sales executive states that **the company "has no plan or understanding" about accessing the PDN market**, and that **endocrinologists will not hand off these patients**

  "The issue is accessing the PDN market. ***Nevro has no plan or understanding of how to access that market. I spent 12 years in the market****. I don't know many endocrinologists that will hand off diabetic patients to pain docs."* ***– Former sales executive***

- A KOL who tries to implant stimulators for PDN today says **their doctors view them as inappropriate candidates and refuse to refer**

  "Even if they get FDA approval, ***the issue is getting referrals. Their doctors do not view PDN patients as ones that you should install a stimulator in."*** ***- KOL***

Source: Consultation calls with experts

11. TAM expansion and growth from painful diabetic neuropathy (PDN) and other new indications are a mirage

One of Nevro's highest volume implanters – a consultant and speaker for the company – threw cold water on the PDN opportunity. He questioned Nevro's TAM claims and explained how referral patterns make it unrealistic to get PDN patients. He described his personal attempts to market stimulators for PDN and why they failed: the only place to find these patients is in Medicare/Medicaid clinics with a low-income population, where PDN patients have extensive comorbidities like infections, amputation risk, and other issues that preclude them as viable stimulator candidates. A former Nevro executive added that primary care doctors have "a huge amount of skepticism" about stimulators and that "a genuine financial disincentive" prevents them from referring their PDN patients.

"Nevro throws around this number of 2 million diabetics a year, but not all of those are painful diabetics seeking out treatment *beyond other therapies. Gabapentin and Lyrica are failures. They don't really do much.* ***The problem is the referral patterns aren't quite there yet****. One, it takes the insurance coding and approval and two, finding these patients, because these patients do not exist in typical pain practices, the ones that treat back and leg pain all day. These practices don't necessarily see PDN.* ***I decided that I was going to start marketing SCS for PDN treatment and ultimately endocrinologists don't have PDN patients, neurologists don't have them. The sick population Medicare, Medicaid practices have them. So you go into Harlem, you go into the Bronx*** *or any hospital that has a sort of Medicaid clinic, they have them. But then the challenge is, they have cardiac disease that keeps them on blood thinners or they have recurrent infections or they are likely to amputate and* ***so it just becomes challenging as to what are we going to do with those patients."*** ***– KOL and one of Nevro's highest volume implanters***

*"****The issue that everyone going into PDN has are the primary care physicians responsible for the patient group.*** *They are not interventional pain physicians. It's convincing that primary care doctor to refer that patient off to another physician to manage that condition.* ***There's a huge amount of skepticism from the actual physicians managing these PDN patients. There is a genuine financial disincentive for them to send a patient*** *to another person to manage something that they feel they can manage themselves."* ***– Former Nevro executive***

Source: Consultation calls with experts

11. TAM expansion and growth from painful diabetic neuropathy (PDN) and other new indications are a mirage

The Nevro consultant/speaker and KOL who failed in his attempts to broaden his practice to PDN patients mentioned two other barriers to commercialization. First, PDN patients do not want implants, and because they're not recurring monthly patients like those on opioids, pain practices don't have the opportunity to "constantly bombard" them with a stimulator sell (we detail patients being pressured into stimulators in a later section). Second, he reinforced the point made by other doctors that Medicare already covers stimulations for PDN today, and that PDN is therefore not a new market for Nevro. Because the PDN population is almost all Medicare/Medicaid, the patients are not an attractive commercial pay opportunity: they're typically unable to work and therefore lack employer healthcare, which is essentially the definition of commercial insurance. He added that Nevro may not even get label exclusivity from commercial insurers if approved for PDN, as Medicare covers any stimulator for it today. meaning that any commercial payors would cover all stimulators not just Nevro's.

"The other aspect is ***how much do these PDN patients really want to have an implant?*** *The back and leg pain patients are constantly getting bombarded with the idea of simulation. Here it's like a one-time consult, maybe a referral from a from a primary care doc and then* ***the patient says "Well that's not really what I expected to hear" and they walk out.*** *The back and leg patient keeps coming back to you and you can keep talking about stim as an option."*

"For PDN it will have to be determined how they do in terms of negotiating with the payers. ***Are they going to get a label exclusivity on it? Because yes, you can code it today as neuropathic pain of the leg****. The commercial payers are not interested in engaging with diabetic neuropathy right now. The trouble is that the diabetic population that has significant enough pain tends to be the Medicare, Medicaid population.* ***You can use any device for Medicare. With the bulk of the population being Medicare, doctors can use the device for PDN today. And commercial-insured patients don't mean much****, because commercial insurance usually means an employed person that generally is not the one that's usually a severe diabetic."* ***– KOL and one of Nevro's highest volume implanters***

Source: Consultation calls with experts

11. TAM expansion and growth from painful diabetic neuropathy (PDN) and other new indications are a mirage

The Nevro consultant'/speaker's point on PDN label exclusivity – that even if Nevro were to get "approval" for PDN, Medicare and others would apply it to all other stimulators – was reinforced by another KOL who remains a moderate Nevro user. He stated that "PDN wouldn't be a Nevro-driven market" and that it wouldn't alter Nevro's sales much, adding that insurers simply do not monitor or care which stimulator doctors use for which indication. He stated that insurers only care "once in a 100" times.

"PDN wouldn't be a Nevro-driven market*. If the numbers increase,* ***you will probably see a distribution relatively equally over all the manufacturers*** *and perhaps down the road, perhaps a little bit more for Abbott. It's not necessarily a uniquely Nevro type of thing.* ***I don't think all of a sudden it's going to dramatically change Nevro's numbers****. The way the game works is that* ***if company A gets FDA approval for indication X, the insurance companies do not really ask which device you're using, so you can technically use another device for an indication approved by Nevro. Very rarely will an insurer ask*** *which device you're using. I've only seen that once in a 100."* ***- KOL and high volume implanter, moderate Nevro user***

Source: Consultation calls with experts

11. TAM expansion and growth from painful diabetic neuropathy (PDN) and other new indications are a mirage

In addition to PDN, Nevro has begun to dangle a second indication expansion as part of its turnaround plan: non-surgical refractory back pain (NSRBP), for which it will present 3 month data in January. Stimulators are generally only reimbursable after a patient has already exhausted other options like back surgery. In plain English, NSRBP – also called "virgin back" or "first line back" - means implanting a $25,000 stimulator right away – without prior authorization - when a patient walks in with back pain. The notion that insurers would allow such an aggressive first line treatment is preposterous. We commend the Street for their morsel of accuracy in at least indirectly trashing the opportunity, e.g., a 10/22/20 report by Guggenheim – otherwise frothing with a $190 TP – which stated that 30% of Nevro's sales are already for NSRBP (after prior auth); that the indication is already on-label; and that reimbursement is the obstacle. Not surprisingly, one KOL after another – including Nevro loyalists – ripped the NSRBP "indication expansion" as a delusion and outside the standard of care.

*"**Spinal cord stimulation as a first-line treatment is, no…it's absolutely not a realistic opportunity.. The insurance companies will never cover that.** If Nevro's saying they'll make stimulators the first line of treatment when a back pain patient comes in, I have never heard of that."* ***– KOL and high volume implanter***

"As far as stimulators being used for first-line back, this is question that's been asked for 15-25 years**. Whenever a company comes out and says, we are using it for back pain, it causes problems. Back pain is a huge diagnosis category. The industry has gotten in trouble by claiming it works better for back pain than another device. Upfront back pain is so multi-factorial. **I don't see that market being appropriate for spinal cord stimulation**. There are a lot of psychological issues as well, so **I don't see non-surgical back as a big market for them or any company." ***– KOL and Nevro user***

*"Insurers are making it even harder. **Getting approval for stimulators is the hardest it has been**. In some local code determinations, they're making doctors send the patient to a neurosurgeon who writes a letter stating the patient is not a candidate. In an age like this, **stimulators for first-line back….there's no way that's going to happen. You can't go right to a $50,000 treatment. I mean, that's way outside of the standard care."*** ***– KOL and high volume implanter***

Source: Consultation calls with experts

12. Investors betting on a Keith Grossman-driven turnaround will shortly face a rude awakening

Nevro's stock was at $45 and jumped 35% the day Keith Grossman was announced as CEO. A herd of sell-side analysts tripped over each other to upgrade and double-upgrade the stock in hours. Given the stock is 4X higher since his hiring while sales are still stuck at the same level as 2018, Nevro is little more than a bet on Keith Grossman's God-like turnaround and quick-flip powers. Given his Midas touch, we were surprised that former Nevro executives implied the emperor has no clothes and that his purported turnaround is nowhere to be seen. We begin with extensive comments from one such ex-executive.

- The former executive believes that **Grossman doesn't understand the SCS market**; that the lack of growth under his tenure is **underwhelming** and "crazy" given the massive salesforce expansion; and that Grossman has a **superficial playbook focused on cutting costs** – which is easily apparent to anyone who looks at the trajectory of his last two "turnarounds."

  "Grossman has a history of working with Bess Weatherman of Warburg Pincus who's on the board, and I think they look for companies that are really ground down. ***They move some people in, move some people out, but at the end of the day, they really control cost. They don't really add true value and that's kind of how I see Grossman****. I don't see Grossman adding value to spinal cord stimulation.* ***I don't think he really understands the market****. He'll reformat all those guarantees that the reps have. From a revenue point of view, the company should be a lot bigger than it is, but* ***I'm very underwhelmed because when I look at sales capacity, there's 150 more field team now, for about the same amount of revenue. It's crazy****."* ***– Former Nevro executive***

- He believes that there's "**no long term plan there"** and that Grossman **was looking for a quick flip**

  "The other side of Grossman is that when that stock hit $90, you saw 3X acceleration according to the public record to his stock, so ***he's all about flipping the company and making as much money as possible in the shortest amount of time. I don't think there's a long-term plan there."*** ***– Former Nevro executive***

Source: Consultation calls with experts

12. Investors betting on a Keith Grossman-driven turnaround will shortly face a rude awakening

The former executive described a dire situation at Nevro with an impending exodus of talent.

- The ex-executive stated **Nevro will now "die of a thousand cuts" and provided a damning assessment**: no growth from Omnia; losing doctors; no market share gains; and being forced to pay doctors to use the product.

  "Nevro has boxed themselves into a corner and ***now they'll die of a thousand cuts****. because unless they start seeing some increased sales, which they're not going to at the price point that they're at, because the high-volume doctors are not going to overpay for Omnia. Maybe the diehard Nevro guys hold on, but how many of those diehard guys are also consultants for the company?* ***How many new customers are they getting? Who are they converting from Boston, from Medtronic, from Abbott? Where are those customers? And you don't see it."*** ***– Former Nevro executive***

- He stated that there will be **an exodus of sales reps at the end of this year – "a bloodletting"** - when options expire, and that **reps are ready to flee to new competitors such as Saluda**

  "The only reason why Grossman stabilized the salesforce was because the stock price went up and those reps had options*. Those options were in general in the high 60's…that's $200,000-$300,000 to those reps, so they're going to stay.* ***Interesting enough, most all those options are going to expire at the end of this year and its going to be a bloodletting. All those reps are going to leave****, because they want to get out of their non-competes and then in a year they go back into the Saluda's, the Nalu's and everything else. It's kind of a rinse and wash type philosophy. If the price of the stock goes down, you'll see a major amount of reps leave the company, and they'll go elsewhere."* ***– Former Nevro executive***

Source: Consultation calls with experts

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12. Investors betting on a Keith Grossman-driven turnaround will shortly face a rude awakening

He concluded by implying that Grossman is more engaged in optics than substance, backed "in a corner," and that his key initiatives like Omnia are failures.

- He described **Grossman as engaged in "window dressing"** and **Omnia as a flop**

  "I think there's ***a lot of window-dressing with Grossman and that's why you're not seeing this big uptake in revenue.*** *If Omnia is so good and you've got a hundred more reps out on the field and you're doing all this great selling and all these customers are happy, why is it not going up? They've eroded their price. Nobody's going to buy Omnia, unless you're getting paid a couple thousand bucks to be put in a study to use it ."* ***– Former Nevro executive***

- The **purported momentum the CEO hypes on earnings calls is a mirage:** massive market share losses, impending defections, and other **signs of a sinking ship with the CEO backed "in a corner."**

  "When I listen to earnings calls, it's "the business has stabilized, we're excited about all these new platforms and new disease states, we're going to do more of this" but ***at the end of the day, I just don't see it. I really don't see it. You've seen massive losses in Australia*** *where that business used to be number one and now they're number three or four.* ***In Europe, high percentages of business are just going away*** *because they don't have the core competency in leadership. Here in the US, they're going to have to start making changes in leadership and when that happens and stock options expire, then* ***Keith is back in a corner****.* ***They're going to lose a lot of their high-quality reps that have been on guarantees****. For their management team, the stock options have already hit.* ***They're going to sell those and get out of there*** *and then you're back to pretty average people with pretty average performance."* ***– Former Nevro executive***

Source: Consultation calls with experts

12. Investors betting on a Keith Grossman-driven turnaround will shortly face a rude awakening

A second former executive, in touch with the management team and now in a senior role at a key competitor, provided a similarly damning view of Grossman's turnaround, describing his understanding of the SCS space as "naïve." He shared his sense from members of the management team that Grossman is "busy on a lot of others things" and questioned who's running Nevro day to day, given that he failed to deliver a quick flip and now finds himself in a role he didn't expect. We note that one executive after another we spoke with described Grossman as a quick-flip artist who now finds himself in an uncomfortable position. The former executive also described an ongoing collapse of Nevro's international business.

"Keith is definitely a more polished individual but ***his understanding of the technology that he's speaking to, and the way that's going to be received by physicians, is naïve****. Grossman describes Omnia as really just the marketing, like the same marketing spin that was being presented at NANS.* ***I don't think he understands the way that these physicians work*** *and their desire to have new and innovative products. Omnia is not a new or innovative product. It's basically just a repackaging of an old product."* ***– Former Nevro executive***

"I also got a sense this wasn't a role that he was expecting and that he's very busy on a lot of other things he's doing. *A lot of other things, and I don't know how much attention - I mean obviously he's spending a lot of time on Nevro - but* ***I think there are other people who are running the ship*** *largely and that's sort of the sense I got from these people on the leadership team"* **– Former Nevro executive**

*"****Three key people, including the person responsible for all of global, have been taken out of the organization*** *and about four weeks later two key people in the European area left the organization. So now there's a fairly junior leadership team within the European organization."* ***– Former Nevro executive***

Source: Consultation calls with experts

12. Investors betting on a Keith Grossman-driven turnaround will shortly face a rude awakening

A third former executive was equally skeptical and described Nevro's predicament as structural and not operational, doubted the possibility of any turnaround, and stated the business model is unfixable: "I would not invest in Nevro today."

- The company's **market share remains stagnant at 15-17% and won't grow** given competitor's structural advantages and scale

> *"If they're tracking at 15-17% share right now, I think the question is,* ***is there anything else that can significantly move the needle? And I don't know that there is with the landscape of the SCS market*** *being what it is. The other big companies, especially Boston and Abbott, have spent enormous time and resources on very strong KOL and relationship development and have very, very strong marketing and sales organizations and* ***that's going to be hard to crack."*** ***– Former Nevro executive***

- The executive is **skeptical of Nevro's value and wouldn't invest**, and explained why the **business model will never be profitable**

> ***"I would not invest in Nevro today. The outlook is so unclear. I don't know that I see the long-term value****. It's just a question of* ***what's the long term business model*** *for a company in the SCS space - the heavy ongoing cost associated with support and retention of physicians and patients. You've got sales being made by experienced, very high-cost sales representatives, so that's going to be your upfront cost and then, in order to retain physician business, their expectation is for continued support of their implanted patient, so you can't ever disentangle yourself from the burden and that base only increases over time. A big reason the company is unprofitable is the cost of sales. You've got a high touch business where they're having to follow up all the time and put in face time with their physicians and you've got the patients needing ongoing support and optimization.* ***Once you factor all of that in, the profit margin is very slim."*** ***– Former Nevro executive***

Source: Consultation calls with experts

12. Investors betting on a Keith Grossman-driven turnaround will shortly face a rude awakening

A longtime C-level executive in the spinal cord stimulation space offered extensive insights into Nevro's plight. Much like Nevro's ex-executives, he described Grossman's "turnaround" as an ongoing failure and current staff as skeptical of "the substance" and confused by the stock.

- Nevro's **market share is not changing** and company's **future is questionable**

  "I question what their future looks like *because if they don't have a strategic initiative that is going to gain them market share, it's going to be just hand-to-hand combat in the spinal cord stimulation space.* ***I don't see the market share shifting a lot."*** ***– Longtime SCS executive***

- **Grossman doesn't understand the SCS market** and his previous Thoratec experience is irrelevant

  "I study a leader's history, and I want to know what adversity they've dealt with. Did they pull a company out of the hole against all odds? Grossman's product sold itself at Thoratec. ***I don't think he has an appreciation for what motivates the spinal cord stimulator customer****. When I say customer, I mean the physician, the patient, the nurse, the payer, and the administrator. There are five different customers in this space, and you have to have products and services for all five, and if you don't, you are going to not be differentiated."* ***– Longtime SCS executive***

- **Grossman may be skeptical of the sharp rise in Nevro's stock**, with the >2x overvaluation making it difficult to sell the company

  "I know for a fact, on the inside, Grossman has said he's scratching his head over why the stock has done what it's done*. Grossman may have bitten off more than he can chew because at a much lower stock price, let's say at $70, he'd have an easier time selling this thing."* ***– Longtime SCS executive***

Source: Consultation calls with experts

12. Investors betting on a Keith Grossman-driven turnaround will shortly face a rude awakening

He added that Nevro's staff are equally mystified by the stock and underwhelmed at the supposed turnaround, and that Grossman's various excuses – the former CEO, COVID, a declining market – will soon run out and expose his lack of performance.

- Grossman's #2 is equally ignorant of the market, and **Nevro staff don't see the substance of any turnaround and are confused by the stock's rise as he is**

> ***"A bunch of the guys that are [titles redacted] at Nevro used to work for me****. I hired them into the neuromodulation space. Grossman's chief commercial officer doesn't know this space. I don't know that she understands the war that she's in for […]* ***Internally at Nevro, I don't think they see the substance, based on what I've been told, and they're scratching their heads and saying, "Hey, whatever. I'll take it. I hope the stock keeps going." There aren't fundamentals behind*** **it."** ***– Longtime SCS executive***

- The executive stated that Grossman **lucked out in having COVID as cover for his lack of progress**, but that Nevro's problems remain massive and that **his excuses will soon run out**

> *"On his first two quarterly calls he basically said, 'I'm too new to give you numbers. I'm not going to commit to anything.'* ***I've said all along; eventually, this guy is going to have to perform. His timing [in getting a pass from COVID] is pretty damn good because I know the people on the street at Nevro who are selling product, and I know the roadblocks they're up against****. They haven't out-performed from a revenue standpoint. They've been given a 24-month pass. Rami was the scapegoat, and then it was, "Okay, let's give Grossman a year to get his feet under him," and now it's COVID. So, when does Nevro actually have to perform in Wall Street's eyes? They were the first company to say that that SCS market was shrinking and that just wasn't true.* ***It's that they were losing market share, and they didn't know how to explain it away."*** ***– Longtime SCS executive***

Source: Consultation calls with experts

12. Investors betting on a Keith Grossman-driven turnaround will shortly face a rude awakening

The longtime SCS executive stated his belief that Grossman "doesn't have a strategy" beyond initially wanting to "flip it in six months," did little diligence before taking the CEO role, and is in now in over his head. He stated this is "why I don't own a penny of Nevro." We view his opinion as credible given his relationships with Nevro's staff.

"Grossman doesn't have a strategy. This is what concerns me. This is why I don't own a penny of Nevro. Keith Grossman may have wanted to flip it in six months. *If you do not know the neuromodulation space and you're listening to the Board tell you that Rami [prior CEO] screwed this up. You think, I've talked to Kasra Amirdelfan [implanter who is the #1 recipient of Nevro payments*] and David Caraway, their Chief Medical Officer, these guys are high on it. I can come in here and look like a rock star and just not be an [redacted] like Rami, and I can flip this thing in no time because I know the investment community because of my history.* ***I would bet that that's about the due diligence that Keith Grossman did, and he was sold hook, line, and sinker. Now he's going to have to roll up his sleeves and say, 'What do I do with this thing?'"*** ***–Longtime C-level executive in the space***

Source: Consultation calls with experts

13. Investor hopes of a Nevro acquisition are delusional and misinformed

A substantial part of Nevro's stock rise has been fueled by investor hopes of a take-out, with the sell-side sainting Grossman as a quick-flip magician. We asked longtime executives in the space for their opinions of potential acquirers, and contrast investor fantasy with realism from a former Nevro executive who bluntly dismissed the company's appeal to potential buyers. We note his dismissive opinion of Stryker, speculated upon as the most logical savior, even at a $2B valuation (~$58/share or 1/3 the current stock price). He stated that Nevro's value as a "one-trick pony" is now diminished because it's a "commodity business" in a "price war"; that any acquirers would rather buy new, smaller stimulator entrants; that J&J was a major investor in Nevro yet never bought them; and that large acquirers with an interest in the stimulator space, such as Medtronic and Abbott, are instead paying "absolute pennies on the dollar" for emerging, inexpensive stimulator companies. He added that Nevro is now boxed "into a corner" and will "die of a thousand cuts."

***"Stryker is fantastic at buying really inexpensive crummy companies, so for them to think about buying a $2, $3, or $4 billion dollar company like Nevro, I don't see it. I just don't. I don't think it's in the culture**. I don't think it's who they are. When Nevro stock was down in the $30's and low $40's, that would have been a great m&a target but now it's an incredibly expensive platform. **If another technology comes up and beats them, it's really not worth much**. All the other stim companies are scaling bigger and they have more options for doctors. **Nevro is still pretty much a one-trick pony.** They're going to have to cut costs to shore up the bleeding, so they're not going to pay reps $350,000. They're going to pay $185,000 and you'll see low-quality reps."*

"If this is going to be a price war, it's going to be a commodity business. Medtronic just did an acquisition of Stimgenics for pennies. Absolute pennies on the dollar.** Medtronic can buy anything they want, yet **they chose to buy one of the low-cost new stimulator companies out there**, because the clinical data looks good. **Abbott bought DRG for pennies on the dollar** and they've never made money off of it. So when you look at the dollars that it would take to acquire Nevro, who would do it? J&J was one of the original investors in Nevro and they never bought it. So I don't see a Stryker acquisition for sure. **And you've got a bunch of other companies that are trying to figure out how to get in the space, so I personally don't see it. Nevro has boxed themselves into a corner and now they'll die of a thousand cuts**."* ***– Former Nevro executive

Source: Consultation calls with experts

13. Investor hopes of a Nevro acquisition are delusional and misinformed

The former executive provided a particularly damning data point that illustrates the depth of investor misunderstanding of Nevro's m&a potential. Nevro disrupted the stimulator space when it launched in 2015 and took 15% of the market. The next disruptor – the "next Nevro" – is a private company called Saluda, backed by Medtronic and Boston Scientific, with a new closed-loop stimulator technology that we discuss in chapter 14. With the best clinical data ever published in spinal cord stimulation, industry executives, former Nevro executives, and competitors we interviewed expect Saluda to rapidly take market share – another impending yet little-discussed catastrophe for Nevro. Saluda has been publicly discussed as the most logical takeout target in the stim space, and the ex-Nevro executive opined that it has found no buyers despite being shopped for 18 months, given price erosion and value destruction in the stimulator market. He speculated that Saluda would have taken a ~$200MM acquisition – a reality check given Nevro's current $__B market cap – and added that there "too many emerging spinal cord stimulation technologies out there."

"When you look at M&A, you have too many emerging spinal cord stimulation technologies out there. You've got Nalu that's coming out. That came out of Stanford. ***You've got companies like Saluda. They've been trying to shop that thing for the last 18 months and they have no buyers and the reason is, how are you going to come in and compete when price erosion is happening all around you?"*** ***– Former Nevro executive***

"If Saluda could have sold for a couple hundred million bucks, they would have sold it. *John Parker has said publicly that he wants a billion dollars for the company.* ***Nobody's going to spend a billion dollars for that company. Nobody. Nobody. Like $800 million is nuts****. Had he positioned it at $500 to $700 million, it probably would have been sold, but John Parker is out of his mind."* ***– Former Nevro executive***

Source: Consultation calls with experts

13. Investor hopes of a Nevro acquisition are delusional and misinformed

A longtime C-level executive in the spinal cord stimulator space provided an equally devastating assessment of Nevro's m&a prospects. He echoed that Nevro is a one-trick company that companies like Stryker or J&J would have no interest in, and corroborated that the space "is becoming increasingly competitive" with a "line of" new entrants "behind Saluda" that are also looking to get bought. He added that Biotronik, a leading European medical device company – privately held with an estimated 9,000 employees – is also shortly entering the stimulator space but is building in-house versus acquiring.

"At these multiples, I can't see anybody digesting a business that isn't diversified*. With St. Jude, I understood the Abbott acquisition because all of your eggs aren't in one basket, and they were a proven entity.* ***But with Nevro, I don't know that a Stryker or a J&J is going to want to bite off that much. I can't see Stryker making an acquisition in the SCS space. I really can't see it.*** *If Boston Scientific wanted to spin off their neuromodulation business, I think their product portfolio is better than Nevro's.* ***But I can't see it."*** ***– Longtime C-level executive in the spinal cord stimulation space***

"The market is becoming increasingly competitive. There are a line of people behind Saluda*. Nalu Medical is probably next.* ***All of these companies just want to get bought*** *and I just don't know that it's going to happen with Nevro."* ***– Longtime C-level executive in the spinal cord stimulation space***

"Biotronik has a keen interest in the SCS space, but I don't think they're going to buy into it*. I think they're going to develop their own product. They've hired a chief technology officer to make sure that their product is shored up before they hire a commercialization expert.* ***Biotronik is going to be, in my opinion, a competitor in that space in the next 24 months."*** ***– Longtime C-level executive in the spinal cord stimulation space***

Source: Consultation calls with experts

13. Investor hopes of a Nevro acquisition are delusional and misinformed

Not surprisingly, whenever we asked former Nevro executives and even KOL's who still use the company's device whether they would invest in the company, they said no. One KOL called it "like a pump in the dump [sic]." Another high volume implanter said he was thinking of shorting it. Others wondered whether the company could survive the "wave of new stimulator" entrants, stated the market is "over-saturated"

"I wouldn't invest in Nevro. I did at IPO. I was thinking of shorting Nevro. Their competitive advantage got eaten away as everyone caught up. *You can never discount what Medtronic comes up with. They were forgotten about yet they were the first stimulator company. They're the biggest device company in the world. Their pipeline across the board will have hits. There's a reason they're so well entrenched. Medtronic and Abbot can contract out stimulators with a broader product portfolio. They can bundle.* ***They can crush Nevro at a systems level if they want to. The big buys can crush them in hospitals."*** ***– KOL and high volume implanter***

"I don't see a whole lot of innovation. ***They're stuck with one product which makes them very vulnerable*** *unlike other companies. I'm a bit wary.* ***I'm not sure they can survive the wave of new stimulator companies****. A number are coming into the field.* ***Spinal cord stimulation seems over-saturated. And a lot of doctors are not enthused about Nevro. That critical mass will turn the ride. They've plateaued****. They won't grow their market further. The competition is key to understand. There are ways to get around their patents."* ***– High volume Nevro implanter***

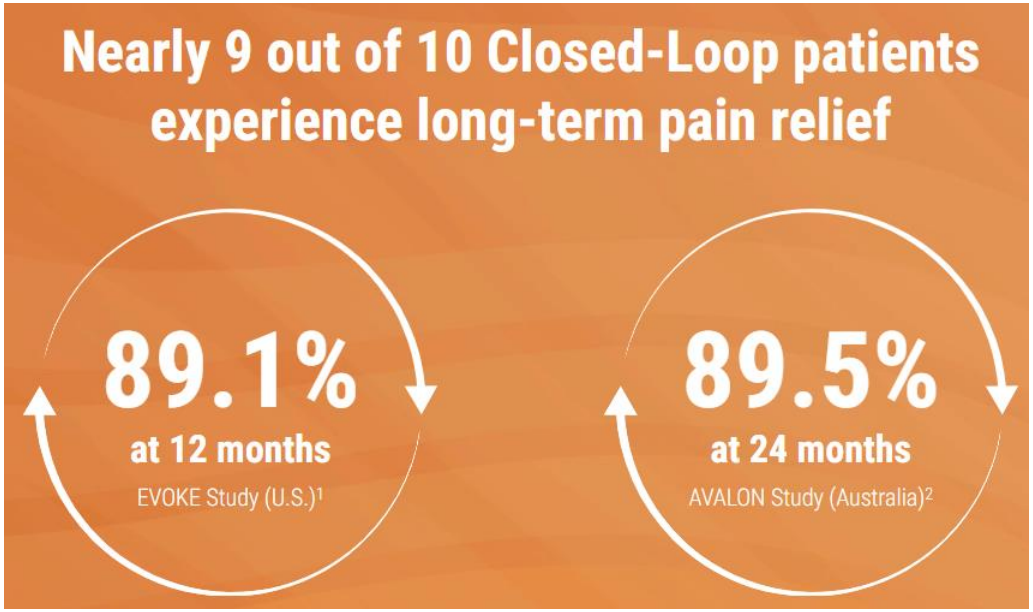
"My broker was really pushing Nevro stock *because [prominent underwriting bank] was pushing them. They're the ones that brought Nevro public and they were saying how great it was doing.* ***I knew the opposite as a high volume implanter. But the bank was still pushing it. I don't know if they didn't know or they didn't care, but I thought Nevro is like a pump in the dump [sic]."*** ***– KOL and former high volume Nevro implanter***

Source: Consultation calls with experts

14. Unknown to most investors, Nevro faces an impending, disruptive competitive threat within 6 to 12 months: Saluda

Nevro faces an impending, disruptive competitive threat with the launch of Saluda Medical's closed loop spinal cord stimulator, called Evoke and supported by the best pain relief data ever published in the space, which industry sources expect to occur within 6-12 months. Existing stimulators are fixed-output and force the patient into one parameter such as a single frequency (Nevro's approach) or waveform (eg Burst), resulting in under or over-stimulation that leads to lack of efficacy or severe side effects like burning/shocking (a frequent complaint by Nevro's patients). Evoke monitors the spinal cord's response in real-time and adjusts the current of each pulse "to maintain activation within the patient's therapeutic window." Saluda's approach – personalize stimulation not only by patient but second by second – is the polar opposite of and a frontal challenge to Nevro's entire reason for existence: a gimmicky one-size fits all approach based on a fixed 10kHz frequency. Saluda has raised $125MM*, including from key Nevro competitors Medtronic and Boston Scientific.

Saluda's data is the best ever published in the space



Saluda's AVALON study

Sustained Long-Term Outcomes With Closed-Loop Spinal Cord Stimulation: 12-Month Results of the Prospective, Multicenter, Open-Label Avalon Study

"Conclusion The 12-mo results from the Avalon study show ***the highest degree of pain relief recorded for an SCS system to date."***

Source: https://www.saludamedical.com; https://academic.oup.com/neurosurgery/article/87/4/E485/5727863; *per Crunchbase https://www.crunchbase.com/organization/saluda-medical

14. Unknown to most investors, Nevro faces an impending, disruptive competitive threat within 6 to 12 months: Saluda

One research interview after another – whether KOL's or Nevro's ex-executives – indicated that the SCS space is driven by product cycles based on the shiny new thing. Nevro was the last such launch, in 2015, and rapidly went from zero to ~15-17% share in the US. With Nevro's high frequency fad having come and gone, KOL's – especially Nevro's highest volume implanters – are eagerly awaiting Saluda. Whether Saluda's efficacy is as spectacular as the data suggest or not, our research indicates that mass trialing of their device is imminent, followed by a market share disaster for Nevro. If we assume that Nevro's share today is 17%, that Saluda quickly reaches 15% as Nevro did, and that share loss is weighted by current market share, then Nevro stands to lose ~2.6% of its share – yet another headwind after basically no growth in 2 years. As an ominous sign that share loss will be far worse than this simple estimate, we note that the authors of Saluda's US study – published in 2020 – are the lead investigator for Nevro's pivotal SENZA trial as well many of its highest volume implanters, including *all 3* of its highest compensated KOL's per OpenPayments.

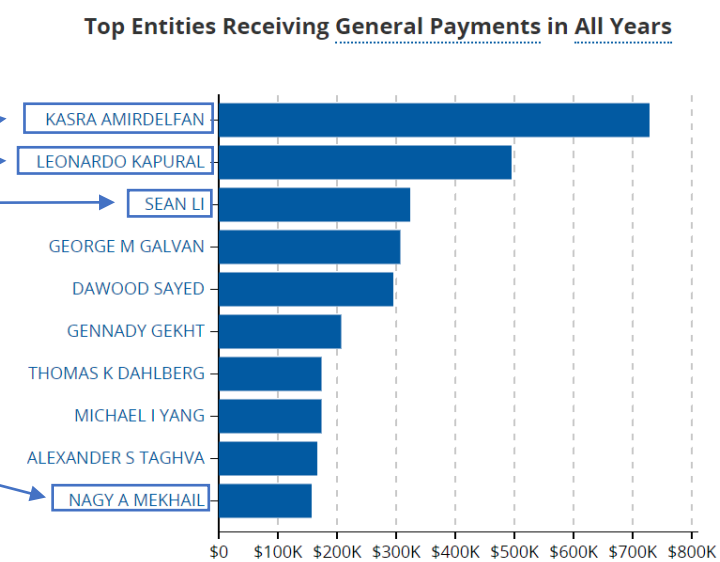
Saluda US study published Feb 2020 in Lancet

Long-term safety and efficacy of closed-loop spinal cord stimulation to treat chronic back and leg pain (Evoke): a double-blind, randomised, controlled trial

*Nagy Mekhail, Robert M Levy, Timothy R Deer, Leonardo Kapural, Sean Li, Kasra Amirdelfan, Corey W Hunter, Steven M Rosen, Shrif J Costandi, Steven M Falowski, Abram H Burgher, Jason E Pope, Christopher A Gilmore, Farooq A Qureshi, Peter S Staats, James Scowcroft, Jonathan Carlson, Christopher K Kim, Michael I Yang, Thomas Stauss, Lawrence Poree, on behalf of the Evoke Study Group**

*"These objective measurements, collected in a double-blind randomised controlled trial, **provide a level of evidence that is unmatched in this field."***

Top recipients of Nevro payments



Source: https://pubmed.ncbi.nlm.nih.gov/31870766/; https://openpaymentsdata.cms.gov/company/100000136428

14. Unknown to most investors, Nevro faces an impending, disruptive competitive threat within 6 to 12 months: Saluda

Interviews with KOL's, Nevro ex-executives and sales reps, and competitors indicate tremendous enthusiasm and anticipation for Saluda's device, with an impending disruption that one executive estimated could eradicate 18-33% of Nevro's business. We highlight comments by a former Nevro executive that the company is the most vulnerable among SCS players, given that it attracted a fickle implanter base that quickly bounces to the next hot launch. The strength of comments broadly across our 35+ interviews suggests a looming and disastrous competitive scenario.

- A Nevro ex-executive states their **customer base is the type that will switch to Saluda** and that the **impact "is going to be significant."**

> ***"Nevro's customers want to try Saluda. They are the early adopters that like all the new technology****. Nevro is being put in a box.* ***New technology affects them more than anybody. The impact that Saluda has on Nevro is going to be significant****, because their customers are the ones who say "Hey, I need something different. Saluda is going to recruit some good commercial leaders and now* ***all of a sudden, Nevro is not the new technology anymore."*** ***- Former Nevro executive***

- A **senior executive** in the space indicated that **Saluda will launch shortly and take 3 to 5 points** of Nevro's current 15-17% share – **or ~18-33% of their revenue**.

> *"The dynamic that's going to happen next is Saluda's launch. I know things have been delayed for Saluda because of COVID. They wanted to initiate their commercialization now, but it's going to be a little while.* ***They are going to gain an adoption rate, I think, similar to what Nevro did in their first 36 months, and people are going to want to try it. The reason is their key relationships in the physician community****. I don't really view Nevro as the new kid on the block anymore. They've been around long enough for physicians to say, "The results are bad and I'm going to explant this product." It's been through a life cycle. They have the share that they have and they're trying to compete with hand-to-hand combat.* ***I see them losing three to five points of share, which is a lot."*** ***– Senior executive in the SCS space***

Source: Consultation calls with experts

14. Unknown to most investors, Nevro faces an impending, disruptive competitive threat within 6 to 12 months: Saluda

Interviews with competitors – at the executive, territory manager, and sales rep level – indicated that they expect Saluda to take "a lot of share." We note comments by a territory manager at one of Nevro's 3 main current competitors, who was previously a district sales manager at Nevro and part of the company's launch team, who stated that Saluda will impact Nevro the hardest, given its disloyal customer base.

*"Omnia is a bump for a couple of quarters. Once Saluda is launched, whenever that may be in 6 to 12 months,, **you're going to see the early Omnia doctors leave Nevro to try Saluda. So, I think if anyone gets impacted by Saluda, it's going to be Nevro more than any of the other three big players**. Nevro when it first came out got the early adopter types of doctors, and Saluda will make an impact with those doctors that try new technologies within the first 6-12 months. **Correct, I'm saying that Nevro's customer base are people that are fickle."** **– Former Nevro district sales manager, now playing similar role at a key competitor***

"Saluda will absolutely take share**. It's totally different than anything out there. Doctors will absolutely want to go to it. **It'll be like having a Nevro launch all over again. They'll take a lot of share**. It's a novel approach to pain.' **– Medtronic territory manager for a key multi-state region

*"I think Saluda will have an impact. **I think there will be a splash."** **– Medtronic territory manager for one of their largest regions***

*"When Saluda comes into play, I think **the market is going to shift and take a look at them."** **– Longtime C-level executive in the SCS space***

Source: Consultation calls with experts

14. Unknown to most investors, Nevro faces an impending, disruptive competitive threat within 6 to 12 months: Saluda

Doctor excitement about Saluda reinforces the severity of the threat described by Nevro's ex-executives and competitors. The superlatives used by some KOLs, including current high-volume Nevro implanters and previous high-volume users who defected because of explants, suggest an impending fervor: "never seen anything like it"; "very exciting"; "the best tonic data ever"; "beats Nevro's data." In a space driven by the trendy new device, the color suggests that Saluda is the "new Nevro" while Nevro is yesterday's fad.

- **A Saluda investigator**, previously one of Nevro's highest volume implanters, said he's **"never seen anything" as good as Saluda**

  "I was on Saluda's trial *and it's published so the data is all out there. It was very good, like really good.* ***I'd never seen anything like it****. And these were normal patients.* ***Real patients, not cherry-picked."*** ***– KOL and previously a high volume Nevro implanter***

- One of **Nevro's highest volume implanters** and speakers states he and his colleagues are "**enthusiastically waiting"** and that it "**looks very exciting."**

  "I guess ***we're enthusiastically waiting for Saluda to come out*** *and to see if that's a game changer. Saluda overall* ***looks very exciting*** *and it makes sense."* ***– KOL and Nevro speaker***

- A high volume implanter who uses some Nevro stated that Saluda has **"the best data ever"** and that it **"beats Nevro's data"** while **another called it "really cool."**

  "No one waveform is perfect for a patient. That's what Saluda is trying to do. ***It's very cool. It's the best tonic device out there. It's the best tonic data ever. Their data beats Nevro's data****. I hope Medtronic or someone buys them because it would give them a competitive advantage."* ***– High volume implanter and Nevro user***

  "Saluda is really cool*. The device has an opportunity to be very efficient. I'm optimistic about it."* ***– High volume implanter***

Source: Consultation calls with experts

14. Unknown to most investors, Nevro faces an impending, disruptive competitive threat within 6 to 12 months: Saluda

Industry executives and KOL's stated that Saluda has locked up the most influential implanters, whose control and leverage over papers, conferences, and other doctors ensures that Saluda will drive substantial conversion to its device. While sources candidly stated that these KOL's were "completely corrupt," their comments reinforced our findings that the space is driven by a small number of high volume KOL's and kickbacks. In our opinion, Nevro exploited this dynamic at launch to rapidly gain 15-17% of share, and that playbook is now about to be used against it. The same gang of KOL's that rode the Nevro pony until it collapsed and are now ling up to ride Saluda – as evidenced by Nevro's three top recipients on OpenPayments, including the lead investigator for its pivotal trial, flocking to Saluda's US study and being listed near the top as authors for its journal publication.

"There are doctors in the landscape with a lot of influence who are completely corrupt who are on board with Saluda. And they will corrupt people with Saluda*. They own stock and options in Saluda and have consulting contracts.* ***Saluda is everywhere."*** ***– High volume KOL and Nevro implanter***

[Saluda executive] is as sharp as can be. [Name redacted] embraces the relationship that he has with [KOL name redacted], who has stock and all that fun stuff. [This KOL] is going to go on the main stage and talk about Saluda and do a roadshow for them and all that, along with several of the current Abbott KOL's. ***He's the ex-president of [society name redacted].*** *He's very well-published. He's also very feared by the physician community because if he wants you to succeed, he asks you to publish in a paper. If he doesn't want you to succeed, he ignores you. The physician community knows that.* ***He'll be a key reason Saluda takes share. because most of the market is doctors who are sheep. There are players that use a decent amount of product and they follow him because they want a name for themselves in the neuromodulation space. They want to be published."*** **–** ***Longtime executive in the SCS space***

Source: Consultation calls with experts

15. Pricing pressure and discounting are a key driver of Nevro's collapse and doom any return to growth

A critical factor in Nevro's sales growth collapse over the last two years is price discounting, a topic we have seen no sell-side or investor awareness of. Former Nevro executives, competitors, and KOL's describe a "price war" as the major stimulator companies fight over a small group of price-sensitive ASC accounts that drive most of the industry's volume. The pattern began as the previous CEO began using discounts in 2018 to stuff the channel as sales tanked, conditioning accounts to expect lower prices every year. Our interviews indicate the new CEO has also focused aggressively on price as a lever to drive volume, and that his actions kicked off a new round of industry discounting – "cutting off your nose to spite your face" according to a competitor. We first detail the magnitude of channel stuffing in recent years, which a former employees stated may still occur.

- A former regional sales director described how **Nevro became hooked on channel stuffing and discounting in 2018/2019**, and described how it has now **conditioned key accounts to expect annual price cuts. He stated he heard that channel stuffing still occurs but with "more scrutiny."**

> *"Nevro was categorically against what we called Quantity Purchases for the first 3 years the product was on the market. Then as they started to fall short and needed to meet quarterly numbers –* ***we say it's like a drug where you try it and then you're hooked. Nevro began utilizing QP's in Q2 2018 and by Q1 2019, within 3 quarters, they were completely hooked. Once you do one, you can't hop off that ride****. You've now provided the account a new price point. You're demonstrated you'll sell at that price, and they're shown willingness to buy at that volume. The company can't say no because they know the volume they can move. As a director, I was the one negotiating those. I'd joke I'd write it as a one-time offer, every time I did it. For my region, on a quarterly basis, as much as 16-17% of my sales were driven by channel stuffing.* ***I've heard it still takes place but more scrutiny of it."*** ***– Former Nevro regional sales director***

Source: Consultation calls with experts

15. Pricing pressure and discounting are a key driver of Nevro's collapse and doom any return to growth

Competitor interviews suggest that the new CEO has "drastically" cut pricing in an attempt to gain market share, and that with Omnia pricing still too high, further discounts are occurring. KOL's confirmed seeing price reductions. A former Nevro rep described a recent 20% price cut by Medtronic and then being undercut by Abbott – providing field-level color into the current price war in stimulators.

- A Medtronic territory manager, who runs one of their largest multi-state regions, stated that Nevro's pricing was too high for ASC's and that the company **"drastically lowered pricing" in 2019 under the new CEO.** A second territory manager reported **price cuts under Grossman** as well.

  "The market will be flat. It should have been flat last year. There are just a lot of players in the market and ***pricing is eroding in the space. ASC's couldn't use Nevro because they kept the price really high****. Grossman said screw that. We want as much market share as possible.* ***Nevro started price reductions in the space after Grossman came in. Nevro drastically lowered pricing to get as much share as possible in 2019. It's cutting your nose off to spite your face****. Cutting prices will lower reimbursements over time."* ***– Medtronic territory manager***

  They've consistently kept their pricing relatively higher than most. But ***under their new leadership, they seem to be falling more in line with local contracts****. From my understanding, Senza II was around $22,400 and around $24,000 to $25,000 for a full kit of Omnia. Omnia it high to the point where some facilities have said, we're not approving it."* ***– Second Medtronic territory manager***

- KOL's **confirmed the discounting** dynamic which a former **Nevro rep described as a price war**

  *"****Nevro has cut prices****. I'm not getting pushback on prices from my facility like I was.* ***They started discounting."*** ***– High volume KOL***

  *"****Medtronic cut prices 20% last week*** *in my territory.* ***Abbot undercuts everyone on price*** *and gave away the generators. There are different ways to get share."* ***– Former Nevro sales rep***

Source: Consultation calls with experts

Scorpion Capital | Nevro (NYSE: NVRO)

15. Pricing pressure and discounting are a key driver of Nevro's collapse and doom any return to growth

A former Nevro executive corroborated the price war. He offered extensive insights into Nevro's pricing predicament and how it dooms any "turnaround." He stated that "discounting is part of Nevro's approach now."

- The ex-executive stated that while Omnia is a flop and Grossman is over-rated. Nevro's biggest issue is that they've **begun heavily discounting their stimulators and that it's a price war** with Medtronic. Abbott, and Boston Scientific

> *"I think it's highly over-valued. And I would say, not only the stock but the company, Omnia, and also Grossman….an outsider looks at what he's trying to do and says, wow that's pretty impressive. However,* ***Omnia is an overpriced product and I don't see it saving the day. And the reason they're not growing is that they never got an impact from Omnia. What really caught them was that they discounted their pricing heavily*** *on their other product line, so they never got any kind of pop on Omnia. Abbott and their other key competitors are also not doing well, and so,* ***it's a price war."*** ***– Former Nevro executive***

- The ex-executive indicated that stimulator **prices dropped a stunning $5,000, or roughly -20%**, and that **"discounting is part of Nevro's approach now"**

> *"A great question that you should always ask every physician that you ever talk to is, what are you paying for a battery this year over last year? And* ***you see erosion in price. Nobody is paying more. That's why there's no big uptick at Nevro****. You have the same level of year-over-year sales and yet you've got a hundred extra reps on the payroll. Why? Well, they're selling the same amount of implants, but there's* ***massive price erosion****. You've probably seen in general,* ***about $5k in price erosion annually****. That seems to be the magic number that gets a lot of attention. If you were paying $27,000-28,000 per device, now you're in the low $20's or if you're a high-volume guy and you were paying $23,000-24,000 and now you're down in th17,000-18,000, that's significant. I think* ***discounting is part of Nevro's approach now."*** ***– Former Nevro executive***

Source: Consultation calls with experts

Scorpion Capital | Nevro (NYSE: NVRO)

15. Pricing pressure and discounting are a key driver of Nevro's collapse and doom any return to growth

He stated that "the massive price erosion" is about to worsen as Covid-hit surgery centers seek to make up lost revenue by demanding even deeper discounts. He painted a grim picture of dependence on a small number of high-volume, price-seeking ASC's with little loyalty, and large competitors slashing pricing to offer "deals." He stated he's "pessimistic" about the company's future and can't see how "Nevro really wins this."

- He stated that **price declines are about to accelerate, worsening the already "massive price erosion,"** as ASC's seek discounts to compensate for the impact from the pandemic. He added that a **small percentage of high-volume physicians drive most of the volume** and use their leverage to extract discounts.

> *"As a perfect example. Dr. [redacted] does 240 cases a year. Nevro used to price him in the high to upper $20-thousands. He's now is buying the same product in the upper teens.* ***That's a huge erosion of price and that's where the market is. This year, I think it's going to come down even more*** *because so many of these ASC's have been kind of done. With* ***25% of the physicians driving 70% of the revenue,*** *you see* ***massive price erosion****, so although Omnia might be their flagship, what percentage of sales is coming from it? 5%? 10% Those are the questions, as an investor I would ask."* - ***Former Nevro executive***

- He implied that **Nevro has no way out** and that ASC's will **crush pricing post-Covid**

> ***"The reason I'm pessimistic is, how does Nevro really win this? They don't have any new technologies****. They only have one real platform, and* ***Omnia doesn't really attract new customers****. They have their existing customer base, which is in real trouble with Covid.* ***When you look at the next 18 months, the high-usage implanters, who are where the value is, are going to be looking for deals. Medtronic, Boston Scientific, and Abbott give out those deals— a $5,000 discount on a stimulator*** *is an immense amount of money if you're doing 75-100 stims a year. So I think there's going to be some* ***real pricing pressure coming out of Covid****. For sure. These guys that own ASC's have payrolls that are a couple of hundred thousand dollars for every couple of weeks because some of them have 20-30 nurses on board.* ***The real importance after Covid s going to be on pricing****. The loyalties go away almost immediately."* ***– Former Nevro executive***

Source: Consultation calls with experts

15. Pricing pressure and discounting are a key driver of Nevro's collapse and doom any return to growth

The ex-executive pointed to several factors that make it impossible to reverse price declines. First, the vast majority of Nevro's revenue comes from ASC's, which are personally owned by doctors who are therefore extremely price-sensitive: "it's a price war because none of the stim companies have created great customers." Given the small number of these "whale customers," they have leverage to play the stim companies against each other on price.

- He stated that Nevro's **dependence on ASC"s, which drive >70% of the company's sales, drives price sensitivity** as the discounts go straight to the doctors who owns the surgery centers.

  *"The percentage of the business that comes from ASC's is **certainly over 70%** on a national basis. The reason **they're so price-sensitive is that the physicians have ownership in that ASC** or they own it outright, so they're getting two fees. They're getting the facility fee. They get the physician fee and the equipment fee. As an example, if I can really knock you down on price, where I was paying $25,000 per stimulator before and now I'm paying $20,000 and I do a hundred cases a year, **I pick up the extra $500,000.** Then if I get reimbursed at $38,000, now I'm making $18,000 back on."* **– Nevro ex-executive**

- The "whale customers" are ones that own their ASC's, and given the small number of such accounts, **stimulator companies fight over them by lowering prices**.

  "And it's a price war because none of the companies have created great customers**. Those big whale customers that own their own ASC are making money off of the generator. Let's say as an example, Omnia is $5,000 more and you do a hundred cases a year. Are you really going to say it's a $500,000 better product than something else? Of course not. That money goes directly to the ASC owner who is the physician that does the cases. **Every stimulator company is trying to fight over a couple of hundred customers a year that are up for play and they want a lower price." **– Nevro ex-executive**

Source: Consultation calls with experts

15. Pricing pressure and discounting are a key driver of Nevro's collapse and doom any return to growth

Second, the former executive stated that Nevro has an "ongoing problem" kicked off by channel stuffing in 2018/2019, which has conditioned accounts to expect ongoing concessions and led to a price-cutting spiral. Our research suggests the new CEO has reinforced the behavior by doubled-down on discounts. The ex-executive described the price conditioning as ruinous: "a stupid move"; "one of the dumbest moves you could ever make."

- Until 2018/2019, Nevro never engaged in channel stuffing – "bulk orders" – given its **dependence on an extremely small number of large accounts and the risk of destroying its ASP.**

> *"We would never allow bulk orders, ever, under any circumstance, given* ***the sensitivity of the pricing. The one thing that I really want you to take away from this conversation are the high-volume implanters. That's really the nuts and bolts of the spinal cord stimulation business****. For example, the highest volume doctor in Wisconsin is [name redacted] and he does over 200 stims a year. The closest guy next to him probably does 30. You can put a similar state-by-state tapestry together.* ***These high-volume stim users own their ASC's****. I can say, "I'm closing out the quarter and my average sale price to you is $27,000, but if you order 25 for next quarter, I'll knock it down to $22,000-$23,000."* ***Rami was trying to save his job. And everybody looks like they win off for one or two quarters. But the problem is that now you eroded your ASP*** *and you're not making it up with new customers, and your existing customers are at capacity at 100 stim's a year."* ***– Nevro ex-executive***

- Nevro then jumped off the cliff and now has an "**ongoing problem" of a downward price spiral.**

> ***"The ongoing problem*** *that Nevro has is that once doctors start paying $2,3,4 thousand dollars less per device they say* ***"Well, I don't want to go back to the high price"*** *and of course an Abbott will match that price because it's new business for them.* ***It was a stupid move. Fundamentally, it was one of the dumbest moves you could ever make****. The reps were dumb enough to go along with it and ultimately,* ***all it does is it drives pricing down."*** ***– Nevro ex-executive***

Source: Consultation calls with experts

16. The SCS market growth story fueled by Wall Street is false and undermined by escalating payor backlash

Interviews with KOL's, ex-employees, and competitors indicate that the reimbursement environment for spinal cord stimulators is becoming increasingly difficult as insurers crack down. Both government and commercial payors increasingly view stimulators as ineffective and lacking in evidence and high-quality studies; expensive with no ROI; and as driving additional costs given their widespread adverse effects. A key part of the Nevro bull case is based on misguided notions of market growth, which our research indicates faces substantial headwinds as reimbursement rapidly deteriorates. Washington state terminated coverage after a lengthy 2018 evidence review by 11 clinicians, slamming stimulators as unsafe with sky-high complication rates of 42-60%, and concluding that they fail to provide pain relief or reduce the need for pain medication like opioids.

Washington State Health Care Authority review - excerpts

- The committee agreed that safety was a significant factor: the number of trial reported complications ranged from 8 to 100%. Device related complication requiring revision ranged from 25% to 38% of patients in short term and 42% to 60% in up to 5 years (not including 54% of patients undergoing pulse generator replacements due to battery life).
- The committee found that evidence overall on important patient outcomes was limited. For all outcomes, there is no evidence of longer term improvement, particularly important when there are significant risks (including 1/3 revision and high removal rate) and the device is intended for permanent implant.
- Given the serious limitations of the studies, the committee agreed that, at best, weak evidence exists that SCS may provide temporary improvement of pain in some patients, but there is no evidence of mid or long term pain improvement.

Source: https://www.hca.wa.gov/assets/program/spinal-cord-stimulation-signal-update-20180807.pdf

16. The SCS market growth story fueled by Wall Street is false and undermined by escalating payor backlash

Our interviews indicate that other states such as California are following Washington's lead. We note that CMS recently proposed a prior authorization requirement, indicating pressure at the national level as well. The findings in the WA study are echoed by numerous independent reviews, in particular the recent Public Citizen review of stimulators (p.31) and a 2018 Yale and Johns Hopkins paper that came to a similar conclusion, expressing "an additional major concern with the SCS efficacy studies": "they tend to be industry funded with numerous financial conflicts of interest."

Study concluding that SCS fails to provide pain relief for workers comp patients

*"In sum, **we found no evidence** for greater effectiveness of SCS versus alternative treatments in this patient population **after 6 months."***

Oregon state review of 6 years of SCS outcomes indicated little impact in reducing pain or opioid use, and found that half of patients needed revision surgery or device removal, within about a year

*"The spinal cord stimulator is considered a permanent device to reduce the injured worker's pain and decrease the utilization of pain medications. **We are not seeing significant positive impact in either of these areas."***

Yale/Hopkins paper notes lack of patient benefit and low quality of SCS studies purporting efficacy

*"It is important to note that efficacy studies often rely on patient-based outcome measures to quantify pain relief, such as the pain visual analog scale (VAS) and patient satisfaction. Such measures are subjective, and patients may report high satisfaction via placebo effects, clinician influences, or secondary gain reasons. The long-term effects and/or benefits of SCS for back pain are also unclear. Most trials had relatively short follow-ups of six to 12 months or even less, and only three trials have had follow-ups of up to 24 months (Table 1). Indeed, one study has suggested that while pain relief can be observed after six months, these benefits from SCS dissipated after 12 months [48]. **Thus, it remains unclear whether SCS provides meaningful long-term benefits to all patients."***

Source: https://pubmed.ncbi.nlm.nih.gov/19875232/; https://wcd.oregon.gov/medical/mac/Documents/meetings/2016/7-8-16/SCS-data-from-SAIF.pdf;; https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6153614/pdf/yjbm_91_3_323.pdf

16. The SCS market growth story fueled by Wall Street is false and undermined by escalating payor backlash

It is therefore no surprise that one KOL after another indicated that reimbursement is now "the hardest it has ever been" and that payors are escalating denials and making it "impossible."

- A KOL indicated that getting stimulators approved is now **"the hardest it has been"**

  *"Insurers are making it even harder. Getting approval for spinal cord stimulation is **the hardest it has been**. In some local code determinations, they're making doctors send the patient to a neurosurgeon who writes a letter stating the patient is not a candidate for spinal cord stimulation."* ***– KOL, high volume implanter***

- The reimbursement environment for stimulators is **deteriorating and states are cracking down**

  *"The reimbursement environment has **gotten progressively worse**. I mean authorizations. Insurance company **guidelines are being very ridiculous**. In California, workers comp only allows you to do stim for CRPS [complex regional pain syndrome] and nothing else. In Washington and Oregon they have similar things. Some states have adopted American College of Occupational and Environmental guidelines and **states where insurers use those guidelines are now denying stimulation**. It's not just happening to me. I hear this talking to colleagues. It's a progressive process. More insurers are starting to do it. Once one does it, others get away with it."* ***–KOL, high volume implanter***

- Insurers are balking at the high up-front cost of stimulators, making it **"impossible to get stimulators approved"** in many cases

  *"The reimbursement environment has **gotten tougher over the years**, definitely. Spinal cord stimulators are a hard-to-get item. They're a big upfront cost, so **it's difficult. You have to fight** based on diagnosis code and so on."* ***–High volume implanter***

  *"I'll explain why **the average insurer doesn't pay. It takes 5 years to recoup the up-front cost of a stimulator**. If a patient goes off that healthcare plan in that time, say in 2 years, the insurer doesn't get the benefit. For example, patients that are 65 are then going on Medicare. If someone is in their mid 60's and not on Medicare, it's impossible to get stimulators approved."* ***–KOL, high volume implanter***

Source: Consultation calls with experts

16. The SCS market growth story fueled by Wall Street is false and undermined by escalating payor backlash

KOL's indicated that payor pressure has become so onerous that many doctors have stopped implanting stimulators altogether. One stated that he sees 50% of implants denied. Another stated that implanting is now "financially not worth it." A third, speaking of insurers, said there's so much abuse that "I don't blame them. I really don't blame them."

- Reimbursement hassles – such as **50% of stimulators being denied** and needing appeals – are so severe that some **doctors have stopped implanting stimulations**

  "I have one full time person who dots the i's and crosses the t's. They handle denials, then the appeals, then the independent medical review denies it again. Most doctors don't take the time and don't bother. ***Some have stopped implanting stimulators because it's such a pain in the ass****. 50% are initially denied and I get 70% covered. It's a lot of hassle to go through."* ***–KOL, high volume implanter***

- A leading KOL stated reimbursement is **"horrible"** and "**it's financially not worth it,"** adding that he doesn't blame insurers for cracking down, given the abuse

  "Reimbursement is horrible. It's financially not worth it. There's not much money in it. There's not much at all. And the equipment now has to be bought by a surgery center and there's hardly any profit in that. ***There's just no profit anymore. They took it all away, which is fine, I don't blame them. I really don't blame them. People abuse it"****.* ***–KOL, high volume implanter***

- A high volume KOL indicated that reimbursement is **"getting worse year after year"** and bemoaned the amount of his time it sucks up

  "The reimbursement sucks. *Insurer rejections are the bane of my existence. Every year I spend more and more time on peer and peers. As we do more expensive stuff like stim, the insurers are raising the ante.* ***Yes, I'm spending more energy on it. It's getting worse year over year****. It's an expensive technology. Reimbursement pressure has gradually increased and slowly trailed the proliferation of stimulators. Right around the time that Nevro appeared. The stim market grew and insurers pushed back. Blue Cross, any of the blues, are all bad. They're the worst."* ***–KOL, high volume implanter***

Source: Consultation calls with experts

16. The SCS market growth story fueled by Wall Street is false and undermined by escalating payor backlash

Both the increasing rate of insurer denials and doctors therefore "not wanting to do spinal cord stimulators as much" were recurring themes of KOL interviews. Implanters indicated it's only a matter of time before reimbursement gets "hammered again."

- Insurers are putting up more **"roadblocks" and "more hoops**," creating denials and delays that extend for months

  "The Aetna's, United Health's of the world have put up more roadblocks. They make docs call, justify it, deny it. The denials have gone up. Also the delays. I have a couple of doctors who took four months to get patients through a stim trial. The insurers kept delaying it for extra info. ***Reimbursement was piece of cake five years ago. Now it's getting more difficult.*** *There are more hoops."* ***– KOL, high volume implanter***

- Insurers are taking "a lot of shots" at stimulators and r**eimbursement will get "hammered again**," leading doctors to **"kind of not wanting to do SCS as much."**

  "Insurers have taken a lot of shots at spinal cord stimulation. In 2015 they tried to split up the coding. ***We're just kicking the can down the road until the reimbursement gets hammered again****. It's just harder to get approved. Doctors are kind of not wanting to do spinal cord stimulation as much."* ***–KOL, high volume implanter***

Source: Consultation calls with experts

16. The SCS market growth story fueled by Wall Street is false and undermined by escalating payor backlash

Former Nevro employees as well as key competitors like Medtronic corroborated the reimbursement pressure highlighted by KOL's: payors are getting smart and pushing back; denials accelerated in 2019/2020; and CMS is poised to cut reimbursement yet again.

"I agree with doctors who are saying the reimbursement environment is getting more difficult. Questions come up on prior authorization forms – is this a DRG, rechargeable, non-rechargeable, HF10? ***The payers are getting more educated in this market and pushing back more****. I do feel like this last calendar year; things got a little bit tighter. I feel like 2019; I had a lot more peer reviews, a lot more denials. We try to track a lot of that stuff ourselves to make sure we capture all of the patients we can and so,* ***we've been noticing a lot more****, I felt like this year, more than ever, people not getting through the insurance process."* ***– Medtronic territory manager***

"There are insurance companies now that are getting ***much more stringent with the way they approve these****. One of the insurance companies hired a third party company to actually deny cases and they're getting a lot more strict, so there's a lot more work that involved if you have to appeal a decision for spinal cord stimulation."* ***–Former Nevro territory manager, now at Abbott***

*"****CMS is watching. They will cut reimbursement*** *like they did with the stimulator leads."* ***– Medtronic territory manager***

"There's huge amounts of pressure *from a worker's comp perspective in California. The key doctor who worked on eliminating workers comp reimbursement in Washington is same person who is leading the charge within California. I think they've had a lot of success."* ***– Former Nevro executive***

*"****The payors say keep the prices down****. I'm involved in some of these pricing discussions. The payers don't care about the bells and whistles. They care about low infection rates. They care about low explant rates, and they don't want to have to pay for complications. Complication rates need to stay low. According to the MAUDE database, Nevro is actually pretty high in complications. They also have a lot of lead revisions. They had a bad anchoring system which was part of their efficacy issues when leads kept migrating."* ***-– Medtronic territory manager***

Source: Consultation calls with experts

16. The SCS market growth story fueled by Wall Street is false and undermined by escalating payor backlash

Reimbursement pressure undermines the SCS market growth narrative that has been a key part of the bull case ever since Nevro went public in 2015. A former Nevro territory manager implied that the narrative was fabricated to get the stock up. A second Nevro ex-employee, who was involved in the market growth calculations the company represented to investors and the sell-side, basically admitted to us that it was a fraudulent exercise. We show the ex-employee's explanation below and note its incoherence and absurdity, in response to our bluntly asking if the company was fabricating a growth number for investors and Wall Street.

"Market analysts look at the spinal cord stimulation market as a bigger growing market than it actually is. ***I believe it has been inflated. In order to get a stock up, you need to show that a market is at a certain growth level****. That's my belief. It's my solid, firm belief, and it's because I've been dealing with these same patients and doctors for 25 years. The market for the number of new implants is* ***not growing as fast as what investors are being told****. That's my belief."* ***– Former Nevro territory manager***

Question: Were data sources being cherry-picked to reinforce a narrative, a market growth number that the stock required, just to be blunt?

*"****Umm…probably to a degree, right?*** *I don't…you know… I think some of the data sources weren't always the full picture that they needed to be. I wouldn't say picking and choosing perhaps but there was, which I'm sure happens in all kinds of angles* ***sort of leaning more heavily on data that maybe people thought supported a narrative*** *and then, to some degree, sure. So, I think, again, it was a triangulation of different data sources, right? The payer data. I mean, I would say the payer data, Wall Street and analysts and other physician market research, and you know, I think…I don't know how would I characterize it. I think it was—I don't know. I think at a specific point that you were referring to, I think—I don't know.* ***I think there were different times where different data sources were weighed more heavily and I think that weighing of different data sources was at times skewed.****"* ***– Former Nevro employee involved in calculating market growth figures***

Source: Consultation calls with experts

16. The SCS market growth story fueled by Wall Street is false and undermined by escalating payor backlash

We queried KOL's and Nevro competitors on the normalized market growth rate excluding a pandemic. A Medtronic SCS product manager stated it's low single digits at best and cast those who claim it's higher as "liars," adding that they simply make up neuromodulation growth rates for earnings calls. KOL's and territory managers at Nevro's 3 key competitors indicated that market growth already hit a wall pre-Covid, due to reimbursement, cannibalization from a flood of smaller entrants, pricing pressure, and cannabis legalization.

"We think the spinal cord stimulator market grows at 3-5%, I don't want to call people liars on these calls [who are saying it's high single dig`it or teens growth]. An honest number is 3-5%. ***I get emails from senior management saying we need a growth rate number for our earnings call. It's an echo chamber.*** *You touch your finger to the wind. There's no database."* ***– Medtronic product manager***

"The market will be flat. It should have been flat in 2019. ***There are just a lot of players in the market and pricing is eroding in the space. In my territory my numbers have dropped. We've come back fighting by lowering our pricing****. My territory is back to $5.5mm, down from $7mm. Loyal docs are being slower than in previous years. It's partly the cannabis situation. Primary care doctors have gotten cannabis licenses. A lot of patients are on cannabis and doing fairly well without interventional procedures.* ***We're seeing very loyal Medtronic doctors where their stim implants are down 30-40% after getting a cannabis license****. I see market growth being flat.* ***I don't see it growing. A lot of new players are cannibalizing everyone****. The market's not like you hope it would be with four legacy players.* ***The market has changed completely****. What hurt Medtronic wasn't the larger players. It's the smaller companies earlier in the pain continuum. Smaller players are having an impact. Boston was smart to buy Vertiflex. Stim placement is an hour, and you can do four Vertiflex in an hour."* ***- Medtronic territory manager***

"Stimulator implant volumes have decreased*. Boston Scientific has decreased. I speak to Medtronic and it's true for them as well. The Abbot rep doesn't complain quite as much in my area but said 2019 was down about 20% and other areas are down more."* ***– KOL, high volume implanter***

"My December 2019 wasn't as busy as before. In December 2018 I was scrambling to fit in procedures. Last year there no scrambling. ***It was slower at the end of 2019."*** ***– KOL, high volume implanter***

Source: Consultation calls with experts

16. The SCS market growth story fueled by Wall Street is false and undermined by escalating payor backlash

We note a key, misunderstood dynamic regarding the market growth narrative pushed by Nevro and Wall Street. Nevro is portrayed as a beneficiary of the opioid crisis, with stimulators pitched as a savior. Over the past five years, the opioid crisis has been the primary explanation used to lend legitimacy to fabricated double-digit growth rates. Our research indicates that Nevro is in fact a beneficiary of the opioid epidemic, not because it's a safer alternative, but because opioids are the "bait" – to quote a Nevro implanter - that drive stimulator volumes at the same sketchy pain clinics. As opioid users flooded clinics, doctors had more patients to push stimulators onto, by threatening to withhold monthly refills, among other pressure tactics. In states like Florida that have cracked down on pain doctors, stimulator volumes have collapsed. One of Nevro's highest volume implanters, in Florida, explained how an opioid crackdown has led to his stimulator volumes dropping by half. As states crack down on opioids, the stimulator market gets hammered as well.

"I've implanted a hundred stimulators in some years but last year it dropped to 50 or 60. The rules for pain clinics in opiate management in Florida changed. Although I had been a low-opiate prescriber, a large number of the patients that came into the practice were already on pain medication or looking to get started or continuing on them. I never wanted to dedicate myself to that or contribute to the opiate crisis. ***Regardless, I think that the end result of us being more stringent with patients that we allowed to enter the practice was a decrease in the overall numbers of stimulator implants. I want to be careful with what I say.*** *The motivation for patients to come in to see the right doctor to manage their pain was sometimes the wrong motivation. They just wanted to continue their pain medications or the status quo.* ***But within those huge number of patients, we could find the appropriate candidates for this type of therapy."***

The number of stimulator patients entering clinics declined in Florida. Unfortunately, there are a lot of bad actors and ***a lot of people on pain medication who shouldn't have been and a lot of the patients that funneled into stimulators were those.*** *There are doctors here in Florida, which I don't consider part of my colleagues or community, but you see these things happening. Their bait is to offer everything, including the pain medication, so once the patients were engaged with these drugs, they would do whatever was financially appropriate, for themselves or for the practice, so those are the bad doctors, the bad actors."* ***– One of Nevro's highest volume implanters***

Source: Consultation calls with experts

17. We believe that Nevro's business model hinges on unsustainable kickbacks to high-volume implanters

KOL's and Nevro's former executives described the spinal cord stimulator space as driven by a small number of high volume implanters who will only use your device if you pay them to do so. Some used the word kickbacks to describe how companies like Nevro attract and retain their top accounts, while others described the same dynamic without directly labeling it as such. We begin with Nevro's practices in Europe, which we believe are more accurately described as simply bribery. An article by the Swiss Broadcasting Corporation in February 2020 alleged that Nevro paid doctors ~$10,000 per device implanted. Journalists obtained a 2019 Nevro contract and stated that "the kickback scheme" began in 2017.

SWI swissinfo.ch

Swiss perspectives in 10 languages

Multinational companies

US company provided kickbacks to doctors in Switzerland

According to a 2019 contract obtained by the German language paper, California-based Nevro, which specialises in the treatment of chronic pain in the trunk and limbs, offered Swiss doctors CHF10,000 ($10,181) for each Nevro spinal cord stimulator implanted in a patient.

Source: https://www.swissinfo.ch/eng/us-company-provided-kickbacks-to-doctors-in-switzerland/45562136

17. We believe that Nevro's business model hinges on unsustainable kickbacks to high-volume implanters

We translated the source article in the German-language publication, using Google Translate. We interpret the article to imply that Nevro terminated the program "with immediate effect" when asked and did not dispute its existence. We note the translation below may be incorrect. If the scheme wasn't terminated until the paper asked about it in early 2020, that would imply that it continued under the current CEO for about a year.

The industry is silent on this subject as if it were a state secret. But SonntagsBlick is now the contract that Nevro had signed for 2019 with Swiss doctors and clinics. For the first time, outsiders get a detailed insight into how the system works.

If a doctor brings implants for 400,000 francs to the public, he receives 80,000 francs in cash back. That's enough for a Patek Philippe watch. Those who put Nevro stimulators in the back of their patients for CHF 800,000 will be rewarded with CHF 160,000. With that you can already buy a Maserati - so it pays off for pain medicine specialists if they opt for the expensive procedure.

Source: Original https://www.blick.ch/schweiz/boni-verleiten-zu-mehr-operationen-firma-belohnt-aerzte-mit-10000-franken-pro-eingriff-id15750793.html; Google Translate version https://translate.google.com/translate?sl=auto&tl=en&u=https://www.blick.ch/schweiz/boni-verleiten-zu-mehr-operationen-firma-belohnt-aerzte-mit-10000-franken-pro-eingriff-id15750793.html; red ours for emphasis

17. We believe that Nevro's business model hinges on unsustainable kickbacks to high-volume implanters

A review of enforcement actions brought against medical device companies under the Foreign Corrupt Practices Act leads us to believe that Nevro and its executives may be one internal whistleblower and/or inquisitive DOJ attorney away from a major FCPA problem. We note that FCPA matters may be criminal and/or civil, and that penalties routinely run into the hundreds of millions of dollars. FCPA medtech legal commentary suggests to us that Nevro's conduct is a textbook case.

Foreign Corrupt Practices Act: High Risks for the Medical Device Industry

"Medical device companies are particularly at risk with respect to FCPA violations*. […] More directly, practices that are common in the medical device industry, such as product discounts tied to purchase volume and* ***incentive programs to encourage increased purchasing, may violate both the letter and the spirit of the FCPA."***

Emerging Risk Trends in the Medical Device Industry: Whistleblowing, Anti-Bribery, Corruption Law and Enforcement

"In recent years, ***the medical device industry has been in the spotlight and subject to increased scrutiny*** *by government regulators. The U.S. Department of Justice (DOJ) and Securities and Exchange Commission (SEC) have pursued several companies in the medical device industry for* ***a number of Foreign Corrupt Practices Act (FCPA) violations, including kickbacks with foreign health departments, payments to consultants in hospitals, unjustified fees and using excessive means to influence healthcare professionals."***

Source: https://www.mddionline.com/news/foreign-corrupt-practices-act-high-risks-medical-device-industry; https://www.kroll.com/en/insights/publications/compliance-risk/emerging-risk-trends-in-the-medical-device-industry

17. We believe that Nevro's business model hinges on unsustainable kickbacks to high-volume implanters

We asked two former Nevro executives to comment on the alleged kickbacks program in Europe. One stated his belief that it couldn't have had happened without participation by the US headquarters ("everyone knows"); and that the staff Nevro terminated in the aftermath were "sacrificial lambs." He called the program "crazy." Another described underpaid government doctors who "make five times" their salary from device companies and described kickbacks as something "easy to happen in that environment."

*"**There aren't any other companies operating the way that Nevro was. There were enough people that would have known that it couldn't have happened without the head office knowing.** There's no Europe-based contracts or accounts payable team. All of those things happen through the California office, so they would have known that the contract existed. The contract would have been approved and the payment made from the US. Nevro did fire both people involved within Switzerland which I think probably left a bad taste as people at the head office would have known. **Obviously, they were used as sacrificial lambs. I think they were trying to paint it as though they didn't know, and there's no way. Like, everyone knows**. There's no way that they couldn't know because the legal team gets involved. [The Switzerland program] is **totally crazy.** Nevro quickly lost probably most of their business […] **I've never heard of that being a ethical practice in any countries in Europe**. In most Western countries, there's a rebate or commercial agreement that's been set up with a hospital directly but those payments would go back through a discount off list price that goes back to the actual institution, but not to a physician directly." **– Former Nevro executive***

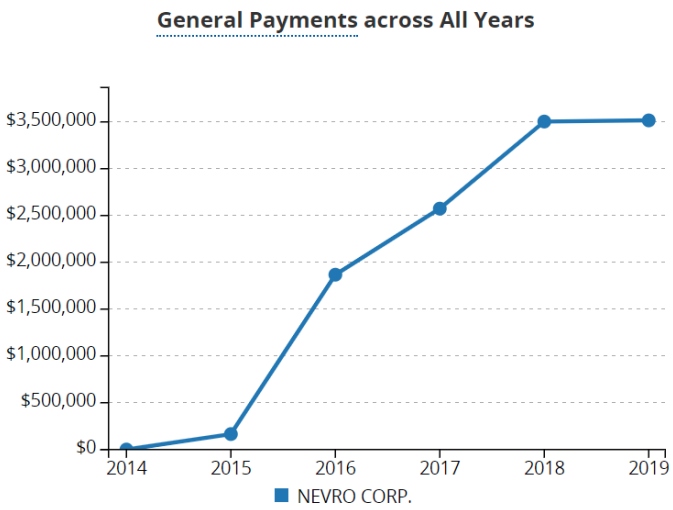
*"Usually the physicians, like in Germany, 85% of them are all university doctors ,in Western Europe, UK. You see them do an immense amount of consulting work and they make five-times the amount of money that they do from their university or doing spinal cord stimulation. You could probably get a rogue distributor as an example, like in the Netherlands or something where they would maybe say, "Hey, I'm making a commission on this thing of, call it, six-thousand dollars—you know—four-thousand dollars and **I'll give you a thousand bucks for every implant." I could see something like that happening. That would be pretty easy to happen in that environment."** **– Former Nevro executive***

Source: Consultation calls with experts

Scorpion Capital | Nevro (NYSE: NVRO)

17. We believe that Nevro's business model hinges on unsustainable kickbacks to high-volume implanters

In the US specifically, the OpenPayments database paints a troubling picture of Nevro's "general payments" to doctors – about $3.5MM/year - which are separate from any alleged inducements via "research payments." The breakdown suggests that most of this spend is for a "speakers program" as the largest category is "food and beverage" followed by "faculty/speaker" fees. As Nevro's three top KOL's appear to be paid up to an astounding $15-20k per speaking event, the breakdown – combined with comments from Nevro's own consultants and ex-employees - suggests to us that the speakers program is a kickback scheme in disguise.



Nature of Payment	Amount	Payments	Amount (%)
Food and Beverage	$1,199,397.00	27,757	34.1%
Faculty/speaker at an unaccredited/non-certified education program...	$1,047,670.22	353	29.8%
Travel and Lodging	$529,621.55	1,888	15.1%
Services other than consulting...	$528,232.50	128	15.0%
Consulting Fee	$209,306.25	87	6.0%
Education	$566.63	15	0.0%
Gift	$33.98	2	0.0%

Recipient	Nature of Payment	Date	Total Amount
KASRA AMIRDELFAN	Faculty/speaker at an unaccredited/non-certified education program	12/17/2019	$22,275.00
LEONARDO KAPURAL	Faculty/speaker at an unaccredited/non-certified education program	01/02/2019	$18,700.00
LEONARDO KAPURAL	Faculty/speaker at an unaccredited/non-certified education program	01/02/2019	$18,700.00
LEONARDO KAPURAL	Faculty/speaker at an unaccredited/non-certified education program	05/15/2019	$15,400.00
KASRA AMIRDELFAN	Faculty/speaker at an unaccredited/non-certified education program	12/11/2019	$13,200.00
DAWOOD SAYED	Faculty/speaker at an unaccredited/non-certified education program	06/26/2019	$13,200.00

Source: https://openpaymentsdata.cms.gov/company/100000136428

17. We believe that Nevro's business model hinges on unsustainable kickbacks to high-volume implanters

We note that speakers programs which are essentially kickback schemes are illegal, e.g., the recent criminal convictions of Insys Therapeutics executives and some of their high volume KOL's, in connection with the "Insys Speakers Bureau." In a DOJ press release announcing the 5 year imprisonment of one such KOL, the US attorney described how the speakers program was used as cover. We leave it to readers to ascertain the existence or absence of any parallels, while noting that a Nevro ex-consultant and previously one of their highest volume KOL's used Insys as an analogy.

FOR IMMEDIATE RELEASE Monday, January 27, 2020

Manhattan Doctor Sentenced To Nearly Five Years In Prison For Accepting Bribes And Kickbacks In Exchange For Prescribing Fentanyl Drug

The Insys Speakers Bureau

In or about August 2012, Insys launched a "Speakers Bureau," a roster of doctors who would conduct programs ("Speaker Programs") purportedly aimed at educating other practitioners about Subsys. In reality, Insys used its Speakers Bureau to induce the doctors who served as speakers to prescribe large volumes of Subsys by paying them Speaker Program fees. Speakers were supposed to conduct an educational slide presentation for other health care practitioners at each Speaker Program. In reality, many of the Speaker Programs were predominantly social affairs where no educational presentation about Subsys occurred. Attendance sign-in sheets for the Speaker Programs were frequently forged by adding the names and signatures of health care practitioners who had not actually been present.

"Doctors that implanted a lot of devices, they hated Nevro. I don't know doctors who were high volume Nevro implanters that liked it and continued with their device. ***The high volume Nevro implanters today who are involved with Nevro's studies – I saw the guys who went to jail for prescribing the Insys fentanyl drug****. An Insys VP was saying how he hired hookers and strippers. You have to remember the doctor runs the show.* ***And the only way I know to change that doctor's practice paradigm is bribing****.* ***It works. You give a doctor some money and they will say whatever you want****. I would imagine Nevro probably doesn't give them money.* ***They just hire them as consultants, pay them to give lectures and to teach classes. Doctors are whores"*** ***– Ex-Nevro consultant and high volume implanter***

Source: https://www.justice.gov/usao-sdny/pr/manhattan-doctor-sentenced-nearly-five-years-prison-accepting-bribes-and-kickbacks; consultation calls with experts

17. We believe that Nevro's business model hinges on unsustainable kickbacks to high-volume implanters

On November 16, 2020 the OIG issued a Special Fraud Alert on speaker programs – an arrow pointed straight at the heard of Nevro's business model. Our reading of the alert leads us to believe that Nevro's program is a textbook case of what regulators are seeking to reign in.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

OFFICE OF INSPECTOR GENERAL

WASHINGTON, DC 20201

Special Fraud Alert: Speaker Programs

November 16, 2020

I. Introduction

This Special Fraud Alert highlights the fraud and abuse risks associated with the offer, payment, solicitation, or receipt of remuneration relating to speaker programs by pharmaceutical and medical device companies. For purposes of this Special Fraud Alert, speaker programs are generally defined as company-sponsored events at which a physician or other health care professional (collectively, "HCP") makes a speech or presentation to other HCPs about a drug or device product or a disease state on behalf of the company. The company generally pays the speaker HCP an honorarium, and often

Source: https://oig.hhs.gov/fraud/docs/alertsandbulletins/2020/SpecialFraudAlertSpeakerPrograms.pdf

17. We believe that Nevro's business model hinges on unsustainable kickbacks to high-volume implanters

KOL's and former Nevro executives describe practices identical to what the OIG Fraud Alert targets, detailing what we interpret as blatant kickbacks and indicating that the SCS space is driven by a small number of high volume implanters who are seeking to be essentially bribed for their device volume. Some doctors used the word kickbacks directly, while others preferred phrases like "they'll throw a lot of money your way" or "it's basically like a reward system."

- A high volume implanter and Nevro user states doctors only use devices like Nevro's if they're **"on the dole" and that you have to "grease" them** with consulting, teaching, and other fees to get the business.

  ***"I know a doctor down the block who was doing a lot of Nevro. He only does procedures when he gets the dole**. He's now doing Abbot. **You have to grease him to get his business**. I don't operate that way and everyone knows it. Consulting is one way, teaching is another. You can get a ridiculous amount for teaching. Then they have these round tables that are junkets." - KOL*

- A second KOL described Nevro's various programs as **financial inducements and "rewards" to do more Nevro volume**, which we believe violates anti-kickback laws.

  *"Nevro will put doctors on studies because it's a way to boost income in their practices. **They'll throw a lot of money your way.** They'll put you on these consulting contracts and give you a bunch of speaking things and everything else and **it's basically like a reward system. If you're doing a lot more Nevro, you get more speaking engagements**. [Name redacted] gets a ton of seeking opportunities because they know he's very influential in the field. **Nevro was giving [name redacted] easily a hundred fifty thousand dollars a year** and they gave him stock, so you can look that up. **He openly has stock, to keep him implanting [Nevro's device]."** – **High volume KOL and former Nevro user***

- A third, a current Nevro consultant and one of their highest volume implanters, **described the wink-wink**

  *"They figure out from their rep "What does he [the doctor] like?" **Companies use those levers to engage with you** and say "**Yeah, we got these opportunities**, would love to get you on board" and talk about those things." – **KOL and one of Nevro's highest volume implanters***

Source: Consultation calls with experts

17. We believe that Nevro's business model hinges on unsustainable kickbacks to high-volume implanters

A former Nevro consultant and previously one of their highest volume implanters described their payments to doctors as aggressive and replied "100%" when asked if they were kickbacks. A second high volume implanter said the speakers program was tied to volume and that he observed reps engage in improper or illegal behavior "all the time."

- **KOL #1**

  "I know a lot of doctors who usually get $350-$400 an hour for being speakers or whatever. ***But I know that Nevro was paying a lot for consultants. I mean, a lot****. I might guess that their top dogs are making a lot more. I've heard a couple of people say* ***what they are getting from Nevro is pretty ridiculous****, but I don't know if that's the norm or that they were just special.* ***I heard anecdotally that Nevro was paying $1,000 an hour." Question: Do you think what they're doing is essentially a kickback or an inducement? "Well, I'm not an ethicist but that certainly seems to be the case. [laughs] I mean, a hundred percent. Hundred percent."***

- **KOL #2**

  Question: Have Nevro reps ever said "If you do a certain amount of volume, we'll put you in the speakers program? "Yeah, because they're just trying to feed their kids. They're saying, "If you do this, we'll take care of you." *I look beyond that because* ***I don't want to be that greaseball doc****. At NANS every January in Vegas or the INS meeting – it really depends on the doctor. Nevro can hoodwink a doctor that's just interested in revenue [..] The Nevro reps spend a lot of money on honoraria. They'll pay you to do a dinner with 20 doctors at a steakhouse.* ***Doctors like me can smell right through that. Question: Have you ever observed the Nevro reps do anything illegal or what you thought may cross the line, or is it just kind of gray? "All the time"***

Source: Consultation calls with experts

17. We believe that Nevro's business model hinges on unsustainable kickbacks to high-volume implanters

KOL's and executives in the SCS space listed various high volume Nevro implanters by name and described them as "their whore for California," "a guy who takes money," "borderline unethical what they do," doctors you could "blow the whistle on," or as "coin-operated."

***"People know I don't take money and other doctors aren't so much like that**. If you look up [name redacted] in my area on doctors for dollars he gets paid for talks. He tells reps to their face wont that **he won't prescribe unless they put him on as a speaker**. He goes 3 talks a day at $3,000 each. [Doctor name redacted] is **Nevro's whore for California. He does lots of studies for them. They promote him. He gets on their papers**. He's not part of the KOL crowd. **[Prominent Nevro implanter] is a guy who takes money."** - KOL*

***"It's borderline unethical** what they do with [name redacted]. They pay him all kinds of stock options. He runs a lot of meetings and programs. He was the head of [redacted]. He makes a lot of decisions on papers and conference presentations. **You could blow the whistle on these guys**. NANS finally beat on these guys but **they're still doing same stuff**. He's now doing that with [company name redacted]" – Key Nevro pivotal trial investigator*

*"The physician that's on stage at a society meeting is usually a consultant for the company. [Name redacted] as an example out of San Francisco, **during Nevro's rise, was one of their strongest consultants. He's coin-operated, and he will say what he benefits from, as do most of these guys**." – Longtime executive in the SCS space*

Source: Consultation calls with experts

17. We believe that Nevro's business model hinges on unsustainable kickbacks to high-volume implanters

A former Nevro district sales manager – part of the launch team in 2015 and one of the longest tenured reps in the stimulator space – described the pervasiveness and centrality of kickbacks to the stimulator space, and agreements around them as hushed and never in writing. He detailed internal conversations at Nevro about tying payments to volumes – which we believe to be flagrantly illegal under anti-kickback laws.

"The guys that you would consider key opinion leaders in the field like [3 names redacted] - ***if they weren't going to get paid, you're not working with them****. A KOL is a marketer in disguise as a physician,* ***They pit companies against each other to get more out of each.*** *They'll say, "I don't need to meet with your regional manager or VP. I want to meet with your CEO because to get me working with you,* ***I need to have high-level communications on how much I'm getting paid."***

*"****If they don't get paid, they're not in the game****. That's almost what it has become like with the big KOLs, not just with the number of implants that they do, but the clout that they have in the pain management community."*

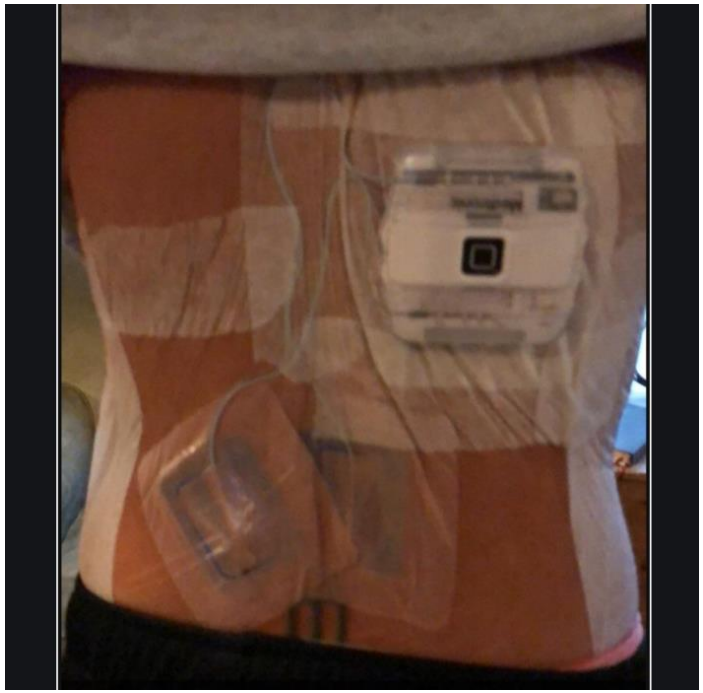
"I was privy to conversations like, you've got to make sure he does X volume over this period of time or we can't have him as a KOL*. But I don't believe it would have ever been anything in writing.* ***If the doc didn't ante up over that period of time, they would have cut him off****. The verbal conversations would never have been with the territory managers. It would have been the area vice president's, with a couple of people in the room."*

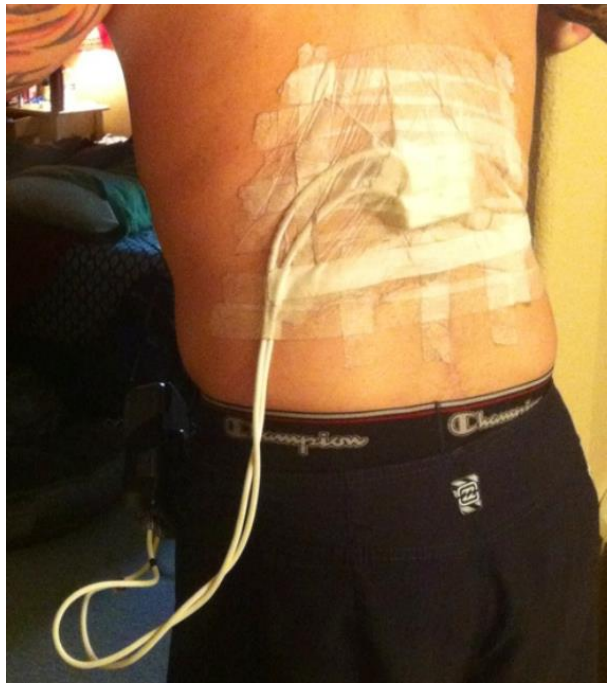
"I hoped that all of this was going to go away with clinical evidence. That's what my stupid belief was. *I truly believe* ***money trumps the evidence*** *every day of the week, unfortunately."* ***– Former Nevro district sales manager***

Source: Consultation calls with experts

18, Over-utilization, unnecessary implants, and patient exploitation are key drivers of Nevro's sales

A number of Nevro's former executives, sales reps, and KOL's described the exploitation of patients – particularly the psychiatrically vulnerable - as a key driver of the spinal cord stimulation business and of Nevro's sales in particular, portraying it as a cesspool of unethical and illegal practices with troubling incentives driving corporate, sales rep, and doctor behavior. We detail five practices: 1) pushing unnecessary trial implants; 2) pushing permanent implants even if the trial implant indicated no pain relief; 3) gaming mandatory psychiatric evaluations; 4) "flipping" implants and pushing unnecessary "upgrades"; and 5) implanters pressuring patients into simulators by withholding pain medication and other widespread, disturbing tactics. We begin by explaining what "stimulator trials" are: insurers require patients to begin with a trial period of a few days to a week, where temporary leads are attached to an external battery/generator. If the trial stimulator indicates at least 50% pain relief, the patients undergoes a permanent implant that is placed inside their body.





Trial stimulator is externally secured and the procedure is not as invasive as a permanent surgical implant

Source: https://www.reddit.com/r/ChronicPain/comments/78yt1a/started_the_spinal_cord_stimulator_trialfeeling_a/; https://nickfener.wordpress.com/2013/02/18/spinal-cord-stimulator-trial/

18, Over-utilization, unnecessary implants, and patient exploitation are key drivers of Nevro's sales

On his first earnings call as CEO, in May 2019, Keith Grossman singled out trial implants as a key lever of his strategy, declaring his intentions around "directing and incentivizing" the sales force to "grow trials" "very intensely." On earnings calls since, amorphous operating metrics about trial implant growth are used to emphasize how well the turnaround is succeeding.

CEO comments on 5/9/2019 earnings call

"Another area where we may have lost focus is around patient trials*. As most of you know, I think patients enter our treatment pathway via a trial, the success of which leads to payor approval for the implantation of our device which is the principal driver of our revenues. Our trials begin to flatten out in the middle of 2018 and this activity is obviously an important one to two quarter predictor of future implant revenues…****we have focused and reengaged our field team very intensely on patient trial growth."***

"And I think trials got kind of lost in the noise, and we simply weren't focused on it*. And I think what is encouraging is that -- is that as we have focus on it in very short order, we've seen very rapid and I think very important responsiveness to trial volume based on our results. I think that's an encouraging sign. It's also very early. And so that's something that we've been focusing on for the better part of the last two months and we've seen a very quick response but we need to we need to better understand that. But I really think it was just for lack of focus.* ***We weren't directing and incentivizing our sales force to do what they should have been doing in my view, which was to grow trials."***

Source: Nevro earnings call transcript

18, Over-utilization, unnecessary implants, and patient exploitation are key drivers of Nevro's sales

We find Grossman's incentivizing of trial implants as troubling, given that former employees and KOL's describe trials as the gateway for misuse, over-utilization, and patient manipulation. First, doctors push as many patients into trials as possible, whether medically indicated or not, given lucrative reimbursement for trials versus permanent implants. Second, sales reps then manipulate patients during the trial to push them into a permanent implant, given that the conversion ratio drives their compensation. A former rep stated that Nevro is abusing the system and his opinion that a Medicare audit is inevitable, with a KOL implying the company is "corrupt" and that clinics are "bamboozling patients."

- A former Nevro sales rep stated the company is "**not on the up and up,"** and will **"invariably be audited by Medicare,"** describing how patients are pressured, manipulated, or lied into implants.

  "There were definitely practices at Nevro that pushed patients into implants. They will invariably be audited by Medicare*. They're doing other things that are* ***not on the up and up****. In the past I worked with a couple of practices where doctors would tell patients they wouldn't get medication if they didn't do a stimulator trial.* ***I had patients show up for a visit and not know they were there for a stimulator trial****. In every town there are one to two bad eggs. They're in it for the wrong reasons."* ***– Former Nevro sales rep***

- A former high volume Nevro implanter states that clinics are "**bamboozling patients" into permanent implants** despite a lack of pain relief during the trial and implied Nevro was **"corrupt."**

  "Clinics are bamboozling patients into implanting the device when, in fact, the device during trial did not provide them adequate pain relief. This caters only to the physician cohort that doesn't really care about outcomes. *It's about how many you can implant. And if they have to be explanted, even better. It's another surgery you can charge for. Nevro's also paying probably great honoraria for the Kapural's of the world to publish this kind of bullshit data that hurts us all. They did it with Senza and now they're doing it again with diabetic neuropathy. They're shooting everybody in the foot with their practices. That's the kind of corrupt stuff that we're seeing."* ***– KOL and high volume implanter***

Source: Consultation calls with experts

18, Over-utilization, unnecessary implants, and patient exploitation are key drivers of Nevro's sales

A former Nevro district manager, one of the longest tenured reps in the stimulator space, detailed toxic incentives and a company culture of "over-aggressive" reps pushing trials and stimulators when not indicated. He implied that such misuse is "incentivized as a big part of the business" and described the "trial to perm" ratio as a key compensation driver, which leads reps to badger and manipulate patients during the trial phase. Pushing trials is a growth strategy that rests on gaming the healthcare system – which the ex-sales manager called a "wink wink". We believe that such an approach is unsustainable and bound to backfire, whether by whistleblower, regulatory, or payor-instigated blowback,

"I would say a third of Nevro's business is driven by these patients that are being pushed into a stimulator by an over-aggressive rep*. One-third of patients are the perfect candidate, one-third are 50/50, and one-third aren't good candidates."*

"You have the new pharma rep who drinks the Kool-Aid, explains it exactly how they were trained and now they're rewarded for being 10 of 10 for the trials and they're brought up on stage. But only three or four of those patients were ideal candidates and the rest never should have been implanted. But if the rep shows them TLC during the evaluation period, you can get them to permanent. ***This kind of aggressive rep behavior goes on a lot. That's a big part of the business and I think it's incentivized as a big part of the business. Wink-wink, not verbally. The companies say it's all about the patient. It has nothing to do with the patient."***

"How reps get paid is trial to perm*. If you're incentivized on trial to perm, and the doctors do 10 trials, and three of them aren't good candidates, and you're a young, hungry rep, what do you think you're going to do? You're going to go out of your way to give the TLC and talk to the brother, sister, father, wife to get to patient to do the perm. Except six months later, all those people are getting phone calls from the patient because they're not satisfied.* ***The don't measure based upon patient satisfaction. They measure the way you close your sales. I get it. I'm not arguing with that. That's just the way that it is. You're going to get the permanent implant, and you're going to get accolades because you're the new young, hot rep."*** ***– Former Nevro district sales manager***

Source: Consultation calls with experts

18, Over-utilization, unnecessary implants, and patient exploitation are key drivers of Nevro's sales

Insurers recognize that stimulator patients comprise a vulnerable population at high risk of being exploited into a device. Stimulators are typically a last resort for long-time chronic pain patients, often with multiple failed surgeries, opioid dependence, and the associated psychiatric toll and vulnerabilities. As a result, prior to a stimulator trial, patients are required to undergo a psychiatric evaluation. Former Nevro executives and reps suggested that employees game the evaluation to ensure a virtually 100% pass rate. They painted a disturbing picture of implant recipients who are "not the best stimulator candidates" and would "never pass the psychiatric evaluation"; suicidal patients calling the central support line; and patients complaining that the Nevro rep lied to them about 100% pain relief and a cure.

*"**The chronic pain patient population has a psychiatric toll. It affects 100% of patients. If a patient failed a psychiatric evaluation, the sales rep would send them to another psychiatrist. It's fair to say they get shopped around**. You don't even need to get shopped around because the psychiatric evaluation is not in depth. It's a bottleneck for time but not for volumes in the sales funnel."* ***– Former Nevro regional sales director for one of its largest territories***

"When Nevro's call center would deal with patients, we'd realize they'd never pass the psychiatric evaluation yet here we are and they have the device." ***– Former Nevro executive***

"We'd get calls from patients, hear their demeanor on the phone, and wonder how they ever got the device**. These were **not the best stimulator candidates.** Our conversations in the call center were with device **recipients who were suicidal, folks with really really high and unrealistic expectations**. They told me I'd get 100% pain relief, it would cure me, it would go away. The call center would say it's not true, it's not a cure. **I don't know if they were oversold by the doctor or rep**. Patients had unrealistic expectations of the device and therapy.'* ***– Former Nevro executive

Source: Consultation calls with experts

18, Over-utilization, unnecessary implants, and patient exploitation are key drivers of Nevro's sales

KOL's elaborated on the dynamic described by former employees, calling the pushing of stimulator trials as "straight up fraud" and "a big problem," saying that doctors "pump bodies" through stimulator clinics, particularly in high-abuse states with "giant billboards" for stimulators.

- A Nevro user described **"straight up fraud" around trial implants** and implanters who "**belong in jail"**

  ***"Trials – that's where the misuse is**. A guy in Brooklyn had a test to permanent implant ratio of 10%. He was just taping the lead to patients' backs and not even implanting the leads. **That's just straight up fraud and he belongs in jail.** That's one opportunity for abuse." – KOL and moderate Nevro user*

- Doctors doing **trials "to make money" with no intent of doing a permanent implant is a "big problem"**

  *"Doctors doing trials to make money was **a big problem**. Companies were charging $1,000 to $2,000 per lead and having doctor putting in 4 leads with **no intent to do a permanent implant."** – KOL and Nevro implanter*

- A KOL and Nevro user characterized the SCS space as **pumping bodies through clinics**

  *"There are doctors **looking to pump bodies through the clinic and install stimulators. There absolutely are**. The trial should speak for itself. I never push the permanent implant. Florida is the big abuse state not only for stimulators but opioids. **There are giant billboards on highways for cataract surgery and stimulators too."** - KOL*

Source: Consultation calls with experts

18, Over-utilization, unnecessary implants, and patient exploitation are key drivers of Nevro's sales

One KOL candidly admitted that he was "aggressive" in pushing trials and pointed to colleagues lining up "10 or 12 of them" one day a week with no intention of doing a permanent implant. Another KOL says he sees widespread abuse in his role working with an insurer, and that he just assumes that any high volume implanter is suspicious. We find this troubling as high volume implanters drive 90% of the SCS industry's revenue.

- A KOL and Nevro user who works with insurers described **widespread overuse that leads him to deny approvals,** especially by high volume implanters.

  "I work with an insurance company so I see lots of requests for stuff. ***When I see high stimulator volumes I'm suspicious. I deny a lot*** *from some high volume implanters* ***They do 5X more surgeries.*** *You can make money on the trial, but you usually don't make money on the implant. And there have been* ***a lot of patients who are just trialed for no reason by shitty doctors*** *just wanting to making money on the trial knowing full-well they're not going to proceed with the implant.* ***There's a lot of crap going on in that regard. That's been ripe for abuse.*** *" -* ***KOL***

- A KOL and previously one of Nevro's highest volume implanters **admitted to "aggressive" behavior in doing "a lot of trials" with no intention of doing a permanent implant**

  "We used to do a lot of trials and they were quite lucrative. Especially for a guy like me who did a lot and I'm kind of aggressive*, like with my billing. They used to pay us per lead. So if you put in four leads, you'd make a lot of money. I would buy the equipment myself so that's where all the money was instead of the hospital buying the equipment.* ***There were a bunch of guys that were just putting in all these trials on Medicare patients, where you don't have to get authorization. One day a week, they'd line up 10 or 12 of them****. Put the trials in and I don't know if they even cared about implanting a device after the trials."* ***– High volume KOL***

Source: Consultation calls with experts

18, Over-utilization, unnecessary implants, and patient exploitation are key drivers of Nevro's sales

Once patients are implanted with a trial, sales reps are then singularly focused on converting the patient into a permanent implant. The fact that reps interact directly with patients during this phase is troubling enough, but KOL's described far worse dynamics: Nevro reps manipulating and pressuring patients and their families, and coaching patients to lie about the degree of pain relief. One KOL went so far as to describe reps as "scum," although we caveat that we spoke with several who we found to be troubled by these abuses.

- A KOL stated that **reps are incentivized to manipulate patients** during the trial phase with leading questions and **coach them to provide false answers**

  "Leading questions are one area of patient manipulation. I've caught reps specifically telling patients what they have to say*. It's an incentive-based thing for reps.* ***Reps are very very incentivized*** *to want the permanent implant and they'll tell patients what to say. The rep will ask, what's your pain relief? A patient comes in and their pain is an eight, and after the trial implant the patients says well now it's a five. The rep says, if you want this device you'll have to say you have 50% pain relief, and you want the device right?" And the patients says, "Well I guess so, I mean, I guess it helped me a little bit."* ***– High volume KOL***

- KOL's describe **catching Nevro reps who are manipulating patients** and banning them from the room

  "I've caught reps telling patients to say they have over 50% pain relief. *I've asked reps to step out of the room while I ask patients whether the rep told them what to say. I've asked if the rep told them to use the phrase "my pain is 50%" because that's an odd thing to say. So, the reps do lead them."* ***– High volume KOL***

  "I've caught Nevro reps steering patients with leading questions a number of times. That's why I don't let them in the room anymore *when I talk to patients. I want to ask what the patient's pain level is. I want to talk to the patient before the rep goes in.'* ***- KOL***

- A high volume KOL described **stimulator reps as "all the same scum."**

  "Neuromodulation reps are all the same scum*. Maybe that's an overstatement. I just look at the reps that I interface with."* ***– KOL and former high volume Nevro implanter***

Source: Consultation calls with experts

18, Over-utilization, unnecessary implants, and patient exploitation are key drivers of Nevro's sales

One KOL stated that Nevro reps were the worst offenders in badgering and manipulating patients during the trial. Another opined that Nevro began pressuring reps more so in the last 18 months to push implants when not medically warranted, which we note coincided with about when Grossman came on as CEO and began to push trials. He added that the industry is "not well regulated."

- A KOL stated that **Nevro reps bombard patients** during the trial phase

> *"**Reps will hammer patients with questions**. I might do a trial implant on a Friday and have the person come back on a Monday for a visit halfway through the trial. Typically, a [non-Nevro rep] will call the patient once on Saturday and once on Sunday to see how the patient is doing. The rep will text me the next day and say thumbs up Mrs. Johnson or I think the leads moves with this person. **According to my patients that have a Nevro trial, they'll get on average of ten calls over the course of two days**. "It's working right? Is it working? Is it working? What do you think the pain level is now? What do you think?" They try to call the patients and send them these nice little bar graphs to show the patient that their pain was an eight and now." - KOL*

- A KOL and Nevro implanter indicated that the company, **more recently began pressuring reps to allow implants when not medically warranted** and bemoaned the lack of regulation.

> ***"Nevro was strict on patient selection early on then they started recommending their device for everything. They overshot**. A doctors says to a rep, I have this patient with low back pain and no prior surgery, I'm going to try scs. The rep should say that's not in guidelines. There's no evidence, no clinical trial for that. But the rep doesn't do that. This started one and a half years ago. **I've dealt with different Nevro reps. There's pressure on them. They have to generate X number of patients. The industry is not well regulated."** - KOL*

Source: Consultation calls with experts

18, Over-utilization, unnecessary implants, and patient exploitation are key drivers of Nevro's sales

KOL's and former executives outlined the distorted financial incentives that lead to abuse around trials. Trials are extremely lucrative, while permanent implants may lose money. Doctors therefore push patients into trials with no intention of doing a permanent implant. The problem is exacerbated by doctor-owned ASC's which drive the vast majority of stimulator volume.

- A former Nevro executive stated that **doctors make far money for a trial than a permanent implant**, leading them to proliferate trial volumes.

  *"**Pain doctors don't make a lot of money implanting stimulators. They make more money trialing. You can make thousands of dollars trialing a procedure**. In the past you used to be paid per electrode, so Boston Scientific created a 16 electrode lead and the government figured out what was happening and then they reimbursed by lead not electrode. **You can make $5,000 to $8,000 for a trial and a couple of hundred to a couple of thousand for implantation. It's not very lucrative to implant**. It's always been that way." –* ***Former Nevro executive***

- Nevro's stimulators are **mostly implanted at doctor-owned ambulatory surgery centers (ASC's)** which greatly magnifies the incentivize to **push and overutilize trials and stimulators** versus hospitals.

  *"I'd say the majority of stim is done in ASC's, in the pain world. **If you own your own ASC you're more likely to push stim therapy and stim trials and implants on your patients**. If you are a hospital employee, you're likely to not care as much and your utilization is going to be far less for a given hundred patients." –* ***One of Nevro's highest volume KOL's***

Source: Consultation calls with experts

18, Over-utilization, unnecessary implants, and patient exploitation are key drivers of Nevro's sales

KOL's indicated that the problem is so pervasive that patients are then stranded and dumped as the doctor who did the trial has no desire to do a permanent implant. Doctors who receive these patients then either reject them since a stimulator was never medically appropriate, or lose money as most of the money is in the trial and not the final implant.

- A KOL indicated that while **doctors always make money on trials**, it's hit or miss for permanent implants by payor, **creating incentives to dump the patient after the trial.**

  "With the trials, you always make money. For the implanted device, it really depends on which payer*. Private insurances, workmen's compensation in New York, very rarely you'll make money. And Medicare is also a wash. I'll see patients a lot where I know a pain doc will send me the patient, and I know they do their own implants, and I know the reason they send them: because it's not a good insurance for them, but they want it done. If a patient comes with Medicare, and I do the trial and I do the implant, the hospital will do okay financially; they won't lose money.* ***If a trial is done somewhere else and we do the implanting, the hospital will lose money, so there are a lot of situations like that."*** *- KOL*

- Another outlined a **pervasive pattern of doctors pushing trials onto patients who "shouldn't be implanted,"** fueled by sales reps, and **then stranding them.**

  "I get patients for implants that, quite frankly, shouldn't be implanted*. Referring doctors will send me a patient that they trialed.* ***They really just did the trial, and the patient claims they were better, and I will literally refuse to do it.*** *There are people out there, because the trial can be done rather easily. They're all out there. They're all the reps. They all get paid on commission.* ***What they're doing is, "I'll do the trial and make money in my surgery center. I don't want to do the implant because I'm not going to make money on it."*** *I do see patients where you have an ethical dilemma, which is this doctor did a trial, and I just don't believe that this is going to work. And you're stuck." - KOL*

Source: Consultation calls with experts

18, Over-utilization, unnecessary implants, and patient exploitation are key drivers of Nevro's sales

Former executives and reps revealed a key lever by which Nevro fans these flames. On top of aggressively incentivizing reps to convert patients from trial to permanent implant, doctors are given free or low-cost trial leads, creating a powerful financial motivation to jam patients into trial stimulators. The wild west dynamic is far from a bug: it is a feature specifically engineered, in our opinion, to promote over-utilization and the abuses that KOL's describe.

- A former Nevro executive stated that **trial leads are basically given away**

  "Trial leads are often given to a facility for like $100, sometimes even less. They're trying to incent physicians to do trial leads. ***The idea from a company's perspective is that if we get the trial we're going to sell a stimulator for $25,000. There are those sorts of things that are happening****. Centers negotiate very low prices on the actual trial leads themselves. They're just trying to maximize their margin and some physicians leverage the number of trials they do to get the lowest price, so if they don't get $100 from Boston Scientific they will go to Nevro or Medtronic might give them free trial leads."* ***– Former Nevro executive***

- A former Nevro district manager explained that **low-cost leads enable doctors to make almost $10,000 on a trial**, creating a powerful motivation to implant patients who are questionable candidates

  "A lot of doctors own a surgical center and ***Medicare reimbursement at ASC's for doing a trial is $4686 per lead****, and how much are the companies selling the leads to the surgical centers for? Say $500. So, you do two leads, you can buy it for a thousand, now you've gotten back 100% of $4686 times two or* ***let's just say $9000,*** *but since it's Medicare, Medicare pays 80% of that, and then hopefully they have a co-insurance, and the co-insurance picks up the 20% that the Medicare does not.* ***So, now I'm an ASC owner, and I'm a doctor. What do I do when I see those questionable patients and injection pays $30?"*** ***– Former Nevro district manager***

Source: Consultation calls with experts

18, Over-utilization, unnecessary implants, and patient exploitation are key drivers of Nevro's sales

Aside from pushing trials and permanent implants onto patients who don't need them, former Nevro sales reps described another troubling revenue driver: pushing unnecessary implant upgrades. Reps questioned the ethics of the company's push, stating that repeated implants and removals at the same site led to infection risk. One estimated that 25-50% of Nevro's revenue comes from surgery centers pushing patients into "one stimulator and then another and then another."

- A former Nevro territory manager, part of the original launch team and one of the most experienced reps in the SCS industry, estimated that **25-50% of the company's revenue comes from pushing replacement devices via ASC's seeking to profit.**

  *"Yes, yes, yes - some of the growth is that **patients are getting one stimulator and then another and then another** as the new ones come out. I don't think Nevro, coming out of the gates in 2015, thought a lot of the market was repeat business. I think they didn't learn that until they started down the road of being in the business of it. I'll be conservative and say 25% of the market is repeat business and the more aggressive number is 50%. Why? Because if you're an ASC owner, by changing the battery, there's revenue involved. If you don't change the battery, there's only the professional fee and a small fee for doing the movement of the battery."* ***– Former Nevro territory manager***

- A former **Nevro sales rep "didn't like the ethics" of the company's push to sell upgrades**, subjecting patients to **infection risk from repeated implants** in the same location

  "We were pushing replacements of old devices**. A number of things can go wrong when you open up the pocket where the device is implant. You're automatically not MRI-compatible and these patients need MRI's. **There was a push to sell upgrades when I was there. I didn't like the ethics. There's infection risk when you do the surgery." ***– Former Nevro sales rep***

Source: Consultation calls with experts

18, Over-utilization, unnecessary implants, and patient exploitation are key drivers of Nevro's sales

Exploiting individual patients are sources of recurring implant revenue is so prevalent that one KOL described stimulators as simply "a lease that you trade in." An executive in the space described the practice as "flipping implants." Disturbingly, reps describe pain practices seeking to profit from both multiple implants as well as multiple removals in the same patient, which one said is "like going long and short."

- Repeated implants are so prevalent that one KOL **described stimulators as just "lease that you trade in,"** implying the industry is run by the same questionable doctors who fomented the opioid crisis

  *"Stimulators have a **reputation as a lease that you trade in**. It's probably the same guys who were selling opioids. They're not the academics, not the ones coming to conferences and meetings."* ***- KOL***

- A longtime C-level executive described it as "**flipping implants" whether patients need a new one or not**

  *"One of their top reps is in [city redacted], **Whether a patient needed it or not, he had his doctors flip those implants**. He did $6-7 million in revenue in one year just because of those flips."* ***– SCS executive***

- KOL's and territory managers described pain practices **seeking to make money on repeated device removals** in the same patient, on top of reimbursement for the repeated new implants

  "Medicare pays them to do the explant. If Medicare doesn't pay, I guarantee they won't explant. ***They get paid on both sides. It's like going long and short. Premier Pain will put them in, take them out, put them in, take them out."*** ***– Territory manager at a large Nevro competitor***

  "There's a whole group of doctors down the street. ***They suck patients in.*** *They implant the device at their surgery centers because they can make a fat amount of cash.* ***They put it in and if they explant it, who cares? An explant is just another surgery they can bill for****, so let's take it out."* ***– High volume KOL and former Nevro implanter***

Source: Consultation calls with experts

18, Over-utilization, unnecessary implants, and patient exploitation are key drivers of Nevro's sales

A former Nevro executive shared his dismay at patients being "flipped" and painted a sordid picture of "bad actors" hustling patients into the company's stimulators and threatening to cut off their opioid refills as leverage to force them into the device. As a longtime executive in the stim space, he stated Nevro implanters were particularly notable for not caring "what happens after the implant." He further described Nevro struggling to find new care for patients ditched by their implanting doctor, highlighting the dynamic we covered earlier of doctors dumping patients en masse after making money on the trial or permanent implant.

*"There are definitely some doctors —**they're business spend first—that's probably the easiest way to describe it**, and they really know how to maximize every patient that walks through that door. **So, they switch them to Nevro**. Bad actors are putting in implants over and over and switching brands. Selling that patient on there's something better, **always keeping that carrot out there**, that there's something new, there's something different that might be the magic pill. And then he also says, **if you don't do what I recommend, I'm going to cut you off from your opioids**, so there's that."* ***– Former Nevro executive***

"Doctors ditching responsibility – we saw quite a bit of this**. We'd get pushback when we'd go back to the doctor who did implant. The doctor didn't want responsibility when Nevro's group opened an investigation. We were like, what the hell. You put it in, how are you not supporting the patient? **We'd end up with patients with an implant and no doctor who wanted the responsibility.** Then a doctor would say, I don't want responsibility because I didn't implant it. It's reflective of the neuromodulation space."* ***– Former Nevro executive

*"At both [key Nevro competitor] and Nevro, I saw doctors that only did trial implants because they could bill for it and wanted no responsibility for the patient after. Then I saw doctors who only did permanent implants but don't want to be the provider for the patient. **The doctor would put it in but take no responsibility after. I experienced more of this at Nevro. The doc doesn't care what happens after the implant."*** ***– Former Nevro executive***

Source: Consultation calls with experts

18, Over-utilization, unnecessary implants, and patient exploitation are key drivers of Nevro's sales

One of Nevro's highest volume implanters elaborated on pain practices threatening to cut off monthly opioid refills to pressure patients into stimulators, and estimated that a stunning 30% or more of implanters in his region – one of the largest metro's in Florida – are bad actors. He stated that main source for stimulator patients are pain clinics that also traffic in opioids, which doctors use to "bait" patients into stimulators. He noted that as the state cracked down on opioid abuse, stimulator volumes declined. Another of Nevro's highest volume implanters, in New York, described New Jersey, Texas, Florida, and Louisiana as notable pockets of abuse, and stated that companies like Nevro are happy to engage with "those docs if they see some legitimacy of usage."

*"**The number of stimulator patients declined because in Florida, unfortunately, there are a lot of bad actors** and there were a lot of people on pain medication that shouldn't have been and a lot of the patients that funneled into stimulators were those. **Their bait is to offer medication, and once patients were engaged with these drugs, they would do whatever was financially appropriate for themselves**, so those are the bad actors. When a patient is on opioids, they have to come in monthly which gives the doctor the chance to convince them to do anything or otherwise their opioids will get discontinued. **We saw that occur for years. That's really bad. Yeah, it is a complicated situation**. If we're talking about my region [large metro redacted] I would say that **at least 30% of the doctors implanting stimulators are bad actors."** **– High volume Nevro implanter in Florida***

*"**New Jersey is probably a pocket of abuse.** They have a high rate of usage in the workers comp and Medicare population and then you see it a lot in Texas and Florida and Louisiana. They're doing a high rate of trials, a high rate of implants. They have surgery centers and have a very high rate of usage of any interventional therapy, stim included. **You do a lot of injections, then you do your stim and then you continue your injection and then maybe revise the stim or you swap it out or put something else and that kind of stuff. Stimulator companies are happy to engage with those docs** if they see some legitimacy of usage." **– High volume Nevro implanter in New York***

Source: Consultation calls with experts

19. Nevro's business model is predicated on employees engaging in the unauthorized practice of medicine

Investors are oblivious to one of Nevro's greatest risks: its business model, far more than any other stimulator company, is predicated – in our opinion – on reps and other employees engaging in the unauthorized practice of medicine. Giving medical advice or treatment without a professional license is a criminal offense. While sales reps in the OR are a common, albeit disturbing, practice in the spine implant industry generally, we believe Nevro reps traffic in more aggressive and dangerous terrain: exercising medical judgment and/or participating in treatment. We begin with a former Nevro district sales manager, part of the launch team, who stated that reps spend only 20% of their time on sales and 80% in the OR or programming or reprogramming patients. If his description of reps' role before, during, and after the implant is even half accurate, we believe Nevro is one internal whistleblower or inquisitive DOJ attorney away from its business model imploding.

"In an average territory with an average team, ***they're spending 40% of their time in the OR. They're spending 40% of their time reprograming and patients visits and 20% of the time on sales.*** *The rep is in the OR so we see the patients pre-op. Average procedures may be an hour. You're in the operating room. You open up the box to make sure that we're using the right stuff because* ***we're still the so-called experts [versus the doctor]. We take images of X-rays. We do inter-op tests to make sure that the leads are in the right area****. The patients go down to post-op and we show them how to use the device, so probably three hours for an average case.". –* ***Former district sales manager***

Question: Are reps helping with lead mapping or placement, or it just depends how skilled the rep is?

"Yup, you're exactly right. It depends on the amount of experience and how much the doctor leans on them. ***Inter-operatively, most doctors will say [to the rep]: "How does that look?" "Do you think that the lead placement is fine looking at the X-ray?' "Looking at your testing that you're doing right now, do you think we're good?" And then the rep and the doctor will make that decision on if the lead should be moved up or down or if they think it's good. I'd say the most experienced reps have a big say once you go within the operating room, because 10% of what doctors do are spinal cord stimulators, but 100% of what we do are spinal cord stimulators."*** ***– Former district sales manager***

Source: Consultation calls with experts

19. Nevro's business model is predicated on employees engaging in the unauthorized practice of medicine

A KOL took the rep's characterization of his role even further, and stated that stimulator reps have a "very unique" role versus typical reps because "You have clinic hours" and "You actually have patients." He stated what reps are "legally, ethically, appropriately" supposed to do versus their actual conduct. A second implanter, one of Nevro's highest volume users, stated that he simply outsources patient care to reps if they still have pain after implant. He stated that reps use x-rays to diagnose the patient and to re-program the device, and that if the rep fails, that a central call center – the "Therapy Optimization Team" – takes over.

*"**Programming is usually done by the rep**. I have a programming computer, but the reps do it all day long. **Legally, ethically, appropriately, the rep is supposed to meet the patient in my office. The reality is that some of them meet at the patient's house. They're not supposed to do that**. They'll go to their house and they'll hook up their programmer and they'll program right there." - KOL*

Question: "Isn't that kind of a risk? A rep isn't licensed to practice medicine."

*"Who has more experience programming the device - me or somebody who spends their entire life programming stimulators? **Being a stimulator rep is not like being a pharma rep selling Viagra. You have clinic hours. It's a very unique sales position. You actually have patients. You actually come into clinic.** I'll walk by a room and go, oh, Mike the rep is in room three and he's programming somebody. Cool, I didn't even know. I can make recommendations to reps but they're really the experts in programming." - KOL*

*"**If a patient is not responding or the pain comes back, I have the rep come talk to them**. They can check in a rough way whether the leads have moved so in most cases, **they get an X-ray of the leads** before they come in so they have a better idea of how to program it. If it's just that the therapy has diminished, **then Nevro has a special group of clinical specialists that manage those cases remotely and guide the representatives** on what to do if they cannot solve the problem themselves. Now, if everything is in place and everything is functioning as expected, but a patient is not getting pain relief, that's when they start trying other programs and they start engaging the Therapy Optimization Team as Nevro calls it.' – **High volume Nevro implanter***

Source: Consultation calls with experts

19. Nevro's business model is predicated on employees engaging in the unauthorized practice of medicine

A former Nevro executive described the role of the central patient support and programming team – and that of reps generally – in a manner we believe to be identical to the practice of medicine: having "a list of patients they were in charge of"; "high patient contact"; using trial and error to direct the correct dosage of stimulation. Determining dosage goes to the heart of practicing medicine. He stated that this central team was unique to Nevro's business model and driven by the programming-intensive nature of high frequency. We particularly note the role of reps and the central team in managing side effects such as "over-stimulation" – given the complex and multi-factorial nature of pain management, we question how reps are making clinical diagnoses of "over-stimulation" and determining its cause and treatment.

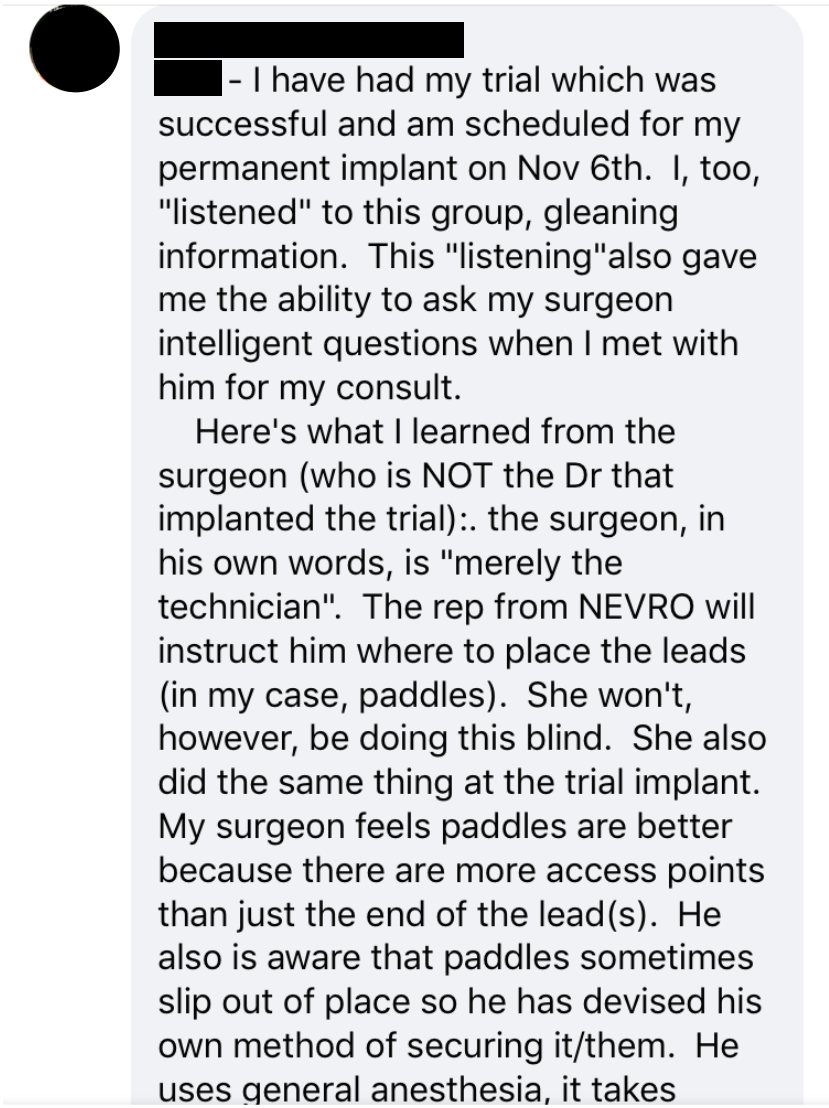
"Nevro put together a brand new patient support and programming team. It's role was to work with patients, call the patient on a daily basis, and advise the patient to turn the stimulator on or off. It was a big organization. ***They would have a list of patients they were in charge of.*** *They would call them daily during the trial, right after, after the procedure, to make sure the stim is set correctly.* ***No other neuromodulation company had that. It was unique to HF10****. A lot of times the patient had to be patient.* ***We'd lower or increase the stimulation. We'd start at a low frequency, would wait 24 to 48 hours, would increase it by 1, then wait, then increase it again. For one algorithm, you'd spend a week and a half just on that algorithm. The reps would ask on the phone if you're getting pain coverage, take notes, then add 3 milliamps.*** *They'd have to go through this over the next 3 to 4 weeks to get correct coverage. If they didn't get correct pain coverage, they'd have to bring the patient back in for reprogramming to see which programs work or don't work."*

*"****Nevro had high patient contact. They had to develop a structure to support patients because high frequency stimulation didn't result in immediate feedback to the patient****. With low frequencies, the patient gets immediate feedback. With HF, there's no paresthesia and feedback. You have to change the program, then wait 24 to 48 hours.* ***Overstimulation exceeds the patient's problem threshold****. The patient then says I'm in worse pain now than before the surgery.* ***We'd need to turn off the device for 24 to 48 hours and shut the patient down to wash the stimulation out of their system."*** ***– Former Nevro executive***

Source: Consultation calls with experts

19. Nevro's business model is predicated on employees engaging in the unauthorized practice of medicine

One Nevro patient, in a Facebook support group, described what her surgeon told her: that "the surgeon in his own words is 'merely the technician'" and the "rep from NEVRO [patient's emphasis] will instruct him where to place the leads."



[redacted] - I have had my trial which was successful and am scheduled for my permanent implant on Nov 6th. I, too, "listened" to this group, gleaning information. This "listening"also gave me the ability to ask my surgeon intelligent questions when I met with him for my consult.

Here's what I learned from the surgeon (who is NOT the Dr that implanted the trial):. the surgeon, in his own words, is "merely the technician". The rep from NEVRO will instruct him where to place the leads (in my case, paddles). She won't, however, be doing this blind. She also did the same thing at the trial implant. My surgeon feels paddles are better because there are more access points than just the end of the lead(s). He also is aware that paddles sometimes slip out of place so he has devised his own method of securing it/them. He uses general anesthesia, it takes

Source: Facebook support group for Nevro patients https://www.facebook.com/groups/213633049377315

19. Nevro's business model is predicated on employees engaging in the unauthorized practice of medicine

Two former Nevro executives elaborated on why "reps engaging in the practice of medicine has always been the concern," suggesting that the risk is known inside the company. One stated that programming their device is so time intensive that the company's entire value proposition and business model are predicated on doctors outsourcing patient care to Nevro. A second stated that Nevro's reps and clinical specialists are "not health care providers in any way, shape, or form" but are "responsible for the care of patients." He added that patients would be "pretty concerned" if they knew the credentials of these employees. He added that it's illegal in Europe for reps to program stimulators, and that Nevro's US model is "weird" and requires "huge overhead."

"Reps engaging in the practice of medicine has always been the concern**. It's very time consuming to schedule the patient with a doctor to reprogram them. **A majority of the doctors don't know how stimulators work or how to program them. The rep is in the operating room doing the programming. The doctors are not involved** in the programming. They understand at a high level that they're driving a current through the spine. From a technical standpoint to use the programmer or remote control, not so much." **– Former Nevro executive #1

"Doctors don't want to give up office space to have patients to come in. They might have a portfolio of several hundred patients that need reprogramming**, who they'd have schedule and reschedule, which would tie up a lot of office space." **– Former Nevro executive #1

"They're not health care providers in any way, shape, or form. Some of them are not educated in medicine** or science at all, and **they're responsible for the care of patients. You can say that's definitely not a great thing**. If the patients knew what the credentials of some of the caregivers are **they would probably be pretty concerned."** **– Former Nevro executive #2

"In Europe because of regulations, reps aren't allowed to interact with the patient. Programming has to be done by a physician**, so healthcare professionals there have learned how to program the patient. In the US having manufacturers on the hook for support is not realistic. **It requires a huge overhead to maintain and support a neuromodulation business. It's a weird model**. Whenever you send a rep to program the device, the manufacturer is not getting paid. The rep spends two hours programming." **– Former Nevro executive #2

Source: Consultation calls with experts

19. Nevro's business model is predicated on employees engaging in the unauthorized practice of medicine

We conclude this section with comments by another KOL, one of Nevro's highest volume accounts, who also expressed his discomfort with reps engaging in the practice of medicine, stating that "the rep is kind of an extension of your practice." Aside from the obvious reasons why handing off patient care to reps without medical qualifications is indicative of a questionable business model, he outlined the dangers from reps caring more about their commissions than their patients, such as lying to doctors about how patients are actually doing and feeding "misinformation."

Question: "Do you have any concern about reps engaging in the practice of medicine?"
"I do and I always debate with myself about whether I should even have the rep in the room when a patient discussion is going on. It is a valid concern. The rep is kind of an extension of your practice. I've seen some really egregious things *where the feedback is really negative about what the rep did in terms of steering a patient that was unsure and pushing them towards implant. The reps will certainly try to be there every time because that's their opportunity to steer the conversation.* ***My concern is that they're potentially doing things that I don't like****, on the phone with he patient.* ***Sometimes practices don't have a bandwidth to engage with their patient every day for a week****. The rep gives text message updates saying "Hey Mr. Jones is going great" and then you call Mr. Jones and he's like "Oh no I am doing terrible. I don't like this". Sometimes the doc is not really paying attention.* ***They start to get misinformation."*** ***– KOL and high volume Nevro implanter***

Source: Consultation calls with experts