Twitter Thread by Harvey ■■



Harvey ■■
@realharveymark



Okay hope everyone having a lovely weekend. Lots of love today. Feeling very blessed ■ Going through NNOX tweets from last week. Time to compile threads and bring you highlights. No need to go digging old tweets if I do for you ■ FDA, Secondary, and 3P510k. Let’s review..

The NNOX news flow been exceptionally good. I tweet about Fear Uncertainty Doubt and how short sellers leverage friction in news flow to mine some of your gains. NNOX published Form F-1/A to remove friction. Investors have answers.

Form F-1/A Link: https://t.co/RQcYLFMXQO

Form F-1 is over 200 detailed pages. Very concentrated. Everything you need for rest of this month in the document. A few notes for you. NNOX FDA approval uses a third party review organization in 510k process. This is abbreviated to 3P510k.

I covered the 3P510K in thread here: https://t.co/w7zE882CVk

Reference to Eagle eyes: https://t.co/gT779MFX82

We discover in F-1 that 3P510K recommended clearance of Nanox Source. This triggers a 30 day timeline to approval by FDA. However ...

> Eagle-eyes \U0001f985 https://t.co/w1wF3Ysmt1
>
> — Harvey \U0001f1fa\U0001f1f8 (@realharveymark) February 12, 2021

Look at you favorite broker news for NNOX. I look at 3 different broker none of them comment NNOX from 60 to 80 on news that 3P510k recommended FDA approve NNOX device. NNOX get a letter and slide 10% we get headline. But no headline for big pop ■■■■ that’s the friction.

As cover in Eagle-eyes thread, FDA has 30 days to approve after recommend clearance from 3P510K. Form F-1 state recommend clearance issued 28 DEC. But FDA send letter to ask question. NNOX reply 3 days later 4 JAN. End of Jan FDA send deficiency letter regard predicate devices.

Predicate device is an existing device already approved and currently on market. Something to compare Nanox Source to. When FDA issue deficiency letter it reference comparability with predicate device and Nanox.ARC. This how we must approach 3P510K 30 day window & FDA decision

A thread on 3p510k: https://t.co/Qj80xn00pI

The short thesis destroyed by the recommend clearance. Go back see where NNOX trade before short report. You will recognize the number. Okay you see the number approx the analyst price targets and secondary pricing.

> NNOX here\u2019s a link about FDA Third Party Review Program. https://t.co/hlrrlXi6Us
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> "The FDA's review timeframe for a MDUFA decision is within 30 days after receiving the recommendation of a 3P510k Review Organization."
>
> — Harvey \U0001f1fa\U0001f1f8 (@realharveymark) February 11, 2021

Good question: why has FDA still not approve? I do not know but I share before I think it about classification of device. Class II ideal otherwise it Class III. This is covered in F-1. You may now recognize “de novo”. This is contingency plan Nanox has if FDA classify Class III

What will “de novo” and Class III mean and how likely? It is not likely but def possible. You smart so you like to know risk exposure. That why I mention. I know you too smart to trade blind. But suppose Class III is FDA decision. NNOX goes “de novo” with approx 150 day timeline

Here’s a tweet from thread about 3P510K: https://t.co/MBS6pK4L7n

I typo 99 mean pg 97 but this covered in F-1. Nanox has mapped this out fully and tell you exactly what to expect.

These are two important NNOX points. 3P510K 30 day, FDA classification decision covered for you

> The \u201cde novo\u201d process is a risk-based classification determination means low to moderate risk novel medical devices can have route to market. Okay this is contingency talk. This is a short seller dream scenario. FUD gonna get all over everything but not you. You go to F-1/A pg 99
>
> — Harvey \U0001f1fa\U0001f1f8 (@realharveymark) February 11, 2021

30 days tweet: https://t.co/6gFP3QQ92x

Tomorrow FDA will publish all approvals that occur last week. It very possible NNOX is there. Maybe 60% chance

> 30 days \U0001f60e https://t.co/Qj80xn00pI
>
> — Harvey \U0001f1fa\U0001f1f8 (@realharveymark) February 12, 2021

We get the approval news in February given the 3P510K and prompt response from Nanox. We get an earnings report and q&a with NNOX, too. Lots to keep in mind. FDA approval, submit multi source to FDA, progress on MEMS chip facility in Korea with SK Hynix, deals after RSNA, and AI

imo it better to get FDA news next week not tomorrow. Get past secondary. So tomorrow we do not get approval news we Big Smilin because we let them beat up NNOX so we get better entry before approval news official. BUT we careful and cautious because we know Class III possible

Okay back to wifey now she rested after morning of love ■ I hope this thread help you organize you thoughts about NNOX. My timeline full of gems. Enjoy!

@threadreaderapp please unroll NNOX lovely thread