Twitter Thread by Sahil Sharma

Sahil Sharma
@sahil_vi

#neulandlab ■■ read on to understand this company and its story of transformation. On twitter, ■ has become synonymous with neuland, and this is how i will use it throughout the thread. If you like the thread, plz retweet & help fellow investors learn

Starting with a simple primer on the Pharma industry. They make medicines for all of us. The part of the medicine which gives it its potency against the ailment it cures is called API: Active Pharmaceutical Ingredient:
https://t.co/B02mlcRXGu
https://t.co/PWgpHwK6NG

(here is a reference few people will get, but have to make it since I love it :D):
If Guardians of the globe (https://t.co/vH2C1TDbPy) were a medicine, Omniman (https://t.co/0DGb1MAtXN) is the API.

@InvincibleHQ Back to ■. There are pharma companies which sell APIs as well as the finished medicine (FDF: Finished Dosage Formulation). Neuland are pureplay API manufacturers. This provides them some advantage since they don't compete with their clients (the FDF makers).

@InvincibleHQ Medicine is diverse. There are medicine which were first discovered in 1920s (https://t.co/6DXNrhOK46), to those being created now (https://t.co/tcr7dAexmO). Naturally then, some of this involves very complex chemistry to manufacture, others are relatively easier to manufacture.

@InvincibleHQ Those that are easier to manufacture naturally have a larger number of competitors manufacturing them. End up becoming commoditized with prices being dictated by market dynamics. These are what constitute the GDS: Prime API segment for ■

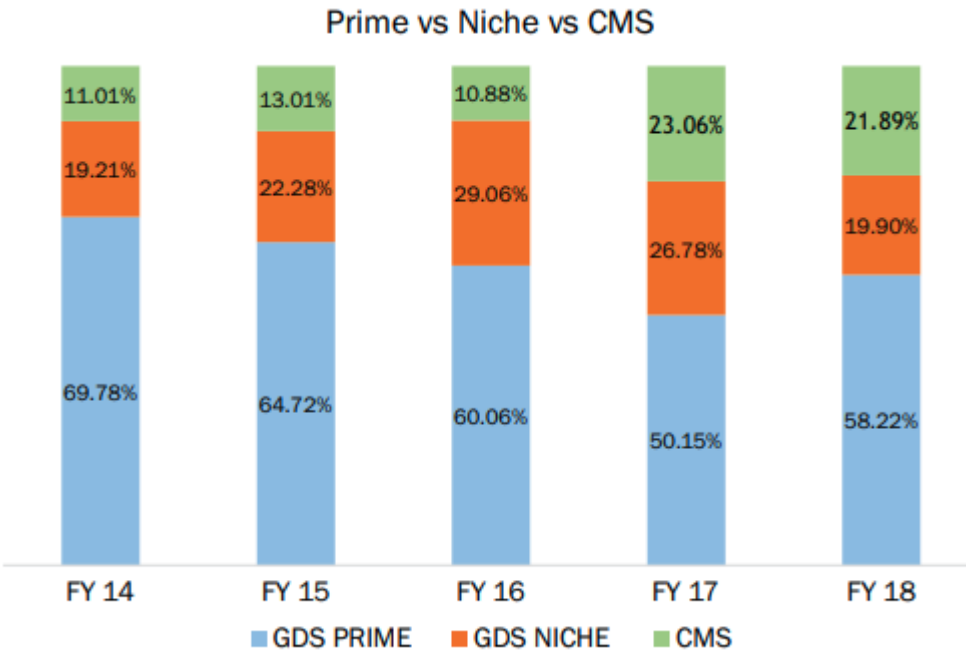
@InvincibleHQ These are typically also consumed and produced in high volume and entry barriers being low, are priced low.

@InvincibleHQ Those that are a bit harder to manufacture, and produced in low volume, higher price per unit, constitute the specialty API segment. Higher pricing power here, but limited by the competitive environment.

@InvincibleHQ There are those APIs that ■ manufactures custom for a customer these come under the CMS segment (Custom Manufacturing Solutions). Often, these are innovator companies, and the molecules are APIs for newly discovered molecules.

@InvincibleHQ An innovator typically only has 1-2 suppliers for a molecule since secrecy is of utmost importance. See @unseenvalue Sajal sir's Webinar to understand this space best:
https://t.co/ufr9SrYgJG

@InvincibleHQ @unseenvalue Story of ■ #neuland is a story of transformation from being a bulk API manufacturer to switching towards more higher value, difficult to make products: specialty (low volume high complexity) generics API manufacturing as well as CRAMS [custom synthesis and innovator synthesis].



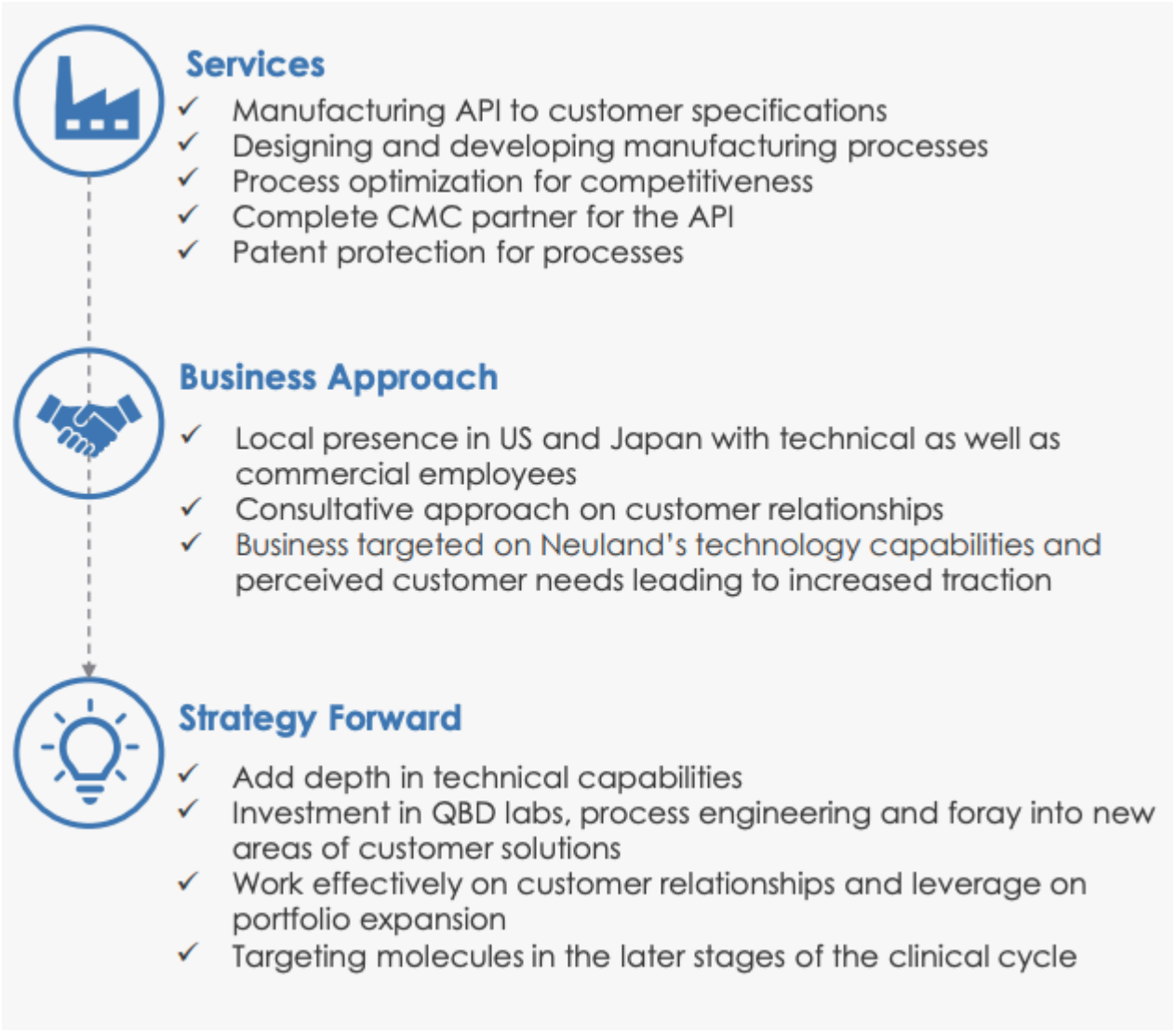
@InvincibleHQ @unseenvalue Let us analyze each business segment now. Starting with Prime APIs. First, you might ask, why do they make Prime APIs, since margins are volatile. This is for 2 reasons: as a strategic decision, #neuland always wants to maintain supply commitments to clients.

@InvincibleHQ @unseenvalue They want to be a dependable API supplier of choice. Second, prime APIs provide volume stability. If Neuland stopped making these, revenues would reduce dramatically. Will improve margins here through operational efficiency and scale.

@InvincibleHQ @unseenvalue Specialty APIs. Strategy here is to focus on high entry barrier molecules, complex chemistries, bring innovation to the process chemistry by improving eco-friendliness, cost efficiency, ease of handling, purity. ■ then files patents to protect their process IP

@InvincibleHQ @unseenvalue CMS. This segment is fastest growing. Poster boy of this segment is the deutetrabenazie API for Austedo (https://t.co/bgoscPHIpx) medicine produced by innovator Teva for treating cholera in patients of Huntington's disease
https://t.co/ywIZxKVm1f

@InvincibleHQ @unseenvalue CMS revenues have gone from 50 cr in FY14 to 270cr in FY21. That is a CAGR of 27%. Neuland wants to grow topline at 15-20% overall. So we can see where most of that growth is coming from.



Lifecycle of a molecule consists of pre-clinical studies (eg: on animals), stage 1, stage 2, stage 3 trials, development, and commercialization. Neuland management clearly communicates the status of CMS projects/molecules each Q.

Number of Active CMS Projects

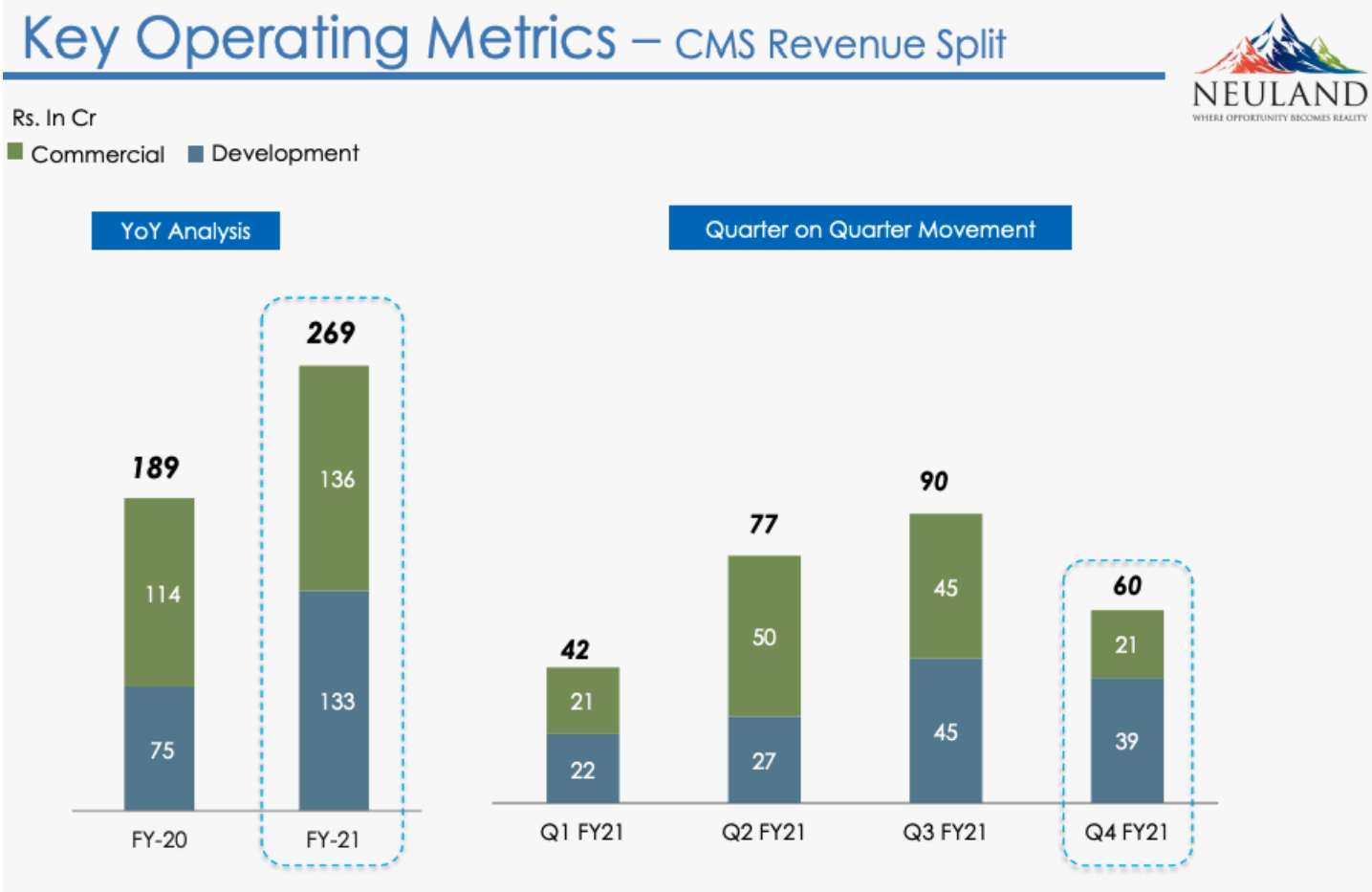
Q4 FY21	Pre-Clinical	P-1	P-2	P-3	Development	Commercial	Grand Total
API	15	3	7	3	12	6	46
Intermediate	7	4	2	0	8	11	32
Grand Total	22	7	9	3	20	17	78

Q4 FY20	Pre-Clinical	P-1	P-2	P-3	Development	Commercial	Grand Total
API	12	4	5	5	9	6	41
Intermediate	7	4	2	5	8	9	35
Grand Total	19	8	7	10	17	15	76

Q4 FY19	Pre-Clinical	P-1	P-2	P-3	Development	Commercial	Grand Total
API	10	4	2	4	5	5	30
Intermediate	0	2	0	6	8	10	26
Grand Total	10	6	2	10	13	15	56

Q4 FY18	Pre-Clinical	P-1	P-2	P-3	Development	Commercial	Grand Total
API	7	2	3	4	5	5	26
Intermediate	1	1		7	0	5	14
Grand Total	8	3	3	11	5	10	40

Those 6 commercial APIs contribute half the CMS revenue, and all other projects half. Management has guided for 6 more APIs in last stages of development to be commercialized in next 2-3 years. What will happen to revenue when that happens?



All of this you could have learned by going through seminars and some investor presentation. Let us now deep dive into the quality and scientific capabilities of Neuland which is what make it a promising investment. Can think of these are durable competitive advantages.

Regulatory Compliance
For anyone to sell APIs in USA, they need to file Drug Master FIle (DMF) which is a description of how they will manufacture the APIs to USFDA (US Food&Drug Administration).

If USFDA approves DMF, then API manufacturer can sell APIs to FDF maker who sells them in US. USFDA then regularly inspects the facilities where APIs for US exports are manufactured to make sure API company is adhering to the specific processes. This is known as USFDA inspection.

See https://t.co/ca0na1yR6p to learn how compliance works.
In over 30 years of USFDA inspections, Neuland has not gotten a negative outcome of these inspections (Called OAI: Official action initiated), even once. Compare Neuland to other pharma companies you know.

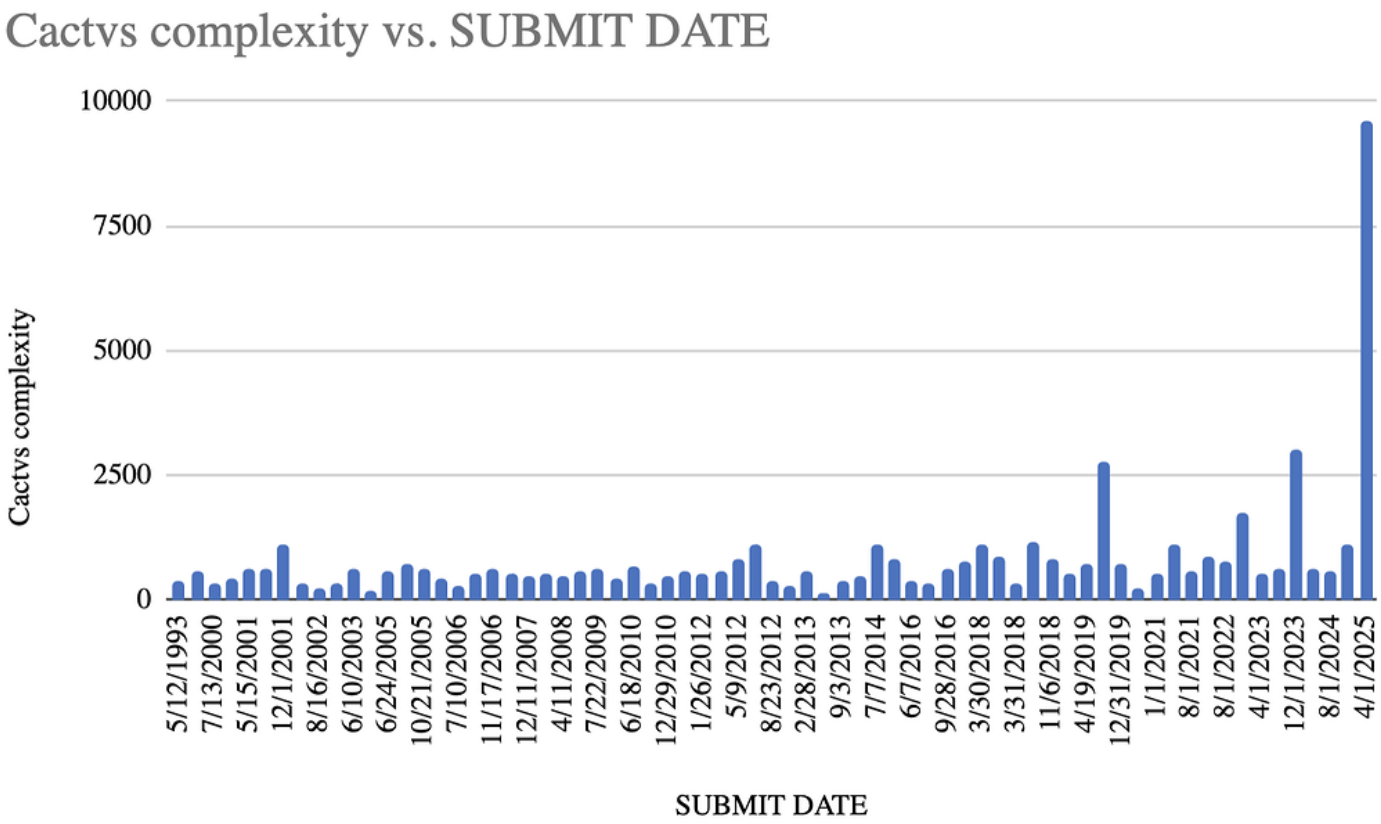
Name of Company	2020	2019	2018	2017	2016	2015	2014	2013	2012	2011	Total
Aarti Drugs	0	0	0	1	0	0	1	0	3	0	5
Ajanta Pharma	0	0	0	0	0	0	0	0	0	0	0
Alembic Pharma	0	0	0	0	0	0	0	0	0	0	0
Alkem Labs	0	0	0	0	0	0	0	0	0	0	0
Aurobindo Pharma	1	4	0	0	0	0	0	0	0	0	5
Biocon	0	0	0	0	0	0	0	0	0	0	0
Cadila Healthcare	0	1	0	0	1	0	2	0	0	1	5
Cipla	0	2	0	0	0	0	1	0	0	0	3
Divi's Laboratories	0	0	0	0	1	0	0	0	0	0	1
Dr Reddy's	0	0	0	0	0	0	0	0	0	0	0
Glenmark Pharma	0	0	0	0	3	0	0	0	0	0	3
Granules	0	0	0	0	0	0	0	0	0	0	0
Indoco Remedies	0	0	1	0	1	0	0	1	0	0	3
Ipca Labs	0	0	0	0	0	0	4	0	0	0	4
Jubilant Lifesciences	0	1	1	0	0	0	0	0	0	0	2
Lupin	0	3	1	1	0	1	0	0	0	0	6
Natco Pharma	0	0	0	0	0	0	0	0	0	0	0
Neuland	0	0	0	0	0	0	0	0	0	0	0
Shilpa Medicare	0	0	0	0	0	0	0	1	0	0	1
Solara	1	0	0	0	0	0	0	0	0	0	1
Strides Pharma	0	1	0	0	0	0	0	0	0	0	1
Sun Pharma	0	1	0	0	1	0	1	1	2	0	6
Suven Pharma	0	0	0	0	0	0	0	0	0	0	0
Torrent Pharma	0	2	0	0	0	0	0	0	0	0	2
Wockhardt	0	0	0	0	1	4	0	3	0	0	8
Total	2	15	3	2	8	5	9	6	5	1	55

Regulatory compliance is a big source of competitive advantage for neuland because innovators can trust neuland to be a reliable API partner. It takes years sometimes to address USFDA OAIs.

Complexity of APIs

I went through all the APIs for which neuland has filed USDMFs and europe CEAs. https://t.co/oc9y5LpsNw has data on complexity of the molecule which is computed using the Cactvs model.

I plotted these as a function vs time. The molecules for which DMFs have not been filed yet were randomly distributed to occur once every 4 months (assuming 3 DMFs every year) to obtain following graph:



Are the APIs getting increasingly complex? That last one, is known as semaglutide. It's formula is C_{187}H_{291}N_{45}O{59} and complexity is 9590.

For comparison Paracetamol's complexity is 139. Ciprofloxacin's is 571. I had tweeted few months ago about it: https://t.co/jPDi8LiWZA

> #Neuland labs is also working on #semaglutide (therapeutic for type 2 diabetes).
>
> Danish Innovator #Nova #Nordisk is also entering semaglutide in phase 3 trials to show efficacy for Alzheimer\u2019s disease:https://t.co/hK4PufYCAf
>
> There are NO USDMF filters for Semaglutide. https://t.co/OCNfDQdfbP
>
> — Sahil Sharma (@sahil_vi) January 17, 2021

Science Advantage.
#neuland has been aggressively investing in building the right workforce. While sales only increased 14% from FY19 to FY20, number of scientists working for neuland increased 40% YoY from 200 to 282

One of the best sources on Neuland's competitive advantages is brochure they have on website. ■ has published peer reviewed article on PharmTech sharing a newly developed strategy to increase sample loading for peptides 12 fold compared to conventional Prep-HPLC techniques.

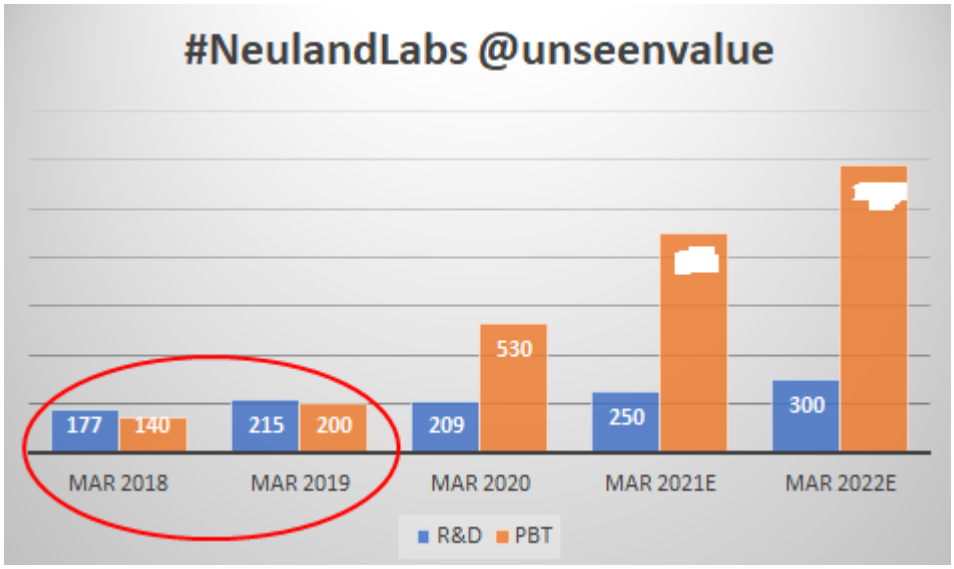
Link to brochure:
https://t.co/r231PC1WnH

High quality Science & Research is certainly not the hallmark of a commodity. Neuland has been investing into this space for over a decade. Imagine the scientific leverage which is building up here.

C. Srihari: And I think in the write-up you had mentioned about focusing on peptides, research in the peptide area, so can you please throw some more light there?

Saharsh Davuluri: Sure. So I think peptides is an area we have been working on for almost a decade now. We have been initially doing only like peptide building blocks and maybe low value items within peptide. But over the last 5-6 years, we slowly moved forward into peptide APIs and we have been working with a lot of innovators in the CMS space on peptide projects. And now what we have been trying to do in the last year or so is to actually develop peptide even for the generic markets and we are very excited with the market opportunity that generic peptides offer, and we have already done some development work on couple of peptide APIs. We are working on at least 2 more peptide projects right now and the idea is sometime next year we want to actually file DMFs for at least one or two peptide APIs and slowly start offering them to the generics market. What excite us about peptides in the generic GDS space is that the market is not very crowded and there could be certain value addition Neuland could have because of our technology where we would be able to offer peptide API at comparable quality but at a lower

Look at how their R&D investments have been. This pic was tweeted by @unseenvalue Sajal sir some months ago: https://t.co/U7a7Hj2Fa8



> Seen - stock price surge during H1 FY21 in this "commodity" #API business
>
> Unseen - the relentless and high R&D (as a % of PBT) in recent years, sacrificing near-term profitability !!! Which commodity company does R&D = PBT ?? Paper, Sugar, Metals, Textile, any other commodity ?? pic.twitter.com/p8X5tr5WDg
>
> — Sajal Kapoor (@unseenvalue) November 3, 2020

Even among the prime APIs, a scientific org finds ways to build competitive edge. Operating leverage & scale advantages are benefits that any & every company would enjoy. But neuland has gone ahead that & filed multiple Process patents for these APIs.

Backed up by sound R&D capabilities

NEULAND
WHERE OPPORTUNITY BECOMES REALITY

Neuland's R&D facility had been inspected by USDFA in February 2016 without any observations

Infrastructure

- 15 Development Labs with space for expansion
- 60 Fume hoods
- Analytical Labs
- Dedicated kilo Lab for Scale up
- Dedicated Labs for Peptides
- Separate facility for D2 analogues

Significant R&D Achievements

- Several NCE APIs added in NDA or commercial stage drugs
- Support for multiple APIs each year in Phase 2 and Phase 3 clinical candidates
- Generic API business -

✓ 898+ DMFs filed
✓ 300+ API processes developed
✓ 204+ patents filed. Received USPTO patent for improved process synthesis of Paliperidone Palmitate

These process patents demonstrate their appetite for applying their research acumen and technical knowhow to improve the manufacturing processes and drive efficiencies. Read each one carefully.

Improved process for the preparation of (1-benzyl-4-(5,6,- dimethoxyind anone-2-yl)methylpiperidine) hydrochloride-form iii

Abstract

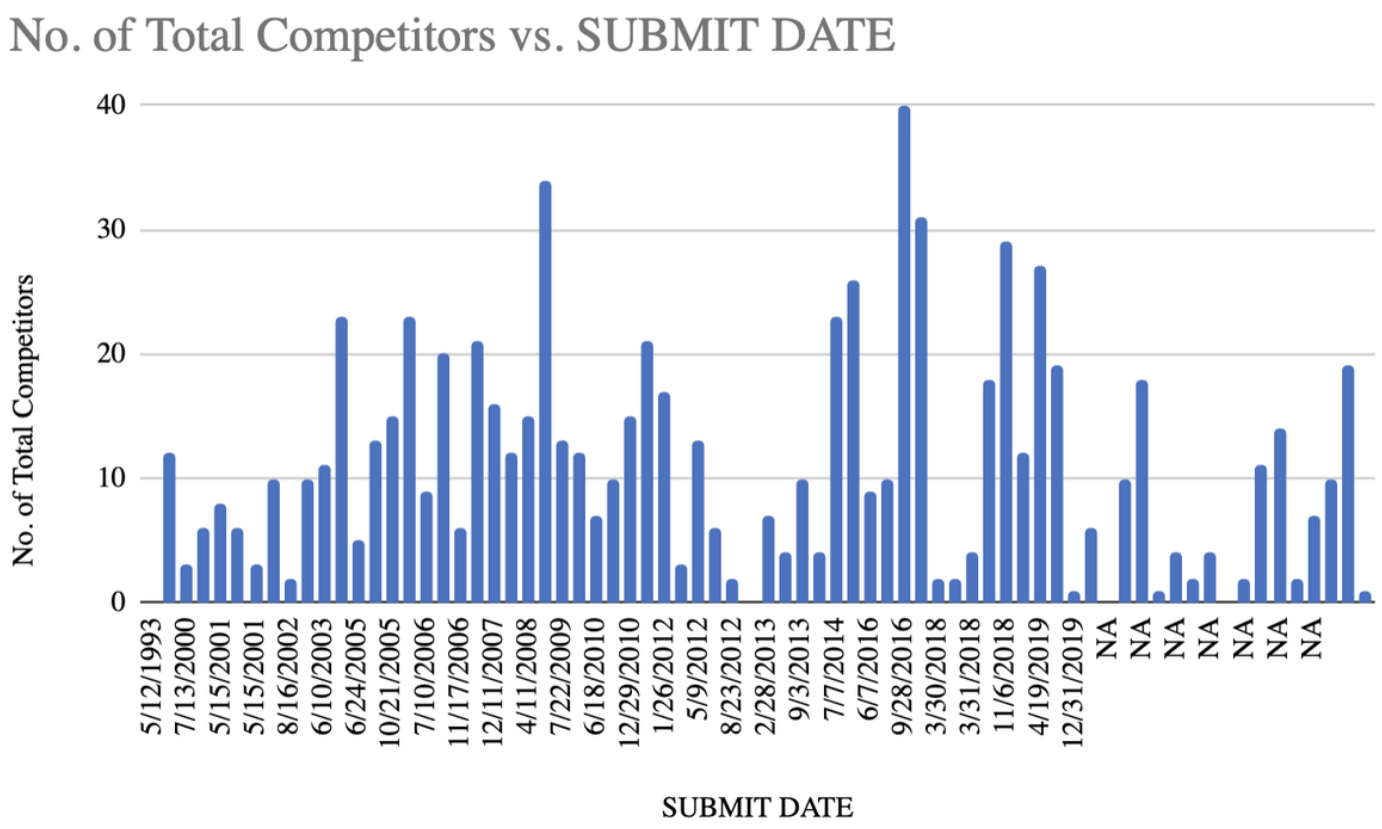
The present invention is directed to an improved industrially viable, cost effective process for manufacturing pure racemic crystalline anhydrous form of (1-benzyl-4-(5,6,- dimethoxyindanone-2yl)methylpiperidine) hydrochloride Form III commonly known as Donepezil hydrochloride with a purity level of greater than 99.9%.

WO2009084030A2
WIPO (PCT)

Download PDF | Find Prior Art | Similar

"Industrially viable", "cost effective", "high purity", "easy handling", "eco friendly" are words we see repeatedly in these neuland patents.

Fewer competitors.
The newer DMFs have fewer competitors. The ones with NA date, DMF hasnt been filed. There is an element of time bias here but we can still see that newer molecules definitely have much fewer competitors than older ones.



Quality of Management

The business suffered two severe down years in FY18 and FY19. A key part of how I judge managements is how they communicate in down years. Both these annual reports are a treat to read:

Neuland Management FY18 AR:

What were the reasons for the below par financial performance in Fiscal 2018?

The management is cognizant of the factors that contributed to the decline in financial performance. While some issues were macro industry and regulatory issues that were not within the control of the Company, we do acknowledge that certain operational issues could have been better managed and we have put in place processes that will address these lacunae in the system. So, if I had to pinpoint and ascribe reasons, the key reasons would be the following:

a. Spurt in raw material prices because of actions by the Chinese government and this has been an industry wide phenomenon. We expect this pain to continue into the foreseeable future

b. From an operational standpoint, we faced a situation of capacity imbalance between our Units 1 and 2 and nonfungibility of manufacturing products, as we operate in the regulated markets, from either of the units aggravated the situation

c. We saw some substantial decline in orders from one of our GDS products – Ciprofloxacin in one of the quarters and this added to the headwinds

d. Lastly, non-receipt of regulatory approval for one of our key products as well slower than expected offtake in the Specialty/ Niche space also meant that orders were not forthcoming in the niche API segment

Every time the business underperformed, the management clearly outlined the problem, talked about concrete remedial steps and one can see them walk the talk as well through the various concalls.

Management has been very conservative in giving growth (15-20%) and profitability (20% EBITDA) guidance which is another thing I like about the management. Management has been very conservative in giving growth guidance which is another thing I like about the management.

In 30+ years of operations, they have been audited 30+ times by USFDA and have not had any warning letters. The compliance track record and culture itself is a huge competitive advantage for Neuland.

Management has talked about how they conduct mock USFDA drills in order to maintain this track record. Compliance is a culture. Neuland has it. Eventually the markets will reward this, imho.

Market Prediction
Many analysts spend time predicting market sizes for APIs, using it to predict revenues. IMO this is very difficult. There is a HDFC securities 2018 research report for Neuland. I quote:

“Beyond 2 yrs, there are many API opportunities for NLL. This list includes Sugammadex, Paliperidone, Posaconazole, Deferasirox, Dabigatran, Lurasidone and Bosentan. Some of these molecules are low volume products but could add meaningfully on EBITDA line”.

Sugammadex today has 19+ competitors. I do not think anyone has much skill in predicting market shares for molecules since we absolutely do not know how competitors pipelines would evolve.

Warren Buffett says that Risk comes from not knowing the biz. Let me clearly state what I dont understand about #neuland:

1. Looking at our 70 odd API molecules portfolio that we work on, why do we continue to file USDMF for APIs with 15-20 global competitors (eg: Sugammadex Sodium, Ticagrelor, apremilast, posaconazole) even after 2018?

These APIs seem like the ones where competitive intensity is high and we should understand whether neuland has any unique or competitive advantages in manufacturing these molecules that lead us to filing these USDMFs.

2. Given that our CMS portfolio has much higher profitability and margins, why do we not spend all incremental capital on CMS business? Is it due to a limited demand for the capabilities or some other reason?

We understand the business viewpoint of continuity for all existing molecules, but why do we continue to deploy capital into newer prime or speciality APIs which have higher competitive intensity and lower profitability?

3. We suffered loss of production in Q42018 and 2019 due to raw material shortages due to supply disruption from China. If the same issues were to repeat today, how much would our topline or bottomline suffer?

Trying to get a sense for the extent to which this risk has now been mitigated with the strategic backward integrations, geographical multi-sourcing and fungible capacities.

Want to add one last thought. From what I have seen, the most durable competitive advantage for a business is its management's ability to create new engines of growth. Neuland management started working on Peptides and Deuteration many many years ago.

These are the sort of managements which sow the seeds for the growth of next decade, today.
Look at this peptide manufacturing technique #neuland has made in collaboration with Jitsubo:
https://t.co/GPViLMCJfV

Molecular Hiving™

Developed by Neuland Labs' collaboration partner Jitsubo Co. (Yokohama, Japan), Molecular Hiving is a manufacturing scale technique which offers tremendous cost advantages over traditional methods, whether LPPS or SPPS (Solid Phase Peptide Synthesis).

The technique uses TAG, hydrophobic benzyl alcohol or benzyl amine derivatives at C-terminus – instead of resins in solid phase synthesis (SPPS). The reactions of coupling to form peptides and deprotection of N-Fmoc or Boc in slightly hydrophilic solvent are performed in homogeneous solution (typical of LPPS).

Precipitation and isolation of a desired tagged-peptide is easily performed by adding a hydrophilic solvent to the reaction mixture.

By using its patent-protected achiral hydrophobic tags, peptide solubility can be controlled. A synthesis begins with the attachment of a patented hydrophobic tag to the C-terminal amino acid.

Peptide chemistry reactions are then performed in a hydrophobic solvent. When the reaction is complete, the tagged peptides can be precipitated and filtered.

The process effectively removes excess reagents present in the reaction mixture, providing high yields of high purity peptides.

Lastly, want to thank @unseenvalue sajal sir, @punitbansal14 punit sir @AdityaKhemka5 aditya sir, @tusharbohra tushar sir, @soicfinance ishomit, & many many others who have contributed immensely to my understanding of this space. ■■■

@unseenvalue @punitbansal14 @AdityaKhemka5 @tusharbohra @soicfinance If you like the thread, please consider retweeting the first tweet and help share this knowledge with more investors. Numbers and ratios are commodity, knowledge is the true edge for a discerning investor. ■

Disclaimer: I am positively biased and this is part of my top 3 holdings.

This is only for education, not a buy or sell recommendation.