2021年5月4日

2021年4月26日、金融市場向けコンテンツサービスの「Seeking Alpha」にて当社が紹介されましたので、お知らせいたします。
記事の内容は以下のとおりです。（権利の都合上、英文での引用となります。）

<掲載元：https://seekingalpha.com/article/4421397-medicinova-riddle-worth-unravelling/>

The MediciNova Riddle: Worth Unravelling

Summary

- MediciNova is a development phase biotech with several highly attractive development candidates.
- MediciNova's plans for developing these candidates are a bit of a riddle.
- MediciNova is a highly attractive acquisition for speculative biotech investors.

In this article I provide an investment rundown on MediciNova (MNOV). It is a curious development stage biotech that has drawn my attention because of its several interesting therapies in development as I will discuss.
My attitude towards MediciNova has changed dramatically for the positive as I have worked through the MediciNova riddle.

MediciNova has a powerful pipeline

MediciNova is a tiny clinical stage biotech
MediciNova's description of itself in its latest (2021) 10-K is routine. It formed itself as a Delaware corporation in 2000. In its initial 20+ years it has managed to accumulate losses aggregating ~$383 million, dwarfing its market cap of $215 million. It characterizes itself as a biopharmaceutical company with a goal of developing novel therapeutics for the treatment of:

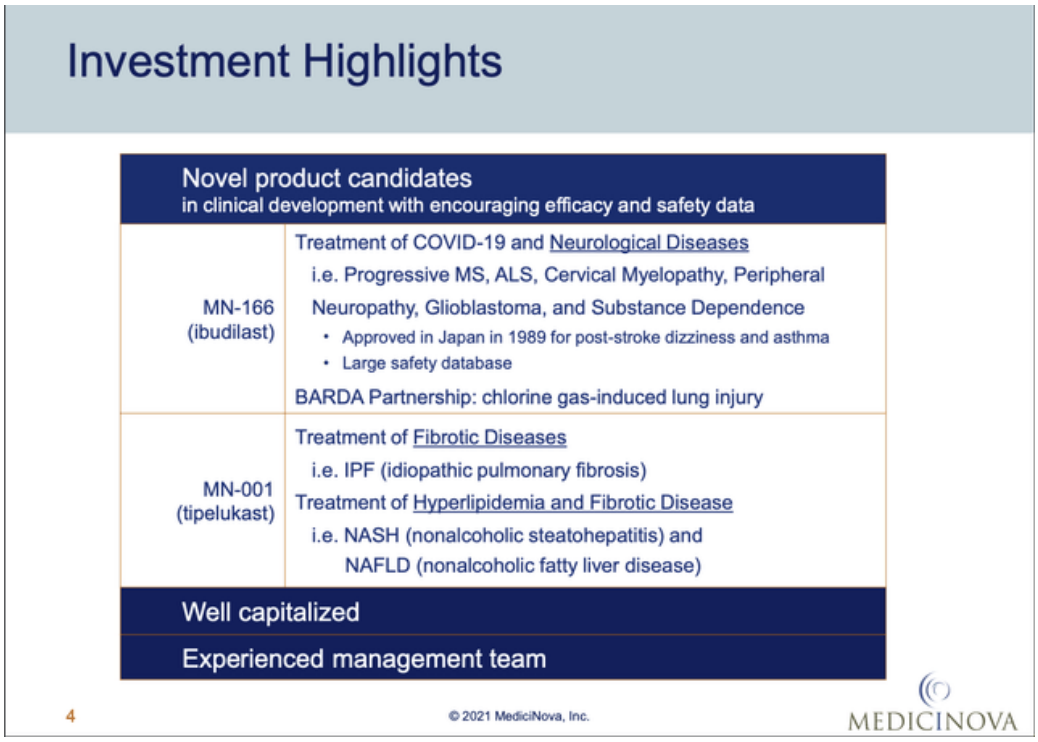
1. serious diseases
2. with unmet medical needs and
3. a commercial focus on the United States market.

Yawn! How many other small publicly traded biotechs are there chasing this white rabbit? If it is less than hundreds I would be astounded. The stories are pretty much the same, hundreds of millions of $$ in accumulated losses, nominal or no revenues, losses expected to pile on for an indeterminate period.

MediciNova's lead therapy is in trial for treatment of ALS

As common as the stories underlying such companies may be in outline, upon further

investigation one often finds potential for value. MediciNova is one of these. MediciNova's 03/21 investment highlights slide summarizes:



It has worked a series of deals into an interesting pipeline as shown by its 03/21 slide below:

MediciNova's lead program, its study of ibudilast (MN-166) in treatment of ALS, is listed in clinicaltrials.gov as NCT04057898. It is a phase 2/3 "multicenter, randomized, double-blind,

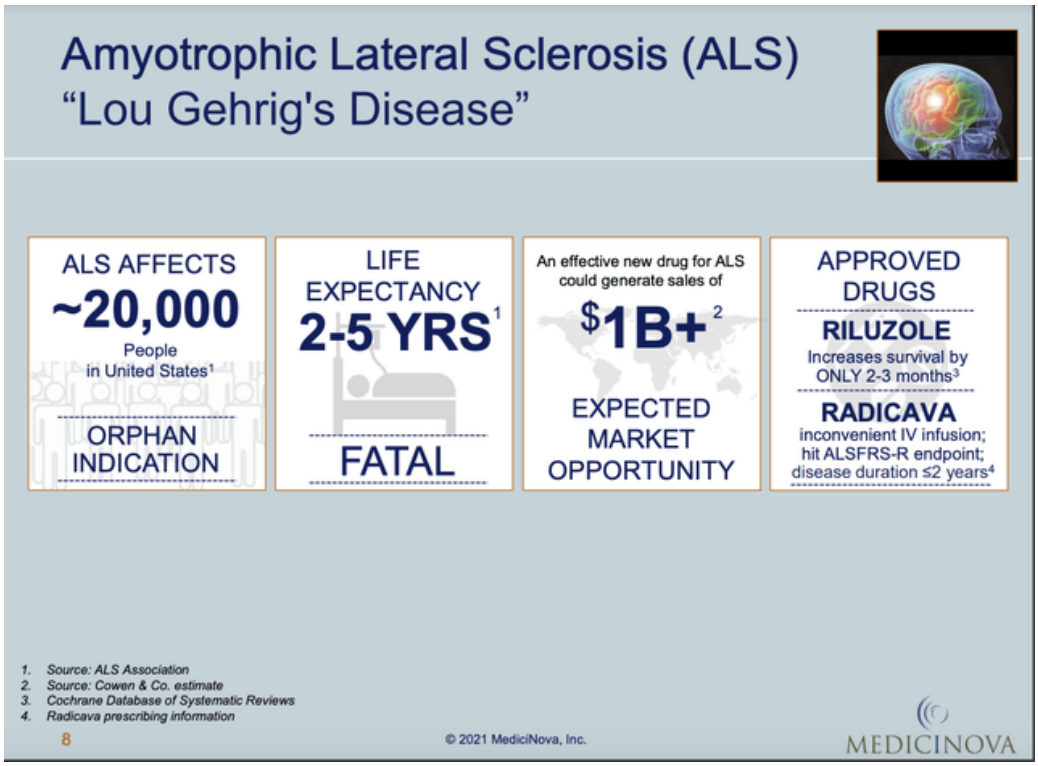
placebo-controlled, parallel group study to evaluate the efficacy, safety and tolerability of MN-166 given to ALS participants for 12 months followed by a 6-month open-label extension phase".

The study is slated for an estimated enrollment of 230 participants and completion date of 12/24. Its primary outcome measure is:

1. Change from baseline in ALSFRS-R score at Month 12 (or last measurement before death in case of censoring) and survival time. [Time Frame: 12 months]

   The amyotrophic lateral sclerosis functional rating scale-revised, or ALSFRS-R, measures the functional status of subjects with ALS. It is based on 12 items, each of which is rated on a 5-point scale (0 to 4). The rate of total functional disability thus ranges from 0 (maximum disability) to 48 (normal function) points.

The ALS indication is significant as shown by 03/21 slide below:



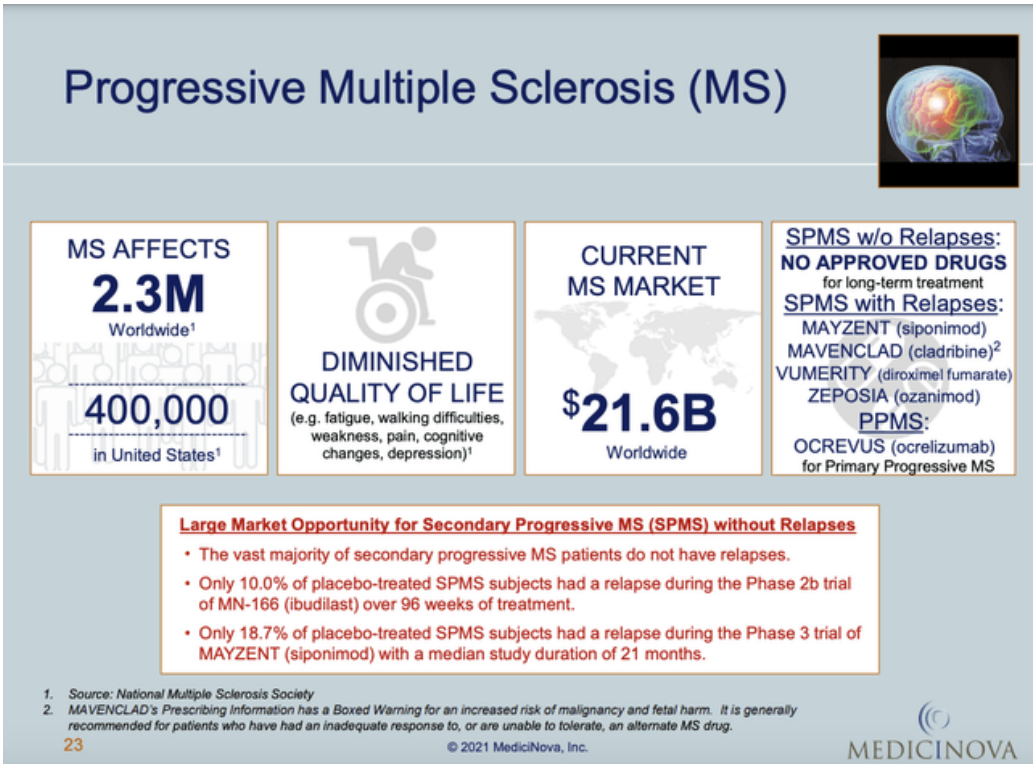
MediciNova's other noteworthy program is MN-166 in treatment of progressive MS

MediciNova's MS program is directed at a particularly pernicious aspect of this disease. The most common form of multiple sclerosis [MS] is known as relapsing remitting MS [RRMS]. The least common and most relentless flavor of the disease is primary progressive MS [PPMS].

Secondary progressive MS [SPMS] is the disease stage which follows RRMS. There are two flavors of SPMS, SPMS with and without relapses.

There are nearly a dozen so-called disease modifying therapies directed at RRMS. The progressive forms of MS have proven more difficult to challenge, even with modestly impactful therapies.

There are FDA approved treatments for PPMS and secondary progressive MS with relapses. MediciNova's 03/21 slide below sets out the current state of the progressive MS treatment landscape:



The key point from the slide above is that there is no FDA approved therapy for long term SPMS without relapses. According to MediciNova's 10-K (p. 25) there are competitors in development "MedDay's MD1003 and AB Science's masitinib".

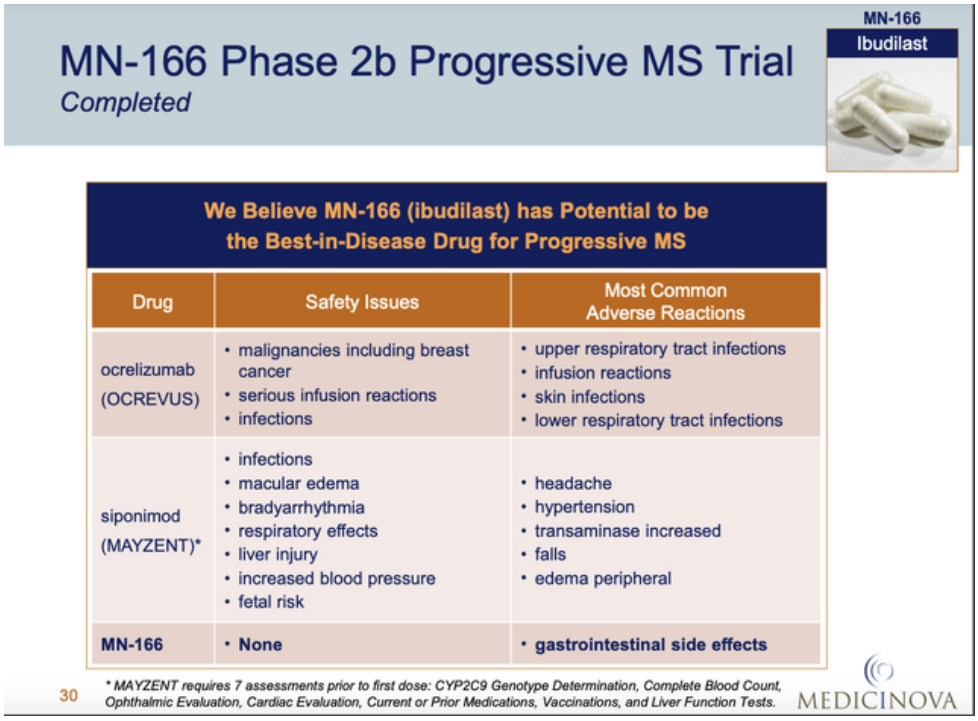
At page 5 of its 10-K, MediciNova describes its MN-166 development in treatment of progressive MS in detail:

> We partnered with investigators on a Phase 2b clinical trial of MN-166 (ibudilast) in primary progressive and secondary progressive MS which was conducted by NeuroNEXT and funded by the National Institute of Health's (NIH) National Institute of Neurological Diseases and Stroke (NINDS). This progressive MS trial, known as SPRINT-MS, completed randomization of 255 subjects in 2015, which exceeded the goal of 250 subjects that were planned for participation. In October 2017, we announced the presentation of positive top-line results from the SPRINT-MS Phase 2b clinical trial of MN-166 (ibudilast) in progressive MS. The trial achieved both primary endpoints of whole brain atrophy and safety and tolerability.

It went on to note that measured by MRI analysis, MN-166 demonstrated a statistically significant 48% reduction in the rate of progression of whole brain atrophy compared to

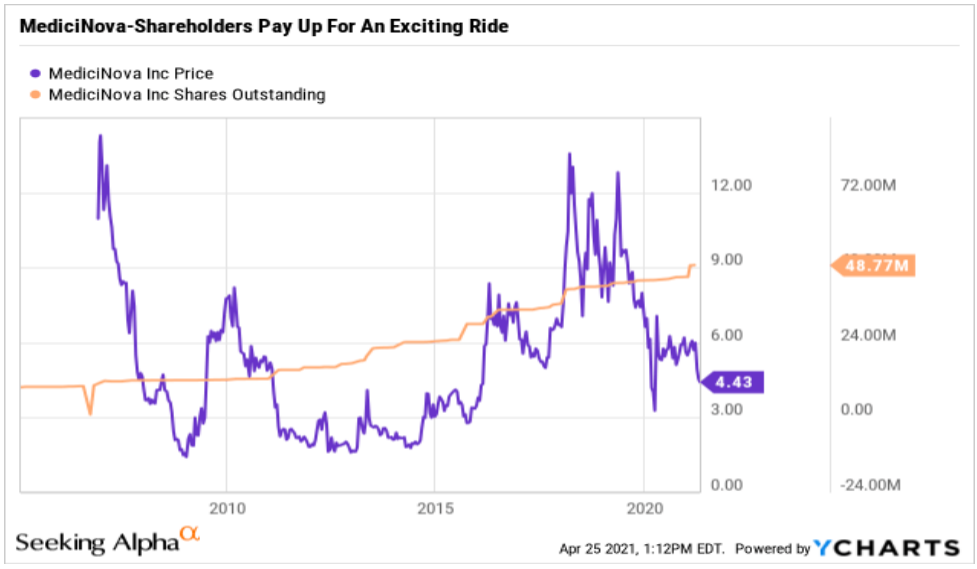
placebo (p=0.04). Serious adverse events in treated group were comparable to placebo. The trial also produced positive results in key secondary endpoints such as disease progression. In 08/18 results were published in the New England Journal of Medicine.

MediciNova's 03/21 presentation slides provide extensive graphic depiction of its trial results (slides 24-31). The following wrap up slide demonstrates MN-166's awesome safety profile compared to its competitors:



MediciNova is a frustrating but potentially exciting hold for retail investors

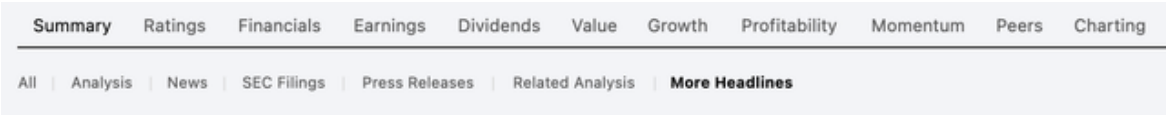
Retail shareholders who bought MediciNova in the early days and held on have had thrills and spills as illustrated by the price chart below. How will it end? That is a tough call for MediciNova, made worse by certain idiosyncrasies.



If you are one of those biotech shareholders who likes to keep track of what their investments are doing on a quarterly basis by reading earnings call transcripts, MediciNova is not the stock for you. As best I have been able to tell it does not do earnings calls, or at least Seeking Alpha uncharacteristically does not carry transcripts of them.

The lead Seeking Alpha page for most tickers, taking Osmotica (OSMT) as a random example, includes a "Transcripts" tabs as follows:

For MediciNova the analogous lead page has no such "Transcripts" option:



The lack of any Transcripts tab means no earnings call transcripts or presentations. The earnings calls are important for multiple reasons. They typically set out management's development priorities. They also provide a feel for market reaction to the company as reflected by analyst questions. Under the best of circumstance small biotechs are black boxes, small biotechs without earnings even more so.

Lacking earnings call transcripts, one might pursue a company's earnings press release as a substitute. Again with MediciNova there is no such beast. All is not lost. It does report its 10's, "-K's" and "-Q's", available on Seeking Alpha under the "SEC Filings" tab. Also as I have referenced several times above it does publish a helpful presentation slide deck on its web site.

Why MediciNova is an interesting acquisition target

The lead to this section above is unintentionally ambiguous. As I wrote it I was thinking of the merits of buying for my own speculative biotech portfolio. However I have also considered that MediciNova is a highly attractive takeout acquisition. I will discuss both in turn below.

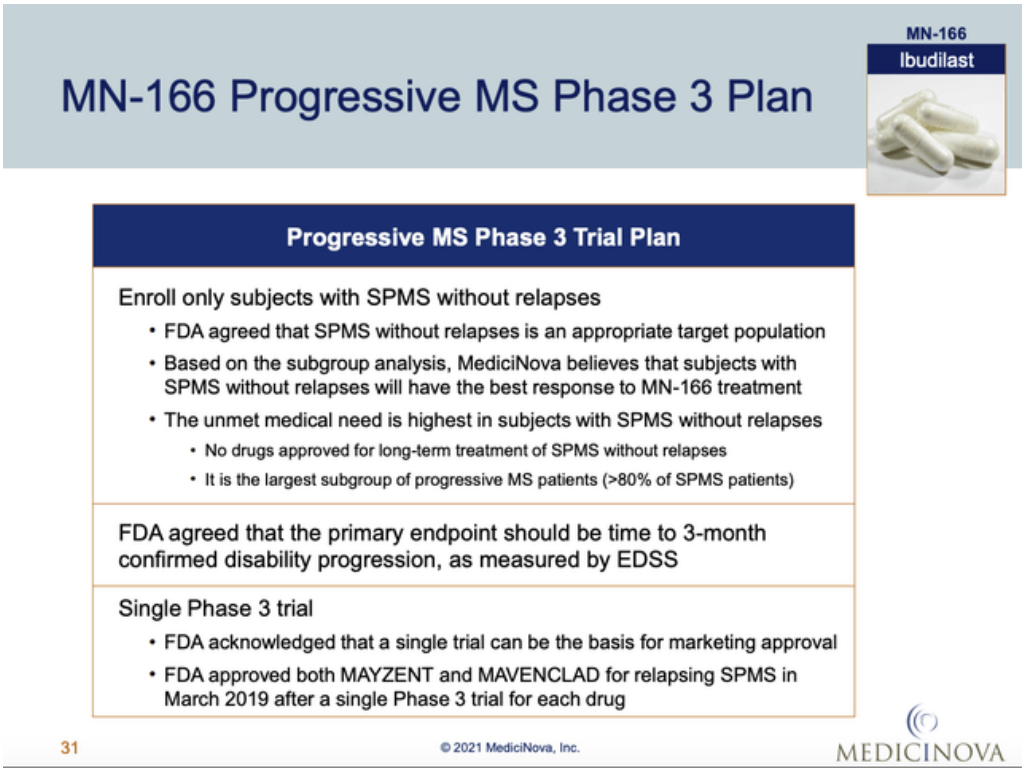
MediciNova is a good fit for a speculative biotech portfolio

MediciNova makes an interesting acquisition for a speculative portfolio based on its MN-166 therapy pipeline as discussed above. It would be a guaranteed frustrating hold. Management's blasée approach to shareholder communication dictate that investors must maintain a "hope for the best, while preparing for the worst" attitude at all times.

The worst is easy to imagine for any stock. For MediciNova I expect the worst would be a

drawn out water torture of delays built upon delays, punctuated by exciting results, capped by disappointing FDA decisions. All this taking place against a backdrop of a management silence.

What about the best? For MediciNova I expect that could be very good indeed. I am most excited about its MN-166 progressive MS indication. I can spin wonderful possibilities here for investors. Consider its closing MS 03/21 slide below:



On its own, this slide shows MediciNova's potential. It is designing a pivotal trial for a therapy with a high unmet need. The clincher is when you go back to slide 30 of this series, as set out above. Slide 30 shows the zero safety issues, a tremendous and rare advantage for any therapy, particularly for dread diseases.

Note that we have no time frame for when this trial might start much less when it might finish. Investors should assume that we are talking several years, perhaps a year or more before the trial commences, then more for enrollment then more for...and so on.

MediciNova is an excellent takeout candidate for big pharma, particularly Biogen, if it elects not to go it alone

With its tiny market cap and its interesting pipeline, MediciNova would be a tasty morsel for most big pharma players. MediciNova comes in a neat manageable package. It has only nine employees. It runs a lean and mean operation, as it states in its 2021 10-K (p. 54):

We have no laboratory, research or manufacturing facilities, and we currently do not plan to purchase or lease any such facilities

While its pipeline would be a welcome addition for most large pharma players. There is one in particular that would be a great, perhaps too great from an antitrust perspective, fit. Biogen (BIIB), with its leading, but challenged MS portfolio immediately comes to mind. MediciNova's ALS indication would also fit with Biogen's developing neuromuscular franchise.

Regardless of who the actual suitor might be there can be no doubt that MediciNova presents an excellent target for big pharma. Both of its lead indications have "blockbuster" written all over them.

The revenue potential for MN-166 should it win FDA approval for either or both of its lead indications in treatment of MS or ALS is significant. Consider the following table from Biogen's Q4, 2020 10-K (p. 56) listing its revenues from its existing MS therapies and from its spinal muscular atrophy therapy SPINRAZA:

Product Revenues

Product revenues are summarized as follows:

	For the Years Ended December 31,			% Change		$ Change	
(In millions, except percentages)	2020	2019	2018	2020 vs. 2019	2019 vs. 2018	2020 vs. 2019	2019 vs. 2018
Multiple Sclerosis (MS):							
Fumarate*	$ 3,905.4	$ 4,438.2	$ 4,274.1	(12.0)%	3.8 %	$ (532.8)	$ 164.1
Interferon**	1,877.5	2,101.8	2,363.0	(10.7)	(11.1)	(224.3)	(261.2)
TYSABRI	1,946.1	1,892.2	1,864.0	2.8	1.5	53.9	28.2
FAMPYRA	103.1	97.1	92.7	6.2	4.7	6.0	4.4
ZINBRYTA	—	—	1.4	—	nm	—	(1.4)
Subtotal: MS product revenues	7,832.1	8,529.3	8,595.2	(8.2)	(0.8)	(697.2)	(65.9)
Spinal Muscular Atrophy:							
SPINRAZA	2,052.1	2,097.0	1,724.2	(2.1)	21.6	(44.9)	372.8

Biogen's MS products generate $7.8 billion. None of them treat secondary progressive MS without relapses. The prevalence of secondary progressive MS is unknown; however a study estimates that it afflicts ~37% of the US MS population. As noted above a substantial majority of those with secondary progressive MS do not have relapses.

Another approach to figuring MN-166 revenue potential would be to consider OCREVUS, an oral therapy approved to treat primary progressive MS. Its retail cost for a year's therapy is $~67,000. Using OCREVUS as an analog MN-166 could generate ~$30,000 per patient year, giving it a potential for several billion in MS alone.

Conclusion

Small cap biotechs with luscious portfolio's are a modern equivalent of the mythic Tantalus, condemned to eternal thirst in a pool of water with relief just out of reach. MediciNova is very much in that vein at the current time with two late stage therapies with >billion $$ potential.

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