

A close-up photograph of a microscope in a laboratory setting. The microscope is blue and silver, with a hand visible on the right side, adjusting a component. The background is blurred, showing other laboratory equipment. A large blue diagonal shape is overlaid on the left side of the image.

PROJECT CASE STUDY

COVID-19 PORTFOLIO DELAY SCENARIOS

ASSESSING PORTFOLIO-WIDE DELAYS

The current pandemic is greatly impacting all of us and also the pharmaceutical industry.

Difficulties in recruiting and keeping new subjects for clinical trials lead to delays, which in the end lead to fewer medicines being launched to serve patients in need. Sponsors are trying understand how trial delays will impact their ability to deliver the R&D portfolio. In this article I will present a case study that perhaps will help shed some light on how delays will impact portfolio value, launches and sales. I will start by presenting the case study portfolio, which is based on recent work. Project names and data have been changed to avoid any misunderstandings. However, it shares a set of common attributes with real drug development portfolios.

CASE STUDY PORTFOLIO

Between 15 and 20 projects, of which the majority are based on small molecule assets. The projects are spread out evenly across the three clinical phases. This could be considered a difference compared to how R&D portfolios are perceived; Many assets early in the pipeline, and few in later stages due to attrition.

Individual assets contribute between 1% and 25% of the total portfolio value. Forecast timelines, costs, sales and PTRS assessments are based on benchmark data.

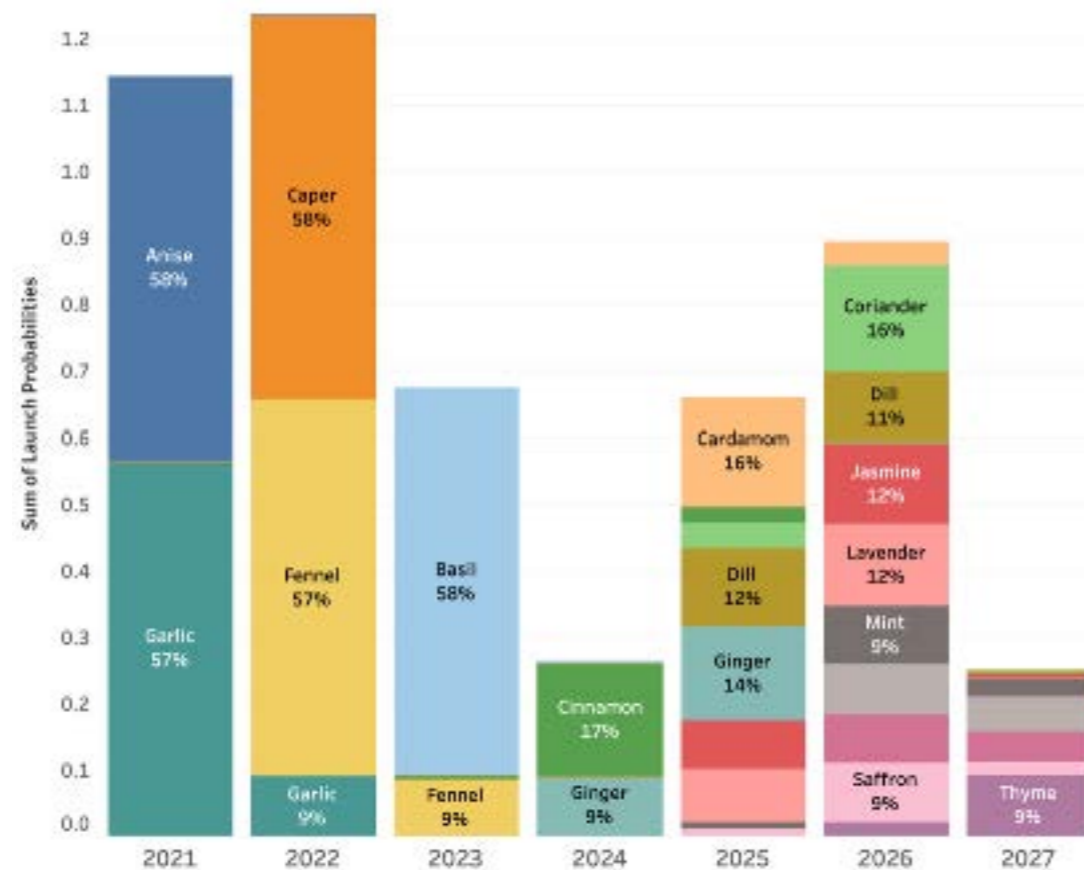
If these attributes were different, we can assume that the effect of a portfolio-wide delay will also be different. Using this portfolio we ran Monte-Carlo simulations to sample the vast outcome space of what might happen in the future in terms of launches, value and sales.

Projects		Duration				Cost				Probability of Success				Market assumptions		
Project name	Current Phase	Ph1	Ph2	Ph3	Reg	Ph1	Ph2	Ph3	Reg	Ph1	Ph2	Ph3	Reg	Sales Ramp	Peak year sales	Loss of exclusivity
Anise	PH3			0.3	1-1.5			20-50	5-10			0.65	0.9	2-3	200-500	2030.5
Basil	PH3			2.3	1-1.5			140-180	5-10			0.65	0.9	1-3	300-600	2035
Caper	PH3			1.2	1-1.5			180-220	5-10			0.65	0.9	4-5	500-2400	2028.3
Cardamom	PH2		1.5	2.5-3.5	1-1.5	13-16	150-200	5-10		0.35	0.65	0.9	2-4	500-1200	2036.4	
Cinnamon	PH2		0.4	2.5-3.5	1-1.5	20-25	150-200	5-10		0.35	0.65	0.9	2-4	250-800	2034	
Coriander	PH2		2.1	2.5-3.5	1-1.5	35-40	150-200	5-10		0.35	0.65	0.9	2-3	300-800	2038	
Dill	PH2		1.8	2.5-3.5	1-1.5	40-50	150-200	5-10		0.35	0.65	0.9	2-4	500-1500	2032.5	
Fennel	PH3			1.6	1-1.5			150-200	5-10			0.65	0.9	1-3	500-1500	2026.3
Garlic	PH3			0.6	1-1.5			20-30	5-10			0.65	0.9	2-4	400-1200	2031.6
Ginger	PH2		0.9	2.5-3.5	1-1.5	15-20	150-200	5-10		0.35	0.65	0.9	2-3	450-850	2028.4	
Jasmine	PH2		1.5-2.5	2.5-3.5	1-1.5	25-60	150-200	5-10		0.35	0.65	0.9	2-4	300-700	2026.5	
Lavender	PH2		1.9	2.5-3.5	1-1.5	40-60	150-200	5-10		0.35	0.65	0.9	2-4	500-600	2032.8	
Mint	PH1	0.5	1.5-2.5	2.5-3.5	1-1.5	5-10	25-60	150-200	5-10	0.6	0.35	0.65	0.9	1-3	600-1100	2037.6
Nutmeg	PH1	0.75	1.5-2.5	2.5-3.5	1-1.5	5-10	25-60	150-200	5-10	0.6	0.35	0.65	0.9	4-5	300-850	2038.1
Paprika	PH1	0.75	1.5-2.5	2.5-3.5	1-1.5	5-10	25-60	150-200	5-10	0.6	0.35	0.65	0.9	2-3	100-400	2039.9
Saffron	PH1	0.4	1.5-2.5	2.5-3.5	1-1.5	5-10	25-60	150-200	5-10	0.6	0.35	0.65	0.9	1-3	400-800	2035.4
Thyme	PH1	1.25	1.5-2.5	2.5-3.5	1-1.5	5-10	25-60	150-200	5-10	0.6	0.35	0.65	0.9	2-4	400-800	2037.1

LAUNCH PROBABILITIES

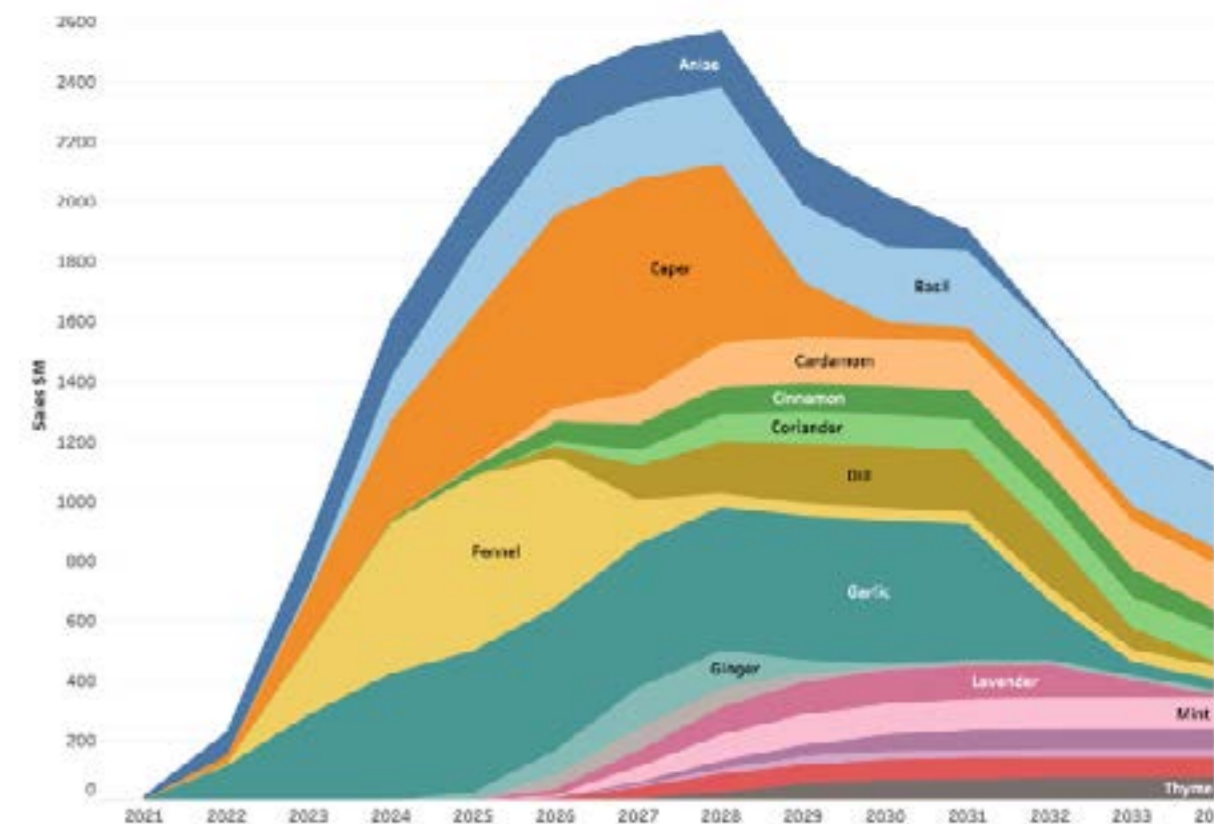
The first view is a common perspective to show future launches. For each year we sum the likelihoods of seeing launches for the different assets. For the baseline portfolio we can note that it is likely that we will have at least one launch per year for the first two years. After that there is a dip in number of launches and then things pick up again in 2025 with several assets forecasted to launch.

Also worth mentioning is that several of the assets seem to be launching in multiple years. They are not, this is an effect of working with timeline uncertainties. Since ranges are used to express uncertainty in phase durations (see the first chart), we will naturally also see that launches have timing windows and not single dates. This also builds credibility in the forecast itself.



IMPACT ON SALES

Sales from the baseline portfolio will increase in the next 8 years. Caper, Fennel, Garlic, Anise and Basil seem to be big contributors. We will have peak sales in 2028 at about \$2.6B, and after that sales will start to deteriorate as compounds start to go off patents.



SUMMARY

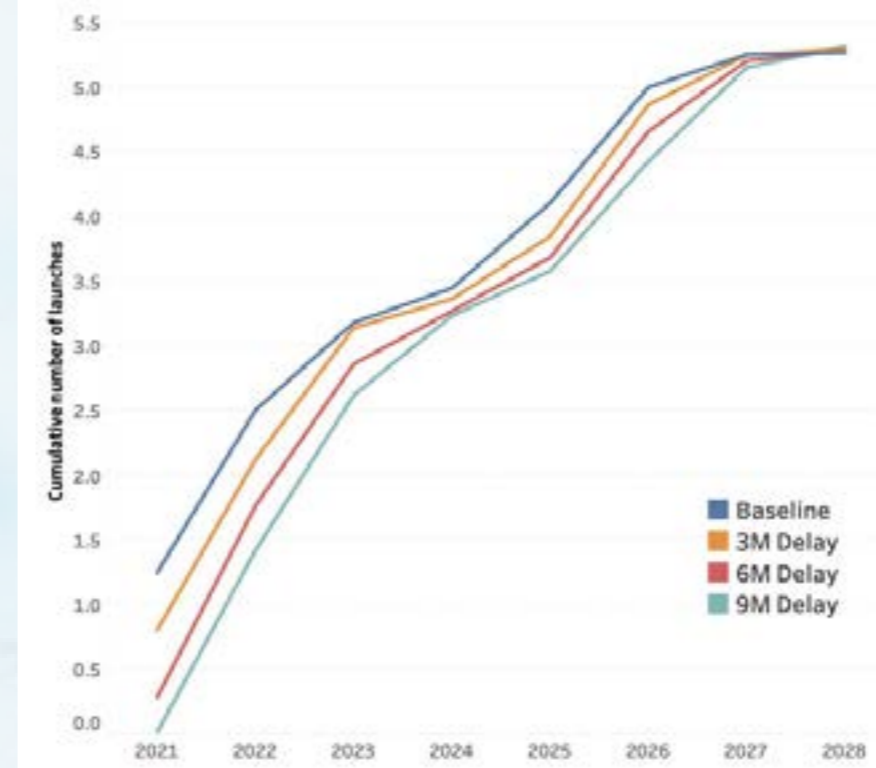
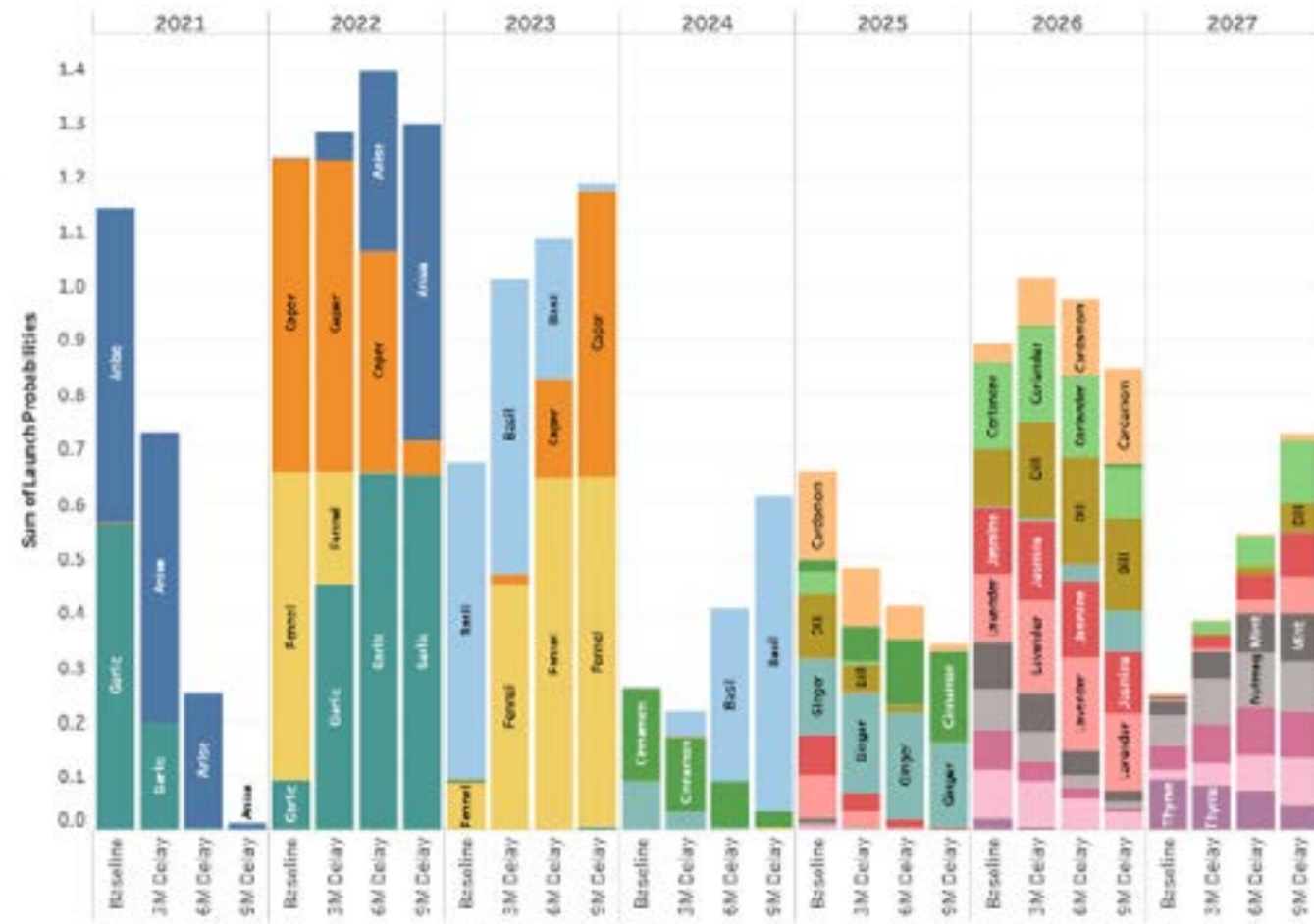
The portfolio consists of 17 compounds spread evenly across the three clinical phases. Sales will peak in 2028 at \$2.6B and the portfolio net value (expected NPV) is \$9B. Now let us see how this is impacted by delays!

COVID-19 SCENARIOS

Next, we run three scenarios with 3, 6 and 9 months of delay to each of the projects in the portfolio.

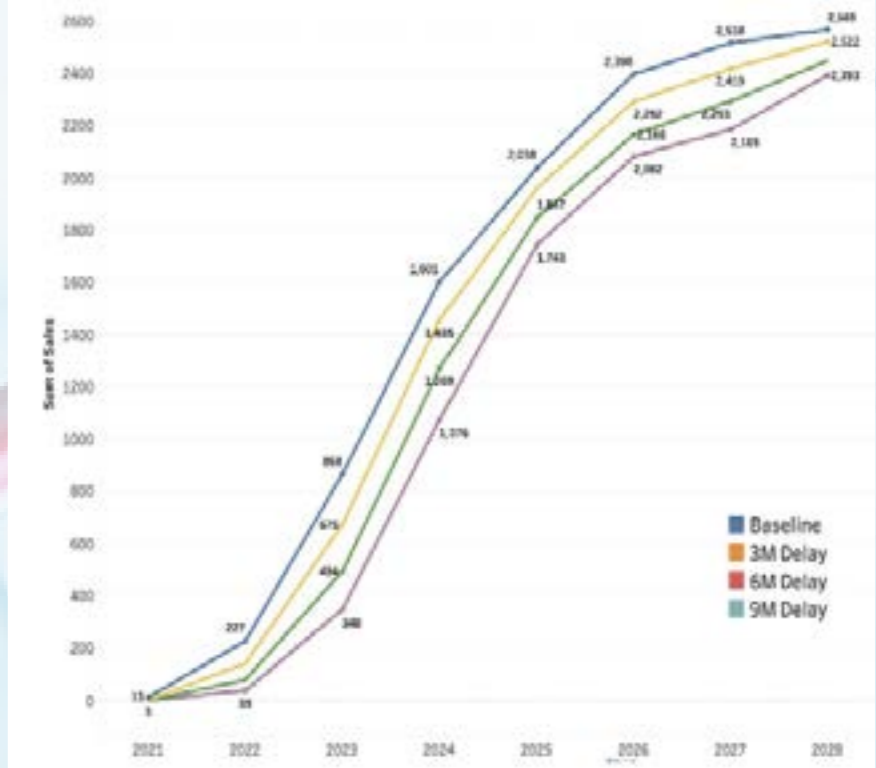
In practice this means launches for all projects will be delayed. This is of course a simplification compared to what happens in real clinical studies, where different countries are hit differently, and where the recruitment will slow down or stop or be unaffected depending on region and indication under investigation. However, having a well-defined delay scenario will help us understand what the delay will do to our ability to deliver the portfolio and can guide us when sizing our mitigative efforts.

Graph 1
comparing launch profiles under the different scenarios year by year. We can clearly see that delays will have a large impact on launches in the next year, and that launch likelihoods are shifted out to later years.



CUMULATIVE NUMBER OF LAUNCHES FOR THE NEXT 9 YEARS

Here we can see the impact more clearly. There is a big impact on our ability to deliver launches in the next couple of years. Also, we see the lingering effect that the delay will have on launches that stretches out until the last asset in the portfolio has launched. By 2028 this portfolio will have delivered some 5-6 launches, and there is no effect remaining from the delay. Efforts can and should of course be put in place to counter the delays in launches. Trials can be sped up by adding more centers or even opening centers in countries that are less impacted by COVID-19. Opening up more centers will add cost to the study, and to understand what we risk in monetary terms we will look at delay effects on sales next.

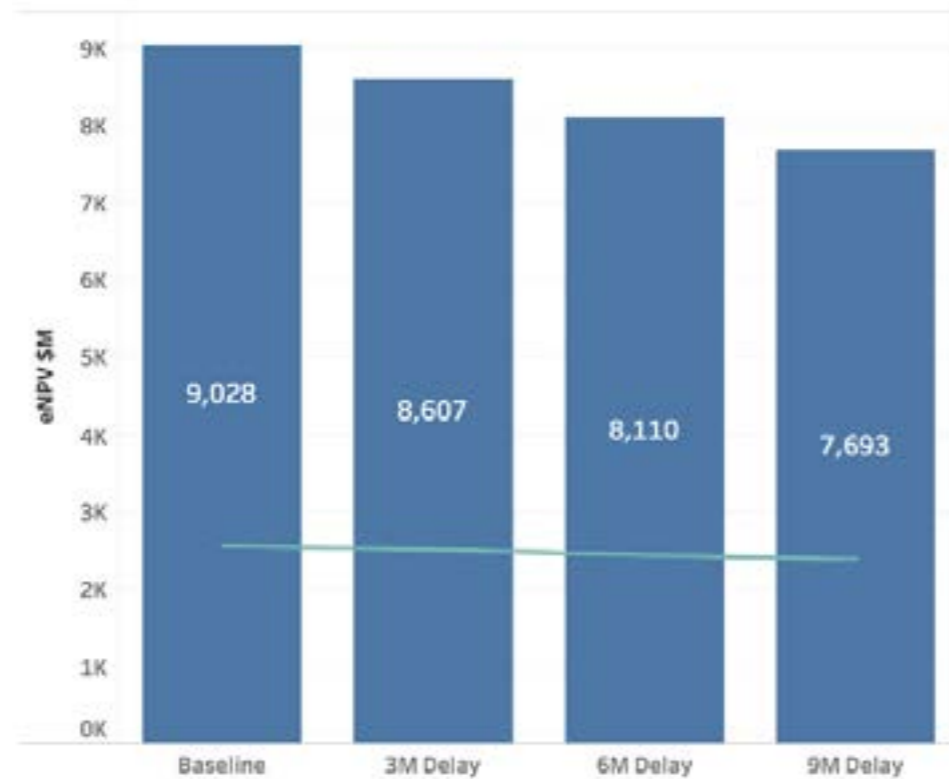


EXPECTED REVENUE FORECASTS COMPARED TO BASELINE

The baseline curve is the same as the area curve we saw earlier. What we can see here is that as sales are picking up in the next 2 years, the net loss of sales is quite small. However, in the following years, the impact is quite dramatic; sales are down by 150 - 200 MUSD per year between 2023 and 2026. This is a huge amount of money, and should give us some indication of how we can size our mitigative efforts. Or to put it in other words, we can open quite a few new centers to try to launch quicker! Another action we can take is to speed up the ramp time to get to peak sales for select assets. By adding funds to our marketing efforts during and post launch to build the brand, we may counter some of the delay effects.

PORTFOLIO VALUE

Lastly, we will look at portfolio value. As we stated in the beginning the baseline value was \$9B. This value is eroded by 400-500 MUSD for every 3 months of delay. Peak sales is also affected, but not as much. It goes down to \$2.4B with a 9 months delay from the starting point \$2.6B.



SUMMARY

After having done this with several live portfolios I see a few common trends. Here are my generalised takeaway points.

KEY POINTS

- » **A delay now will have a large impact on launches the next 2 years, and will continue to have an impact until the last project in the portfolio has been launched - unless we can stop it!**
- » **Sales are down 25% - 40% in the next 2-3 years, and down by 5%-10% per year for the next 4-5 years**
- » **Portfolio value is eroded by 5% for every 3 months of delay**

In specific terms this means that a portfolio with an NPV of \$9B, and peak sales of \$2.6B will loose 150-200 MUSD per year and will see portfolio value drop by 400-500 MUSD for every 3 months of COVID-19 delay. This should be translatable to your portfolio as long as it is reasonably sized and proportionate according to the 5 attributes in the beginning of this text.

There are no portfolio wide mitigations for a Corona crisis, at least not that I know of. Instead, mitigations are done in the individual clinical trials and projects, where analysis of how the crisis affects centers and countries can lead to action. Opening new centers or even looking at opening centers in less affected countries are actions that I have seen being investigated. This will have an effect on launch profiles. Increased marketing efforts can be a way to counter sales deterioration. At the portfolio level we can guide which projects are mostly affected, and where mitigation will do the most to counter negative effects.



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