

# Kallyope – HMDS – Executive Summary

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## Business Question

Kallyope, a NYC-based biotech with clinical-stage therapeutics, is looking to replenish its pipeline. More specifically, they want to target de-risked indications for their discovery pipeline i.e. indications currently served by biologics that would be suitable for the accelerated development of a small molecule.

## Analysis

We believed that Kallyope would benefit from a structured approach to indication selection as a mechanism to build consensus among the team. To address Kallyope’s pipeline challenge, we built a framework to select for indications of interest. As indicated by the company, indications needed to be treated by an FDA-approved biologic. So, we pulled the list of all biologics approved in the U.S. from the FDA Purple Book and organized the data to output 222 unique indications.

We focused on 3 main pillars when developing our criteria list based on our conversations with Kallyope:

- 1) De-risked approval pathway
- 2) Opportunity for Kallyope to succeed
- 3) Within time and cost constraints

Using these pillars, we created a criteria list of 7 actionable questions to assess the 222 possible indications.

De-risked approval pathway	Opportunity for Kallyope to Succeed	Within Time and Cost Constraints																		
<p><i>How many biologic products are approved in the current indication?</i></p> <table border="1" style="width: 100%; text-align: center;"> <tr> <th style="background-color: #28a745; color: white;">Good</th> <th style="background-color: #ffc107;">Medium</th> <th style="background-color: #dc3545; color: white;">Bad</th> </tr> <tr> <td style="background-color: #d4edda;">1+</td> <td style="background-color: #d6d8db;"> </td> <td style="background-color: #f8d7da;">0</td> </tr> </table>	Good	Medium	Bad	1+		0	<p><i>How many small molecules are approved in the current indication?</i></p> <table border="1" style="width: 100%; text-align: center;"> <tr> <th style="background-color: #28a745; color: white;">Good</th> <th style="background-color: #ffc107;">Medium</th> <th style="background-color: #dc3545; color: white;">Bad</th> </tr> <tr> <td style="background-color: #d4edda;">≤1</td> <td style="background-color: #d6d8db;">2</td> <td style="background-color: #f8d7da;">3+</td> </tr> </table>	Good	Medium	Bad	≤1	2	3+	<p><i>Average estimated time to endpoint completion for selected indication?</i></p> <table border="1" style="width: 100%; text-align: center;"> <tr> <th style="background-color: #28a745; color: white;">Good</th> <th style="background-color: #ffc107;">Medium</th> <th style="background-color: #dc3545; color: white;">Bad</th> </tr> <tr> <td style="background-color: #d4edda;">&lt;6mo</td> <td style="background-color: #d6d8db;">6-12mo</td> <td style="background-color: #f8d7da;">&gt;12mo</td> </tr> </table>	Good	Medium	Bad	<6mo	6-12mo	>12mo
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	<p><i>What is the patient population for the target indication?</i></p> <table border="1" style="width: 100%; text-align: center;"> <tr> <th style="background-color: #28a745; color: white;">Good</th> <th style="background-color: #ffc107;">Medium</th> <th style="background-color: #dc3545; color: white;">Bad</th> </tr> <tr> <td style="background-color: #d4edda;">&gt;200,000</td> <td style="background-color: #d6d8db;">&lt;200,000 and &gt;10,000</td> <td style="background-color: #f8d7da;">Low</td> </tr> </table>	Good	Medium	Bad	>200,000	<200,000 and >10,000	Low													
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## Recommendation

Our team identified six indications using the above framework. All six indications met our criteria equally, achieving a medium level on Kallyope's expertise and good levels on the other six criteria. We then performed a detailed analysis of each indication by compiling market research, competing products, and internal capability considerations. Based on our research and Kallyope's insights, we categorized them into different levels of opportunity:

- High opportunity: Thyroid eye disease, Macular edema following retinal vein occlusion
- Medium opportunity: Chronic sialorrhea, Spasticity, Diabetic neuropathic ulcers, Gout flares
- Low opportunity: None

We developed this framework and found it to be effective in identifying indications. We also recommend using a structured approach to help build consensus and address difficult questions.

## Final thoughts

Many thanks to Kallyope for giving us this opportunity. It was a joy for our work to always be met with such enthusiasm and interest. We appreciated the challenge of taking an unbiased approach to indication selection. We were pleased with the initial conversations we observed taking place at Kallyope regarding the novel indications we proposed. Thank you as well to Carri Chan, Taylor Sewell, Peter Tollman, and Jennie Fu for your support and instruction this semester.