

Disclaimer:

Some data have not been verified and include assumptions.

This presentation is only for illustration purpose.

lenalidomide cap Export Business Plan

Presented to: Company X Biopharm

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Lenalidomide is used for treating multiple myeloma patients as a preferred regime recommended by NCCN¹.

Taiwan FDA Approved Indication:

Combined with dexamethasone as

- 1. Primary therapy for non-transplant candidates.
- 2. Therapy for previously treated multiple myeloma.

Quality Accreditations of lenalidomide generics:

- 1. PIC/S GMP
- 2. BE study: 25mg, 15mg; Dissolution testing: 10mg, 5mg

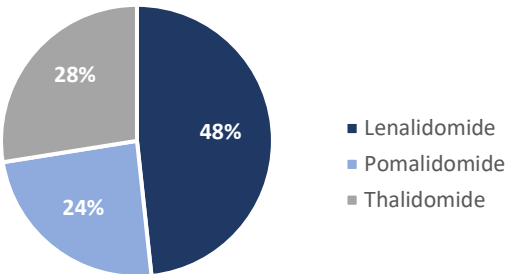
Regular Dosing Schedule:

- ✓ 25mg QD, days 1-21 of repeated 28-day cycles

2018 Quick Fact of Taiwan Lenalidomide Market^{2,3}

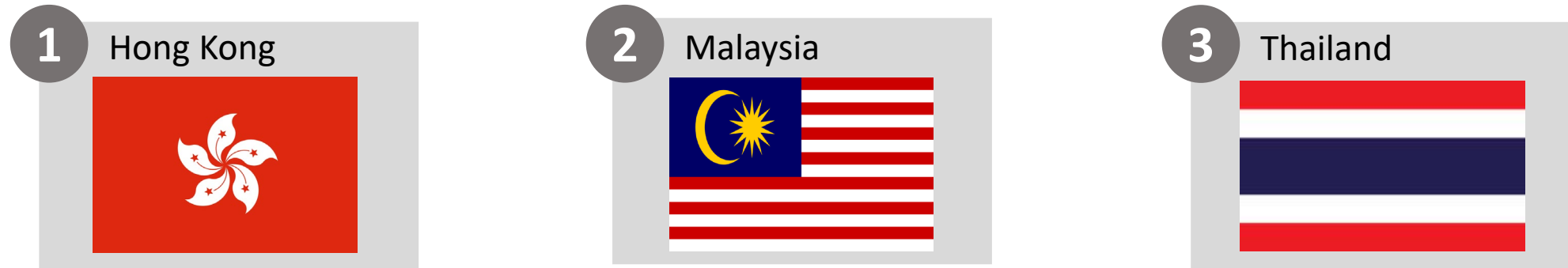
ASIR	No. of MM Cases	Annual Consumption	Drug Price (25mg)	Market Value	CAGR (2015-2018)
1.71	664	58,567 caps	123.7 USD	7.03 M USD	25.88%

2018 Immunomodulatory -imide Drugs Market Size: 14.7 M in USD, CAGR: 19.5% (2015-2018)



➤ Business Growth Problem: where is the most favorable export market for lenalidomide?

Market Selection Methodology: Evaluates results of both internal and external analysis to identify the most feasible market.



Selection Methodology



Internal and External Analysis: Thailand is the most favorable market in terms of the Company X's operating business capability and the opportunity for the lenalidomide business in the country.

Country	Internal Analysis ⁴			External Analysis ^{5 - 13}				Rank
	Sum of Share of Profit/Loss (5 years) USD	Business Operation Type	Approved Licenses	Market Perspective	Payer Policies & Channels	Pricing USD & Annual Consumption	Competition	
Hong Kong (Worldco)	(202,603)	Subsidiary	10	PPL: 7.5M ASIR: 2.0 Case/year: 286	Self-financed item w, w/o safety net Major Channel: Pharmacy	MNF: 81.9 Units: 40,761	Lena: C Poma: C	3
Malaysia (Pharm-D)	Unknown	Distributor	6 (includes Thalidomide®)	PPL: 32M ASIR: 0.71 Case/year: 344	Self-financed or insurance Major Channel: Private Hospitals (85.7%)	MNF: 128.97 Units: 8,883	Tha: Company X Lena: C, Dr.Reddy Poma: C	2
Thailand (Company Y)	4,820,078	Affiliate	11 (includes Thalidomide®)	PPL: 69.6M ASIR: 0.74 Case/year: 1,411	Public Health Insurance Major Channel: Public Hospitals	MNF: 287.33 Units: 8,022	Tha: Company X, C Lena: C, Alvogen Pome: C	1

*Assumptions: Sales revenue in each country goes directly into subsidiaries or affiliates' Profit/Loss, not the parent company's. The Sum of Profit/Loss is a strong indicator of business performance for subsidiaries or affiliates in each country. In Hong Kong, only Worldco is represented for business performance. Gligio International Limited only sells Painkyl®. If the country market is profitable, Company X will set up subsidiaries or affiliates instead of distributors. If Company X has a registered Thalidomide® license in the country, meaning it has existing networks for selling drugs for MM patients. Abbreviation: PPL, population; ASIR, age-standardized incidence rate; C, Celgene. Colors: green = favorable, yellow = moderate, red = not favorable.

Market Insights (1/3): Majority of multiple myeloma patients are under the Universal Coverage Scheme, and lenalidomide is not fully reimbursed.

Availability: Drug Registration^{*,14}

Technical Document Evaluation for Generic: 59,000 THB

Application Fee: 2,500 THB

License Fee: 2,000 THB → Total: 63,500 THB = 2,050 USD

Time: 18 Months

Step 1: the permission to import/manufacture drug samples.

- 1) Application form: Nor Yor 8
- 2) Labels
- 3) Leaflets

Step 2: Application for product registration approval

- 1) Chemistry
- 2) Manufacturing
- 3) Quality Controls
- 4) Labeling
- 5) Bioequivalence⁺⁺

Accessibility: Three main public health insurance schemes

Lenalidomide is not included in the National List of Essential Medicines (NLEM), the accessibility is different among three schemes.

Comparison Table¹⁵

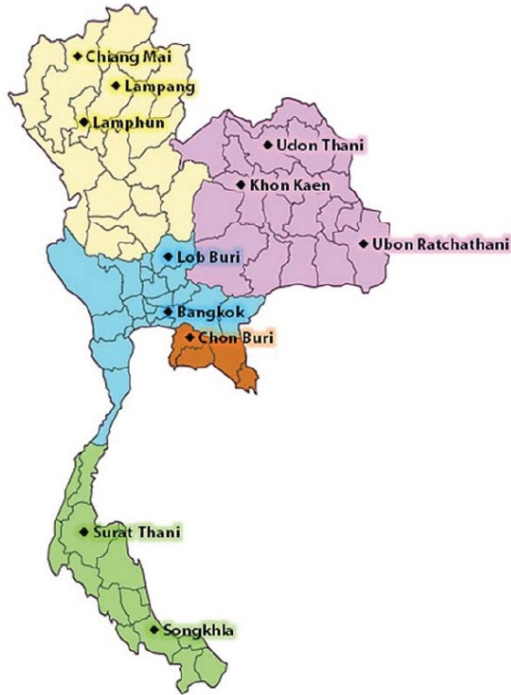
Scheme	Covered Population	Lenalidomide Category	Reimbursement (Outpatients)
UCS	72.2%	Non-NLEM Non-protocol	Max 4,000 THB/visit
SSS	18.5%	Non-NLEM Non-protocol	Max 50,000 THB/year
CSMBS	7.6%	OCA	Fully reimbursed, if eligible

Note:

- *Thalidomide is not included in the NLEM.*
- Pomalidomide is included in the CGD's negative list.

^{*}ASEAN harmonization on pharmaceutical registration: ACTD, ACTR. ⁺⁺Bioequivalence study results from foreign institutes or laboratories are acceptable based on Ministerial Regulation on Drug Registration B.E. 2555(2012)
Abbreviation: ACTR, ASEAN Common Technical Requirement; ACTD, ASEAN Common Technical Dossier; UCS, Universal Coverage Scheme; SSS, Social Security Scheme; CSMBS, Civil Servant Medical Benefit Scheme; OCA, Oncology prior authorization; CGD, Comptroller General's Department.

Market Insights (2/3): The business might need to be operated in centralized model with satellites to optimize efficiency and effectiveness.



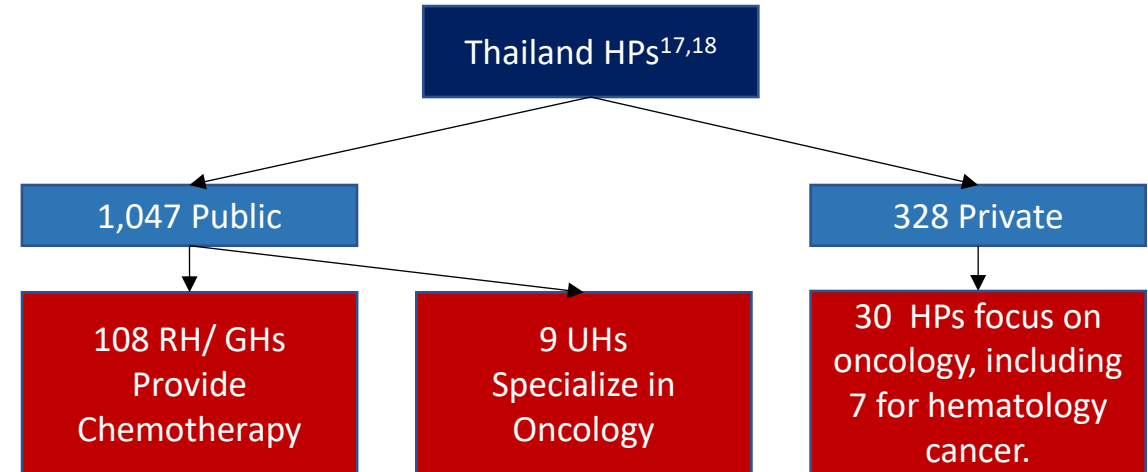
Multiple Myeloma Population Distribution ¹⁶ , 2014				
Region	Cancer Registry	Case No. 2014	Registry, %	Region, %
Northern	Chiang Mai	25	7.69%	14.46%
	Lampang	17	5.23%	
	Lamphun	5	1.54%	
Northeastern	Udon Thani	6	1.85%	21.23%
	Khon Kaen	32	9.85%	
	Ubon Ratchathani	31	9.54%	
Central	Lop Buri	7	2.15%	48.92%
	Bangkok	152	46.77%	
Eastern	Chon Buri	15	4.62%	4.62%
Southern	Surat Thani	7	2.15%	10.77%
	Songkhla	28	8.62%	

From Bangkok to	Chon Buri	Lop Buri	Chiang Mai	Lampang	Lamphun	Khon Kaen	Udon Thani	Ubon Ratchathani	Surat Thani	Songkhla
Car (hr)	1.25	2	8.5	7	8	6	8	8	8	12.5
Flight (hr)			1	1.3	1	1	1	1	1	1.3
R.Ticket (USD)			52	107	52	47	47	47	47	52

*Warning: data might be obsolete, so they might not represent the current situation. Moreover, the case number was estimated, not the actual number.

*Assumptions: data collected can still represent the current patients' landscape.

Market Insights (3/3): The business should focus on around 150 key hospital accounts that provide oncology service out of 1,400+ hospitals.



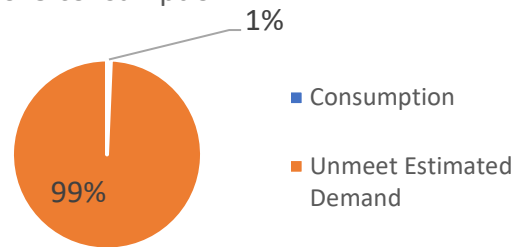
Region	Regional	General	Total	MM, %
Central	8	19	27	48.92%
Eastern	5	3	8	4.62%
Northeastern	8	24	32	21.23%
Northern	6	15	21	14.46%
Southern	6	14	20	10.77%

*Please see appendix 2, 3 for full university hospital and private hospital list. Abbreviation: RH, Regional Hospital; GH, General Hospital; UH, University Hospital; Assumptions: data collected are accurate and updated.

Market and Pricing: The pricing objective is to increase the usage of lenalidomide and expand the market share in Thailand instead of margin.

Thailand Lenalidomide Market Sizing (based on Taiwan model):

Estimated demand: $1,411 \times 88.2 = 124,451$ caps / year
2019 consumption



Due to the high price, lenalidomide is not included in the NLEM, limiting its usage in public hospitals. However, the Thai FDA has approved Alvogen's generic drug on February 20, 2020. As a result, the annual consumption is expected to grow in the next few years so that the market share would be significant than the margin.

Pricing:

1. Competitive Analysis:

- Assume generic price is 70 % of the originator's price.
- Our price would be the same as Alvogen's price, around \$200.

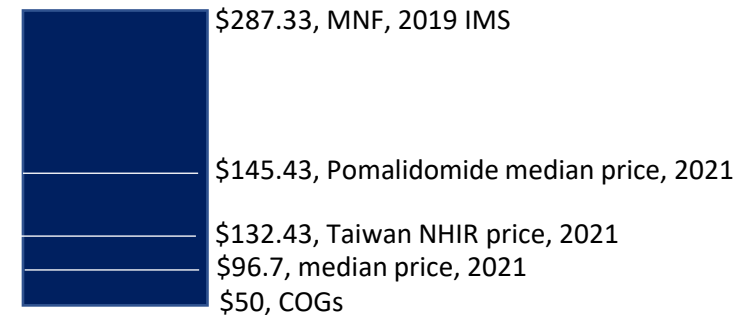
2. Cost-based Pricing:

- The COGs is usually 32.8% of the sales, so the price would be \$153.

3. Price-based Costing:

- Maximum \$145 as Pomalidomide median price

***Assumptions: public price \$200 , private price \$220.**



* Price in IMS data is before the Thai FDA approves generic, so that the price might be different now.

Business Strategy and investments: Assume Company Y has an established sales team (cost includes in SG&A as add-on cost), so major investment goes into marketing activities to cultivate the business for the long-term.

Business Objective:

1. Increase market share.
2. Minimize the cost.

Marketing Plan:

1. Increase touchpoints with multiple myeloma patients and form a patient network.
2. Build a strong brand image in cancer caring and charity.
3. Engage with oncologists and hematologists societies.
4. Promote affordable lenalidomide.

Sales Plan:

1. Company X: (assume Company Y already has a sales team to cover lenalidomide business activities.
 - Focus on central and eastern regions, including 39 key accounts.
 - Create KOLS profiles and tender & listing schedule.
 - Manage public and private differently to optimize outcome.
2. Distributor: contract for 5 years, 15% service fee.
 - Manage northern, northeastern, and southern regions.
 - Grow these regions and cultivate patient bases.

Major Investment: \$100,000 (includes drug registration)

1. Establish Multiple Myeloma Foundation:

- Set up cost: 16,000 USD
- Annual salary: 12,000 USD per person
- Gather patients and oncologists through this platform.
- Convert patients into PAP program.

2. Patient access program (PAP):

- Provide long-term benefit: buy 4 box get 1 box free (20%).
- Expect 50 patients per year and grow with the awareness of the foundation.

3. Foundation Website:

- Set up fee: 2,000 USD
- SEO & SEM & Management: 12,000 USD

4. Sponsor TSCO and National Cancer Institute Foundation:

- Sponsor patient activities: 3,000 USD
- Sponsor doctor activities: 5,000 USD

Implementation - Timeline: Assume all patents of Revlimid® expire at the end of 2021; Company Y files the dossiers at the 2021 Q3 and successfully gets approval by 2022 Q4.

Item	2021	2022	2023	2024	2025	2026	2027	2028	2029	2030	2031	2032
Drug Registration												
Approval												
Product Launch												
Establish multiple myeloma foundation												
Create patient access program												
Foundation's website and SEO&SEM												
Sponsor TSCO and NCIF												
Partner with distributor (in N, NE, and S Regions)												
Direct sales team (in N, NE, and S Regions)												

* There is no price war and significant changes in the Thailand government's regulation on the reimbursement policy for expensive oncology medicines like the pomalidomide in the realistic case setting. Moreover, there is no new entrant from India in these ten years.

Financial Projections: Projections have been made in the three different scenarios to test the feasibility of the lenalidomide business plan in Thailand. All net present values in these scenarios are positive.

Year	2023	2024	2025	2026	2027	2028	2029	2030	2031	2032
MM patients.	1,560	1,613	1,668	1,724	1,783	1,844	1,906	1,971	2,038	2,108
Acquired patients.	106	218	226	302	369	465	418	525	582	638
Market share	7%	14%	14%	18%	21%	25%	22%	27%	29%	30%
Net Sales	4,840,455	9,939,047	10,047,816	13,190,901	15,817,391	20,883,309	18,300,146	22,671,061	24,634,598	26,510,525
COGS	1,391,940	2,868,525	2,977,414	3,973,926	4,855,279	6,120,252	5,509,658	6,918,781	7,659,298	8,399,815
Gross profit (loss)	3,448,515	7,070,522	7,070,402	9,216,975	10,962,112	14,763,057	12,790,488	15,752,281	16,975,300	18,110,710
SG&A, 30%	1,452,137	2,981,714	3,014,345	3,957,270	4,745,217	6,264,993	5,490,044	6,801,318	7,390,379	7,953,157
EBIT	1,996,379	4,088,808	4,056,057	5,259,705	6,216,895	8,498,065	7,300,444	8,950,962	9,584,921	10,157,553
Income tax, (23%, EBIT)	459,167	940,426	932,893	1,209,732	1,429,886	1,954,555	1,679,102	2,058,721	2,204,532	2,336,237
Net profit (loss)	1,537,212	3,148,382	3,123,164	4,049,973	4,787,009	6,543,510	5,621,342	6,892,241	7,380,389	7,821,316

* Amount in USD. COGS equals \$50 per cap with 4.5% import tax. SG&A includes marketing and sales activities cost. Income tax is based on Company Y's income statement. The table presented is the moderate case.

Optimistic Scenario

Breakeven time: < 1 years

Accumulated Net profit: \$ 76,806,191

NPV: \$28,371,596.16 (Discount rate:15%)

Realistic Scenario

Breakeven time: < 1 years

Accumulated Net profit: \$ 50,904,537

NPV: \$18,776,533.56 (Discount rate:15%)

Not as expected

Breakeven time: < 1 years

Accumulated Net profit: \$ 37,378,117

NPV: \$13,765,778.64 (Discount rate:15%)

* Settings for the financial model: the multiple myeloma patients' growth rate uses Taiwan's CAGR in the mature phase. Market share is defined as the annual consumption divided by the regular usage of a patient / projected patient population. COGS includes the import tax of around 4.5%. SG&A is usually about 48% at Company Y, and the assumed rate is 30% for the lenalidomide case. The income tax is based on the Company Y's current tax rate.

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Problem

Methodology

Analysis

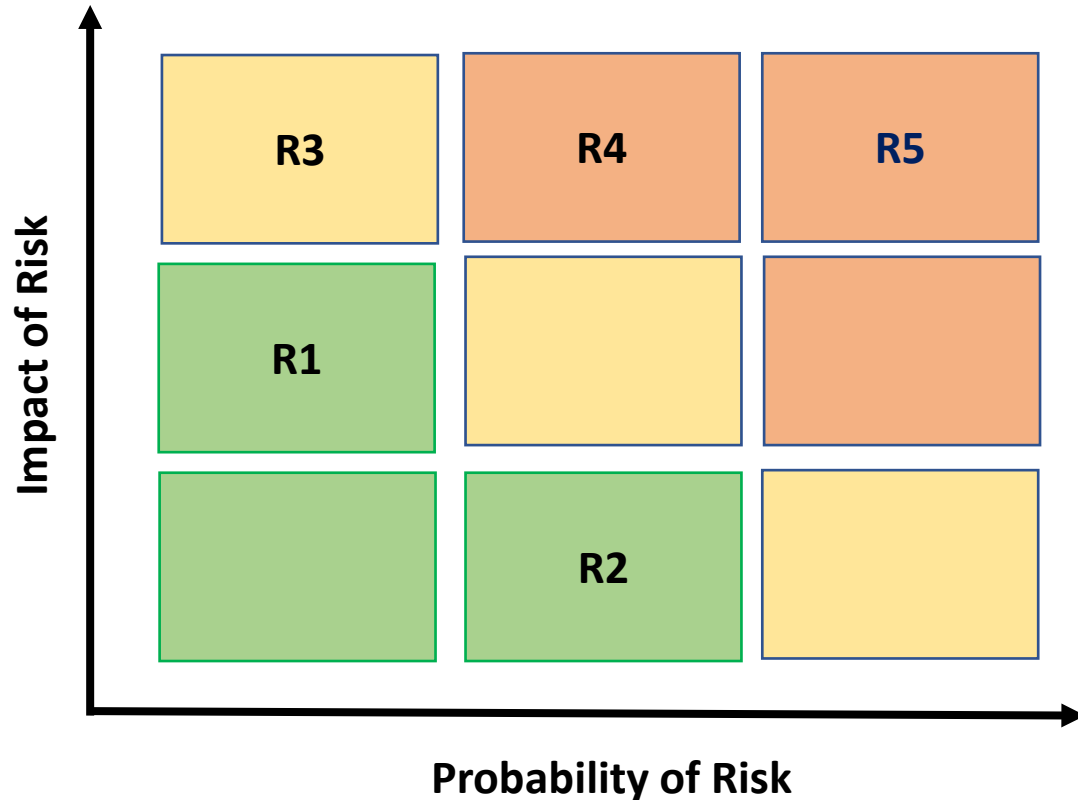
Market

Business Plan

Risk Mitigation

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Risk - Mitigation Plan: To cope with uncertainties in the Thailand market, we should have a contingency plan for various scenarios to mitigate the risk.



Id	Risk	Mitigation action
Risk 1 (R1)	Counterfeit drugs	Select trustworthy distributor and anti-counterfeit package
Risk 2 (R2)	Cannibalization of Thalidomide market due to lenalidomide launch in Thailand.	Offer preferential plan to retain and convert patients to use lenalidomide.
Risk 3 (R3)	Price of pomalidomide drops sharply in these ten years.	Start evaluate whether develop pomalidomide generic is feasible.
Risk 4 (R4)	Other lenalidomide vendors start the price war.	Conducting stress testing to formulate the contingency plan.
Risk 5 (R5)	Entry of Indian competitors like Natco Pharma, Dr. Reddy's , etc.	Build up the multiple myeloma network through MMF and PAP.

Risk - Stress Testing: Assuming in the extreme case of the price war, Company Y takes a small market share, and the price is half of the realistic case. The NPV is still positive. Moreover, Alvogen and Celgene are in an inferior financial status compared to Company Y in Thailand.

Year	2023	2024	2025	2026	2027	2028	2029	2030	2031	2032
MM patients.	1,560	1,613	1,668	1,724	1,783	1,844	1,906	1,971	2,038	2,108
Acquired patients.	40	82	85	113	138	174	157	197	218	239
Market share	3%	5%	5%	7%	8%	9%	8%	10%	11%	11%
Net Sales	836,010	1,770,046	1,769,397	2,338,562	2,811,717	3,678,578	3,183,490	3,992,815	4,351,265	4,693,779
COGS	521,978	1,075,697	1,116,530	1,490,222	1,820,730	2,295,094	2,066,122	2,594,543	2,872,237	3,149,930
Gross profit (loss)	314,033	694,349	652,867	848,340	990,988	1,383,484	1,117,368	1,398,272	1,479,028	1,543,849
SG&A, 30%	250,803	531,014	530,819	701,569	843,515	1,103,574	955,047	1,197,844	1,305,379	1,408,134
EBIT	63,230	163,336	122,048	146,771	147,472	279,911	162,321	200,428	173,649	135,715
Income tax, (23%, EBIT)	14,543	37,567	28,071	33,757	33,919	64,379	37,334	46,098	39,939	31,214
Net profit (loss)	48,687	125,768	93,977	113,014	113,554	215,531	124,987	154,329	133,710	104,501

Financial Information ¹⁹			
Company	Company asset (THB)	Sum of net profit (2014 - 2019, THB)	COGS
Company Y	799,938,766	373,828,080	32.9%
Alvogen (Thailand)	293,642,814	34,247,086	66.2%
Sell China (Celgene)	303,033,337	45,384,718	90.5%

In General, Company Y's company value is two times higher than competitors' and has more budget to invest in price war if needed. In a rational setting, the risk of price war is relatively low.

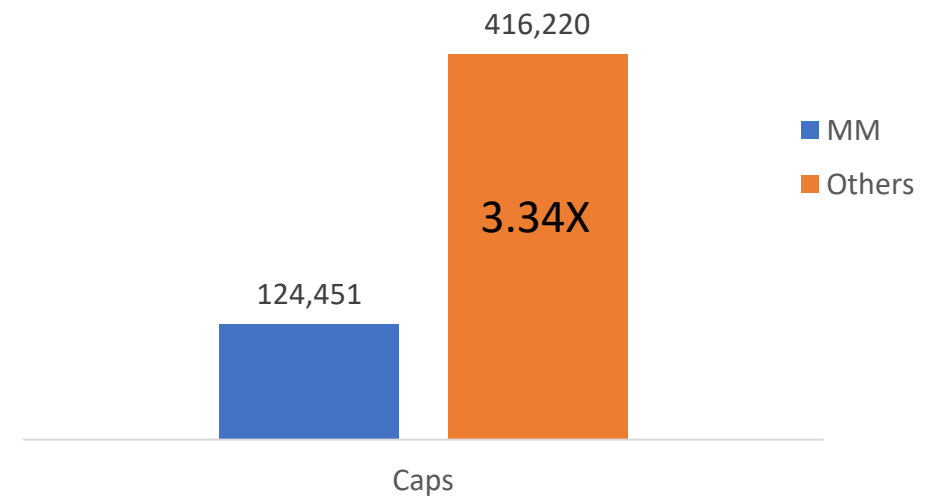
One more thing - new Indications: assume Company Y has established sales team, so major investment goes into marketing activities to cultivate the business for the long-term. 20, 21, 22, 23

Alvogen got additional new indications in Thailand:

- 1. Myelodysplastic syndromes (MDS):** Lenalidomide as monotherapy is indicated for the treatment of adult patients with transfusion dependent anemia due to low- or intermediate-1-risk myelodysplastic syndromes associated with an isolated deletion 5q cytogenetic abnormality when other therapeutic options are insufficient or inadequate.
- 2. Mantle cell lymphoma (MCL):** Lenalidomide as monotherapy is indicated for the treatment of adult patients with relapsed or refractory mantle cell lymphoma.
- 3. Follicular lymphoma (FL):** Lenalidomide in combination with rituximab (anti-CD20 antibody) is indicated for the treatment of adult patients with previously treated follicular lymphoma (Grade 1 - 3a)

*Celgene's indication has not changed in Thailand currently. Celgene also got approval of marginal zone B-cell lymphoma , but not in Thailand.

Type	Case per year	Dosage	Market Sizing (caps)
MDS (del 5q)	104	10mg QD daily, repeated 28 days cycle	34,944
MCL	257	25mg QD, days 1-21 of repeated 28-day cycles	64,764
FL	942	20mg QD daily, repeated 28 days cycle for 12 cycles	316,512
Total			416,220



*Due to lack of IMS data on the treatment of MDS, MCL, and FL. This presentation does not include the market analysis and business plan around these new indications.

THANK YOU FOR YOUR ATTENTION