ASSET EVALUATION
IN-DEPTH CASE STUDY

Situation

The client, PharmaA, was a **medium-sized pharmaceutical company with a market cap of £3 billion**. The client was **interested in launching an antibiotic asset**, AX, for treating pathogens with limited treatment options in Central and Southern Europe, as well as the Middle East. AX is a particularly strong candidate for commercialisation due to its novelty in tackling multi-resistant antibiotic pathogens and the extremely high unmet demands in the targeted regions.

Since the commercialisation of antibiotics in the 1940s many successful antibiotics have been developed, but these gave rise to a growing number of pathogens with one or more antibiotic resistance.[1] It is increasingly challenging to develop novel therapies, leading to a severe shortage of antibiotics for overcoming multiple drug resistance in difficult-to-treat infections.[1] This is particularly alarming in regions with low healthcare budgets as they can only afford generics and are most at risk of infection pandemics. The targeted regions have a high rate and overall number of multiple-resistant strains, with a clear concern amongst physicians. AX is therefore a strong candidate to tackle this high unmet need and deliver significant social and commercial impact.

AX was designed to combat a variety of difficult-to-treat, multi-drug resistant pathogens including X-resistant strains. The drug was in an on-going phase 3 trial with high treatment potential but faced challenges around recruiting patients. The market environment was favourable for the asset as these regions have high demand (incidence rate of target infections) and unmet needs. However, **the client was unsure whether the health economy of these regions could sustain the drug's desired price point.**

The client engaged Deallus to work with their business intelligence manager for Europe, the Middle East and Africa (EMEA) region to evaluate the commercial value of the asset and to advise on the best route to commercialisation (i.e. whether to operate in those regions, and if yes, how best to go about it).

Key client questions

Market
› What are the incidence rates in the target country?
› What are the patient numbers/market share?
› What are the unmet needs? Could AX fulfill these needs?

Competition
› What comparable treatments are currently available?
› How would competitors impact AX?
› Are there prospective competitor products?

Should we go ahead investing to setup operation in these regions? If yes, where and how?

Financial
› How should it be priced?
› How much does the potential investment cost?
› What is the volume that could justify the investment?

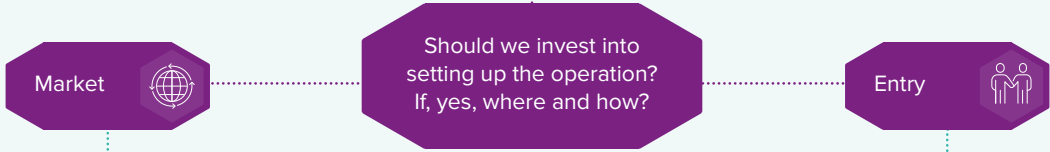### Product
› What indication(s) should we target?
› How frequently should the drug be consumed?
› What are the potential risks of AX?

*Company and drug names have been changed for confidentiality purposes.

[1] Walkden, Brendan. Antibiotics: pharma's Cinderella story. PMLiVE. [Online] 03 11 2014. http://www.pmlive.com/pharma_news/antibiotics_pharmas_cinderella_story_607271?SQ

What factors should we consider for assessing the feasibility of setting up operations for AX development in Central and Southern Europe, and EMEA?

Should we invest into setting up the operation? If, yes, where and how?

Market

Entry

Market

Competition
- Comparative drugs available (branded or generics)
  - Price
  - Access
  - Market share

Size/trend
- Number of incidence for targeted infections
- Preferred indication(s) (broad or narrow spectrum)
- Potential volume at x price
- Estimated market share

Economy
- Local healthcare economy (GPD per capita)
- Pricing
- Profitability (revenue vs cost)

Barriers for entry
- Regulatory limitations
- Unsuccessful clinical trials
- Counter-launch from competitors

Entry

- Start from scratch
- Acquire an existing player
- Form a strategic partnership with an existing player

Action and analysis

Deallus forecasted market size, growth and potential indication(s) of AX in 15 targeted countries supported by primary and secondary data.

Conducted online market research and interviews with key stakeholders in the target countries to:

> Quantify level of drug resistance observed
> Evaluate target product profile for AX
> Predict usage frequency
> Understand preference of AX pricing
> Assess potential risks of AX
> Evaluate current available treatment regimes
> Assess and evaluate treatment regime decision-making process, including preferences in diagnostics, prescription, and treatment switch triggers

Reviewed and analyzed epidemiology data of bacterial infections (validated against primary research data) to quantify potential patient size via:

> Incidence rate
> X-resistance rate
> Microbiology testing rate
> Comparable treatments
> GPD per capita for healthcare

Primary Research

Secondary Research

Financial and scenario forecast

Created a financial forecasting model to estimate market size and assess feasibility of out-licensing in each target country by using insights from primary and secondary research.

> Designed an Excel financial forecasting model including all key assessment parameters:
> Revenue
> Pricing sensitivities
> Cost
> Profitability
> Built a bespoke scenario forecast model quantitatively assessing the feasibilty of out-licensing deals:
> Percentage loyalty
> Length of treatment
> Frequency of use
> Choice of indication(s)

> Prioritised regions out of the 15 countries via:
> Likelihood of drug usage from physicians
> Level of infection
> State of healthcare economy (GDP)

Key insights

PRIMARY RESEARCH

> Microbiology testing became more significant as patients progressed further through the antibiotic treatment regimen.

> Factors affecting antibiotic prescription decision process included: efficacy, spectrum of coverage, safety and cost.

> AX is expected to treat X-resistant strains and be used as last line of treatment.

> Russia, Poland, Greece and Saudi Arabia could be most likely to switch from empiric to targeted treatment.

> AX is predicted to be used in approximately 50% of X-resistant infections.

> The main concerns for AX included: long infusion time, side effects, limited efficacy and high cost.

> AX was predicted to be on formulary lists within a year in all countries.

SECONDARY RESEARCH

> X-resistance varied across the target countries, which reflected the physician' perceived need to tackle this problem.

> Turkey, Russia and Greece had the highest X-resistance rate and thus unmet need.

> Bacterial strains for testing differed between countries; the AX antibiotic resistance was only routinely carried out in Poland and Greece.

> A wide range of phenotypic and genetic testing methods are available to prescribers for verifying the antibacterial resistance.

FINANCIAL & SCENARIO FORECAST

> Analysis of healthcare spend/GDP for each country gave an indicator of the likelihood of the healthcare economy to accept a premium price for a novel antibiotic.

> This was triangulated with epidemiology data and "bottom-up" forecasting which incorporated physician reaction to the product profile and treatment patterns in their own hospitals.

> AX was forecasted to have the highest commercial opportunity in Russia and Egypt driven by demographics and incidence of targeted infections.

> Saudi Arabia was predicted with potential high market share despite the relatively low incidence of targeted infections.

> Expected AX price varied between countries.

Key recommendations

Prioritize key markets

- Physicians across all countries showed positive reaction to AX's treatment profile and concerns for the limited treatment options for targeted infections.
- X-resistance was high in these countries and trending to greater levels that could create further need for antibiotics of targeted infections.
- Deallus recommended the client to prioritise certain markets, focus their investment, and gain a strategic foothold to support other priority assets.
  - Deallus made strategic recommendations to the client highlighting that 75% of the forecasted revenues for the region would be realised from 4 of the countries out of the 15 in scope. This allowed the company to selectively invest in go-to-market models tailored for these 4 countries, whilst evaluating partnerships to access the remaining markets.
- In the non-priority markets, Deallus recommended that the client strategically partner with companies with an existing infrastructure and sales related royalties, allowing the client to recognize the major market and minimize market entry costs.

Impact

AX is currently under phase 3 clinical trial with positive results, and is well-received by industrial experts

Equipped with clarifying, tailored insights regarding the most lucrative markets, the client was empowered to make selective investments

The client followed Deallus' advice and decided to out-license AX for optimal financial gain