What you know:

The product: Diclofenac is a drug that your company acquired from BayRx earlier this year and is an oral anti-inflammatory agent indicated for the treatment of rheumatoid arthritis (RA).

The company: Dr. Pala and Dr. Martinez are CSO (science) and CCO (clinical), respectively. Rob Watson oversees Sam Davis and Andrea Nguyen. Sam Davis and Andrea Nguyen are from the commercial arm of the company and have done extremely well in bringing other projects you oversee to a successful outcome on the market. Dr. Ross is a senior clinician that you consult from outside the company, and is a cancer expert. David Smith is also a member of clinical and was present at the meeting. Dr. Star and Jeremy Russet, a research associate in Star's group, have recently expanded into the area of skin cancer and have developed promising assays with 3 publications and 2 patents related to the assay. It is possible that studies with Diclofenac using their new assays would increase the scientific impact and provide rationale for developing Diclofenac as a general skin cancer drug.

Additional information: You've analyzed FDA-approved drugs that have topical and oral delivery methods. You've found that 20.5% of approved drugs were first approved as an oral and then subsequently approved for an additional indication (condition) with the same oral delivery method. On the other hand, 23% of FDA approved orally administered drugs have also been approved for topical use for the same indication. You've also surveyed the clinical trial landscape and know that other anti-inflammatory agents are coming into the market in the next 3-4 years. The deadline for finalizing the team's recommendation for presentation to the CEO regarding what additional indication and/or formulation for Diclofenac to pursue for FDA approval is April 10.

Meeting #1:

Excerpt From Monday April 5 Meeting Notes.

You: Let's move to our next topic, re-visiting the indications for Diclofenac. Now, it's currently approved as an oral anti-inflammatory for rheumatoid arthritis, and several folks have stated in previous meetings that there are other indications or formulations we can push and seek FDA's approval.

Dr. Pala (CSO): It's critical that we settle on whether we're pursuing a new indication, new formulation, or seeking approval for a new delivery method.

Rob Watson (commercial manager): I think we should really be considering the topical application for RA. We could really be accessing a whole new set of patients and consumers. Andrea?

Andrea Nguyen (commercial): Our analysis of the market shows that we would break into new markets, and increase our earning potential by 10% up to 20% over last year's profit margin.

Sam Davis (commercial): We did a small survey of RA patients at the local hospital and found that of the 200 patients surveyed, 80 patients claimed to be hesitant to take oral anti-inflammatory medications and of those 80, 55 were more amenable to trying topical gels
instead.

Christian Martinez (CCO): The topical gel sounds like a good idea, but shouldn't we be talking about the data from clinical on the possibility of a new indication for skin cancer treatment.

Dr. Ross (Clinician, cancer expert): That's why we propose following up on the actinic keratosis indication. Last meeting I presented pre-clinical data we gathered on the oral and gel formulation of Diclofenac. This slide shows some promising preliminary data on our mouse models for actinic keratosis with both delivery methods.

Jeremy Russet (research associate): Don't you think we should be expanding to melanomas or other types of skin cancers?

Lindsey Star (R&D Scientist): I still think we should look into Diclofenac as an injectable, it would be more effective than the oral or topical applications. It really is a shame that the folks at BayRx didn't try that in their exploration of Diclofenac.