Global Insulin Opportunity

a generic solution to supply constraints

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Insulin Pricing Can be Undercut by up to 50%

By leveraging a unique manufacturing process, Privium will capitalize on pricing inequities and penetrate the global marketplace

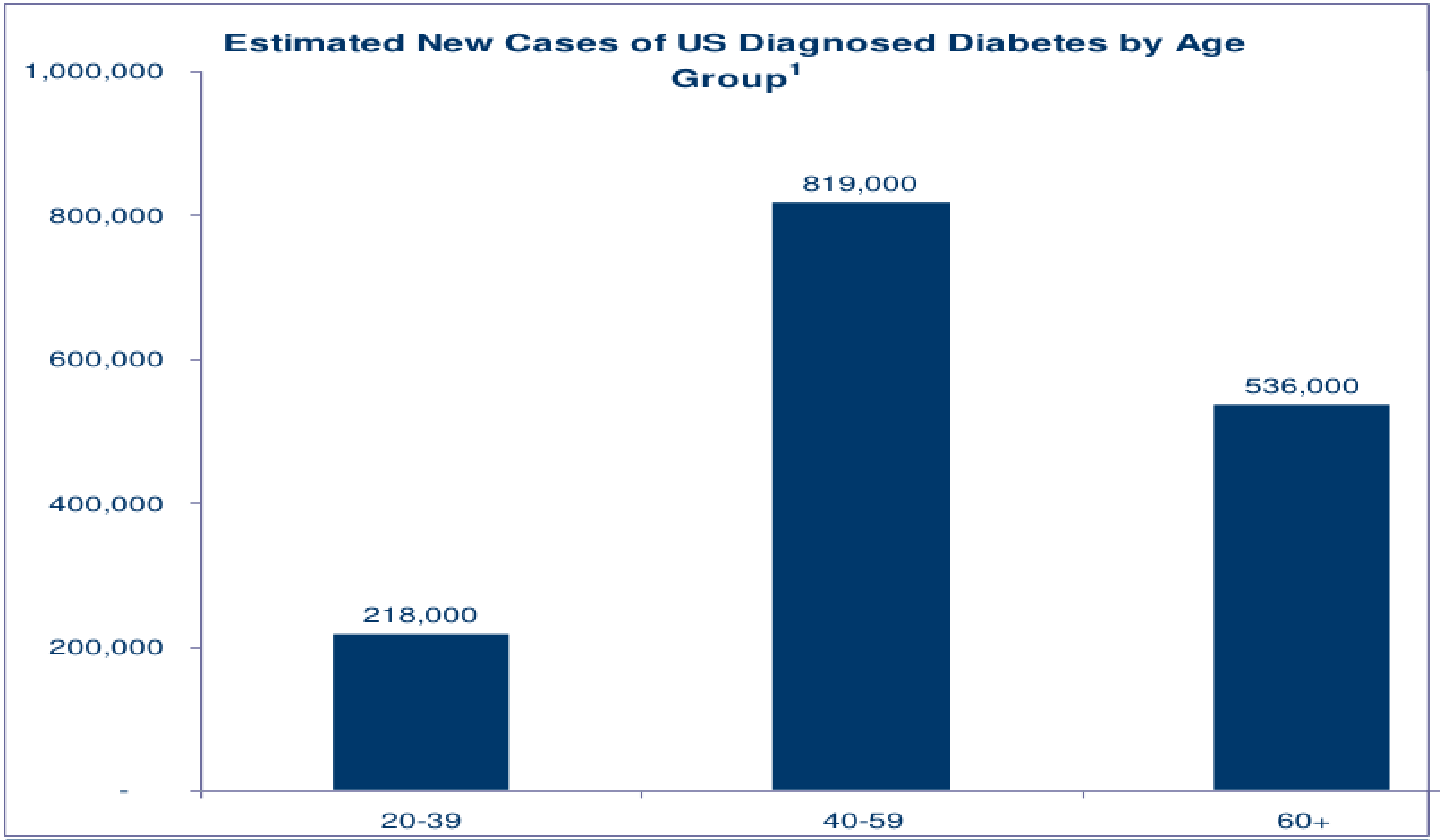
Strategic Overview

- Become renowned for making available the purest form of insulin to the widest number of users in target countries worldwide, offering it through the most convenient distribution channels in the most cost effective manner, thereby playing a role in alleviating the suffering of diabetic users
- Foment and nurture long term business partnerships with the leading medical providers in each target country to ensure speedy approval, effective and cost efficient distribution of our products to the widest user base

Market Trends

Diabetes is an under served epidemic due to supply and cost constraints

Over 1.5MM New Cases of Diagnosed Diabetes/Year in the U.S. Alone



- 6MM individuals in the U.S. alone take insulin and 50MM people worldwide
- As there are 27MM people in the U.S. with diabetes and 250MM worldwide, oral insulin would expand current usage by several fold

1. Estimated number of new cases of diagnosed diabetes in people aged 20 years or older, by age group, United States, CDC 2007

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‘Bio-Same’ not Biosimilar Product: 1st True Generic Insulin

The likelihood of an AB-rating should mandate health insurers to convert to this product globally

‘Bio-Same’ not Biosimilar Insulin Therapy		
Category of Data	**Non-AB Route**	**AB Route**
CMC Data	Comparative analysis	Rigorous comparative analysis
Bioassay Data	One comparative bioassay	Two comparative assays
Preclinical DATA	May be waived (1)	May be waived (1)
PK/PD	Rigorous comparative PK study to listed reference drug	Rigorous comparative PK studies to listed reference drug
Immunogenicity Data	Comparative data (2)	Comparative data (2)
Efficacy from Clinical trials	Efficacy data required (3) (immunogenicity data can be obtained simultaneously)	Not mandatory
Additional Considerations for CMC Data for Filing		

(1) If the CMC data is found acceptable.

(2) Fifty (50) patients are allowed for 6 months. Comparative data may would be either historical data or an active control obtained through a clinical efficacy trial.

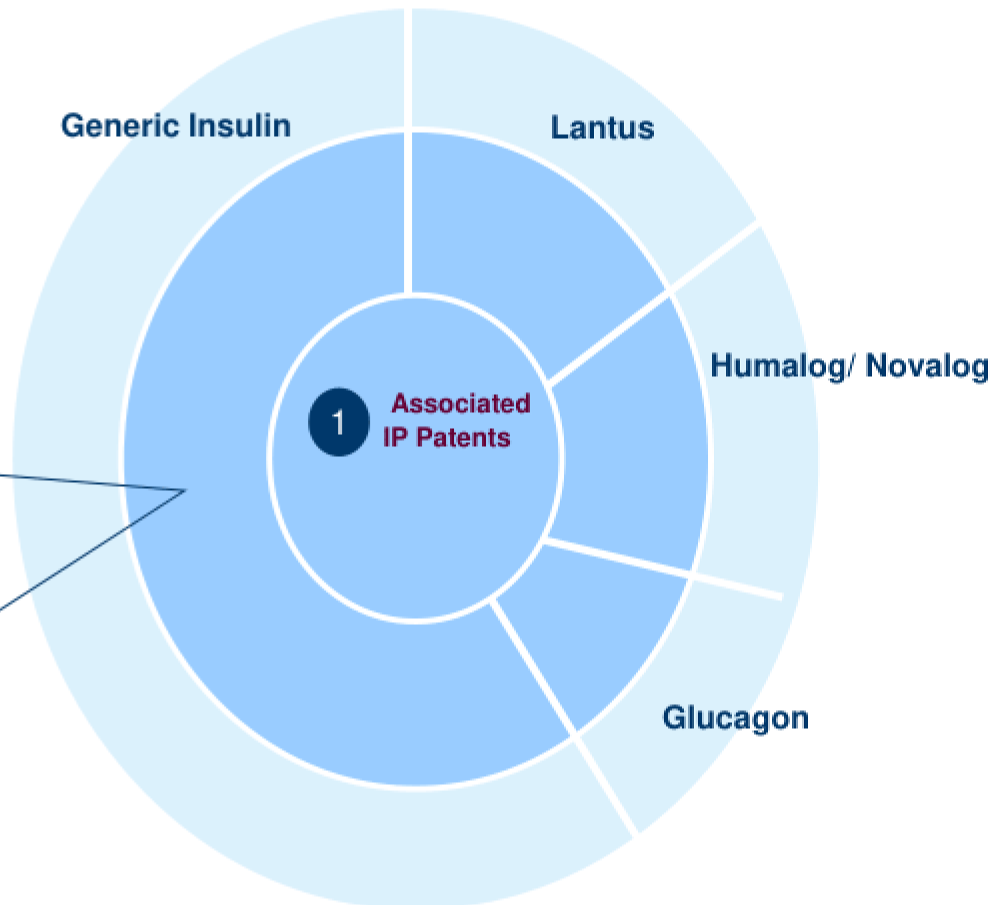
(3) A non-inferiority study is recommended. The demonstration of non-inferiority with respect to one indication (for the listed Rx) may be sufficient to obtain all of the indications described in the listed Rx’s prescribing information (provided there is no active market exclusivity that precludes this).

Intellectual Property (IP) Scope

There is an opportunity to own the entire sphere of core insulin products. Initially, we will cannibalize the vast opportunities in the regular generic insulin market; an expansion into other forms will follow

The generic insulin scope has been defined as:

- All insulin related products including glucagon
- All products related to insulin, including oral and inhaled bulk suppliers
- The production of insulin as a minor fraction of the cost
- Advanced methodology such that no other generic player can come in for duration of IP (18 years)
- Analytical tools and capabilities to support protein therapeutics in other areas



Scope of current core IP

Other WIP activities that will expand the IP scope

2 Manufacturing IP is the center of the patent estate and a full suite of patents have been filed and issued globally

3 In each division, there is room for IP discovery to move into other formulations, such as oral insulin

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Next Steps

- U.S. regulatory authorities have approved IND for human clinical trials and regulatory approval abroad is ongoing for generic-rated product in the next several months
- Current facilities have capacity for twice the current U.S. demand and country-specific agreements are being negotiated for regular injectable insulin
- Production and facility infrastructrure costs are a fraction of the cost of current processes, thereby opening the potential for a first-in-class pill-form insulin, which is subject to negotiation with Privium
- Other analogs of insulin are also being developed in conjunction to complement current therapeutic usage and also subject to in-licensing with Privium
- Glucagon in both injectable and pill form are available for discussion separate from insulin and insulin derivative agreements
- Contact Privium for partnering discussion related to Human Growth Hormone opportunities that are manufactured in the same U.S. facility