



InsuLine Medical

Medical Devices for
Faster Insulin Action

Update
January 2012


InsuLine

Disclaimer

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Agenda

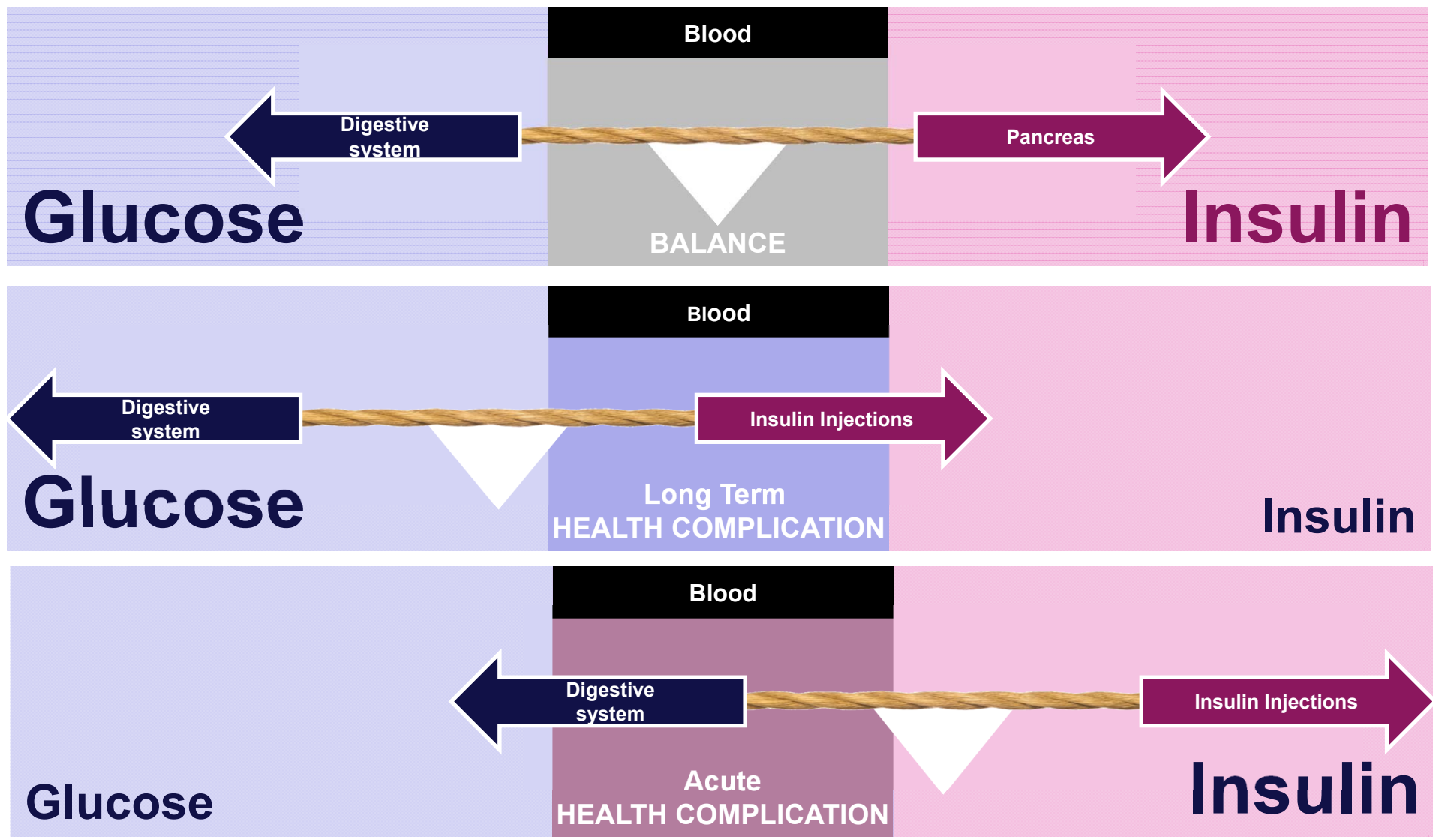
Reminder	Company, Market & Products Overview
	Initial Market Potential in Germany
Progress in past 18 months	
Work-plan for 2012	
Beyond 2012	

In a nutshell



Unique technology > Device instead of new drug	✓
Potential for sales in Germany as first market	✓
2011 – FDA study: efficacy part ended with good results Germany – achieved support of health insurers	✓
Plan for 2012 – Complete FDA study Start sales in Germany	✓

Diabetes 101



But the cost of complications is the biggest issue

First order Chronic disease, daily treatment



Over 10m patients
365 days per year

Multiple Daily Injections

- Insulin* - \$4.0bn
- Pumps & Sets - \$1.4bn
- Other disposables - \$5.0bn

* Sales of rapid analogs in 2009

Second order Serious long-term complications

Heart problems
Kidney failure
Stroke
Blindness
Amputation
Death

**#4 cause
of death
by
disease
globally**

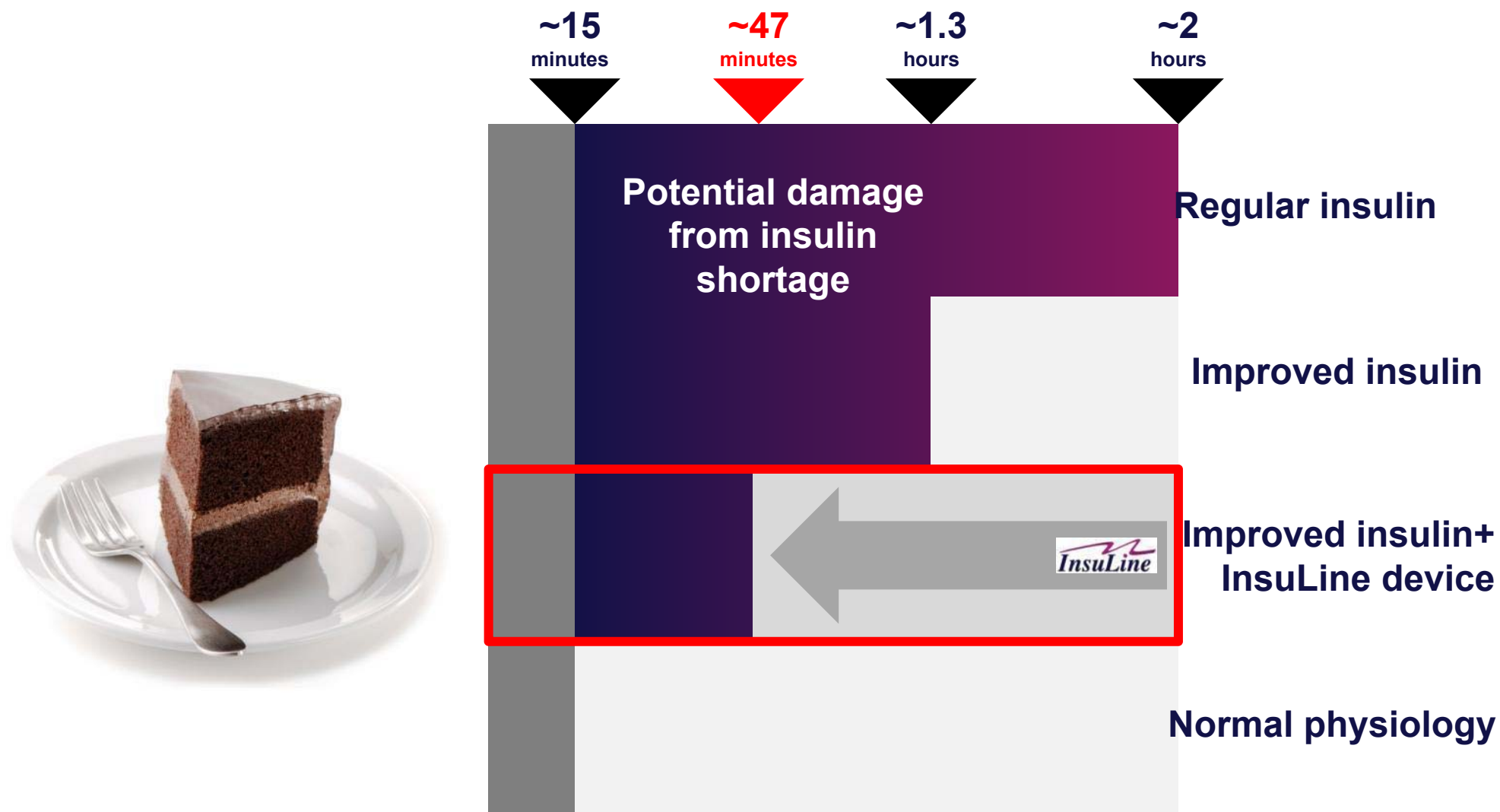
Estimated healthcare burden as a
direct result of diabetes:

>\$100bn

Source:

The InsuLine Innovation

Use of device to achieve shorter time to peak plasma insulin levels – instead of new insulin development

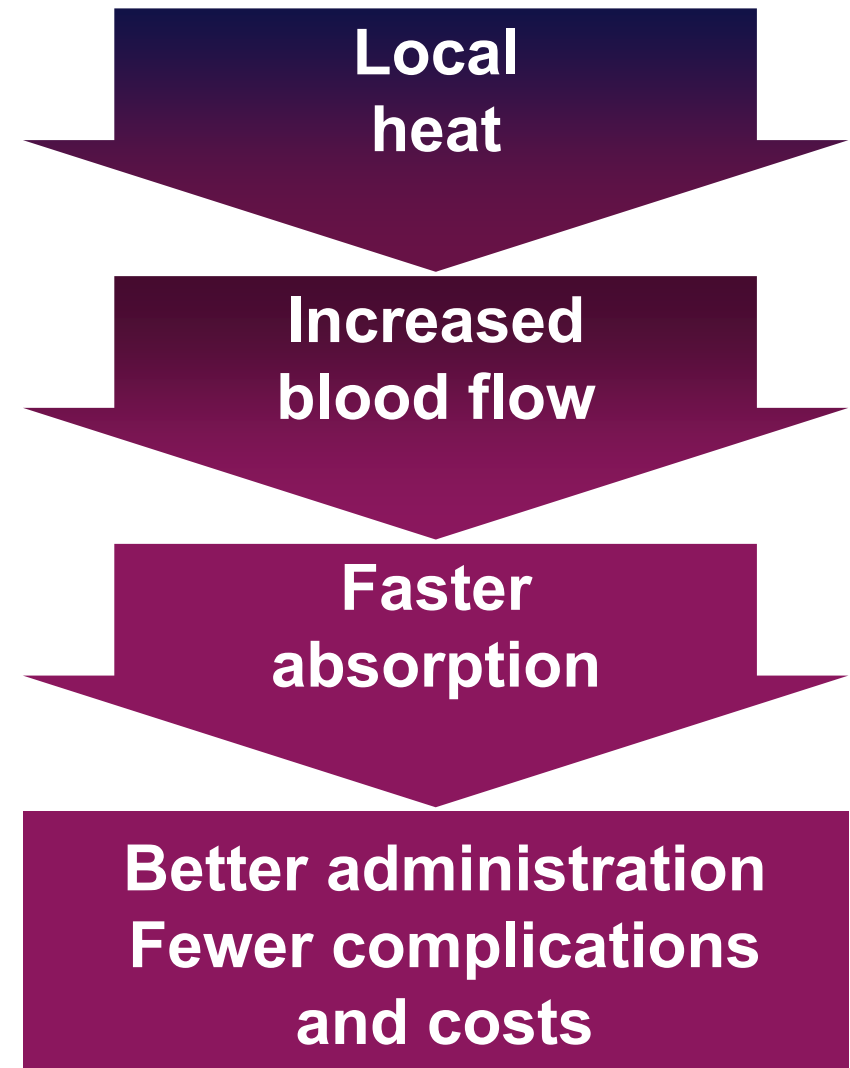
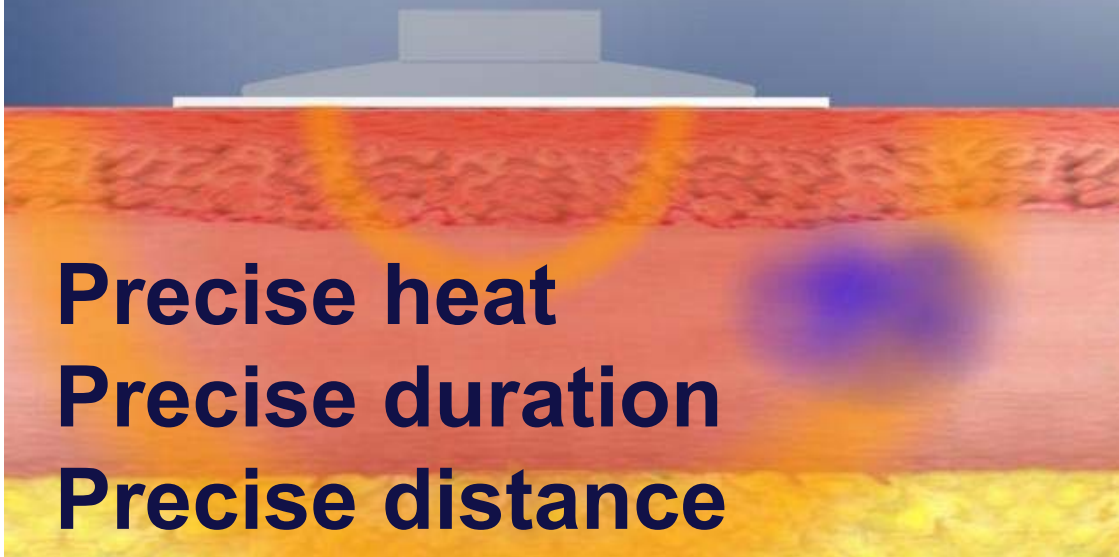


Principle of Operation:

Heating the point of injection, **not overheating the insulin**

Disposable device

**Engineering solution
to a pharmaceutical problem**



Seamless integration in existing treatment process

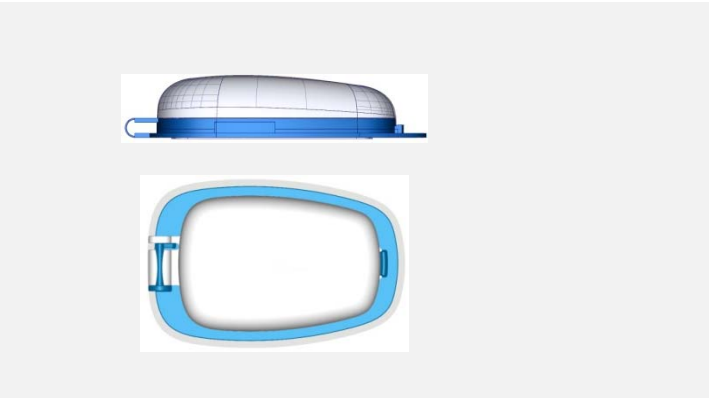
Two common treatment options

Two matching InsuLine device options

1

Injection

CE
InsuPad™
Patch for syringes



2

Insulin pump

CE
InsuPatch™
Catheter for pumps



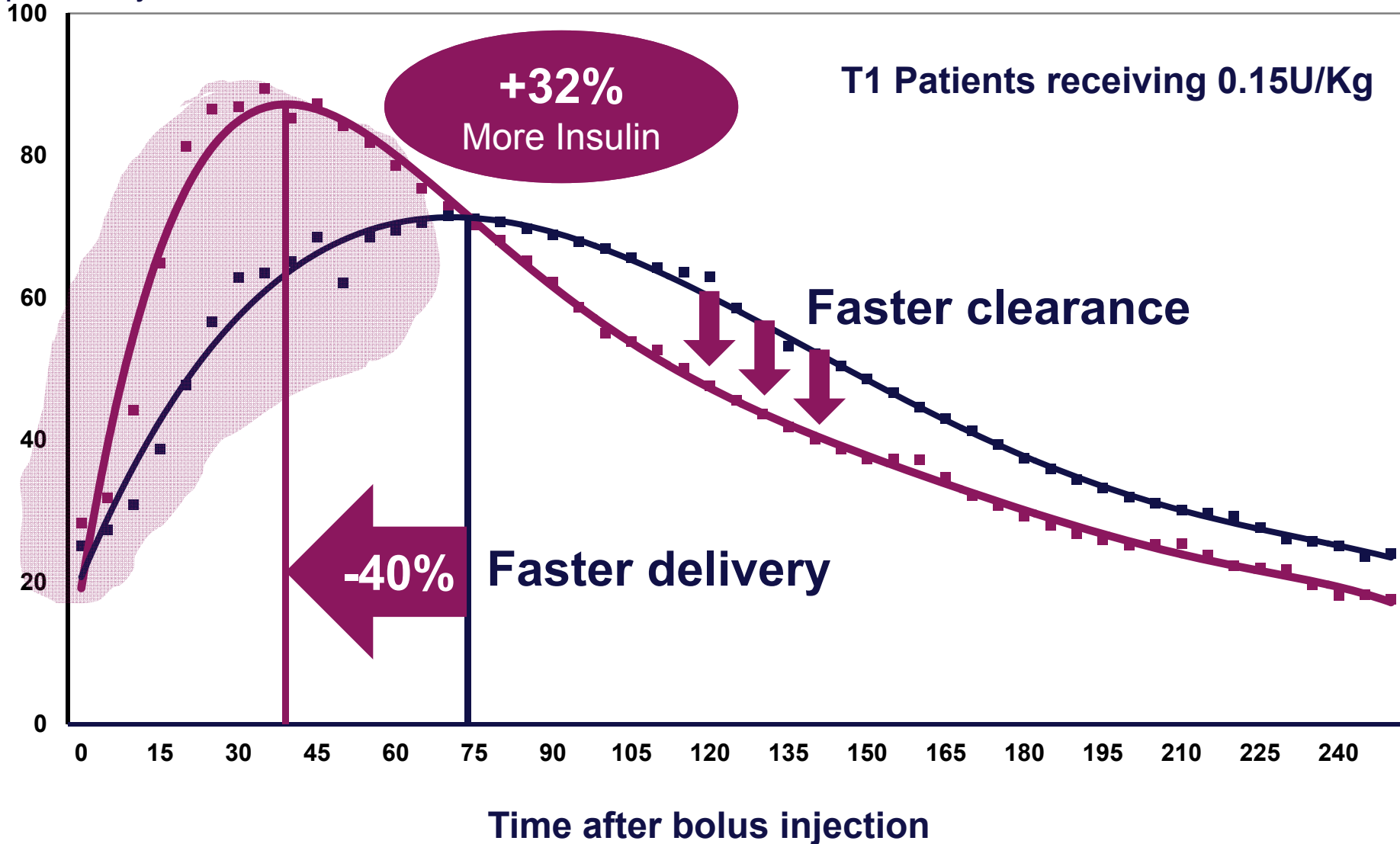
Faster delivery, faster clearance

Insulin concentration mU/l, results, n=14

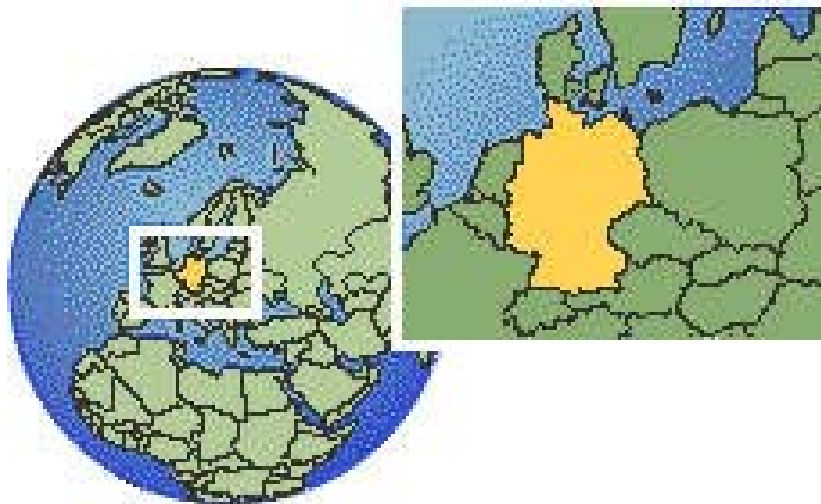
study performed by InsuLine in 2009

With InsuPatch™

Without InsuPatch™



The Market in Germany



Attractive large market

- About 10m diabetics of which about 1m MDI. About 4% YY growth
- Relatively compliant patients with high awareness

- Patient are treated regularly in Diabetics Centers, on average about 1,000 patients per center. Relatively easy to reach
- Payers are aware of diabetes costs and are constantly looking for ways to reduce costs.

Approach to the German market

Using Outsourced Sales force

- The company will use CSO to reach the physicians

Studies with KOL

- Clinical studies in Bad Mergentheim – one of the largest diabetes treatment centers in Germany

- Get support of KOL in Germany, some joined the Advisory Board

Effective lean management

- Experienced manager in Germany with a small dedicated team
- Using Outsourcing and cooperation

MFG & Logistics

- Outsourced Logistics
- Consumer oriented product design
- Outsource manufacturing

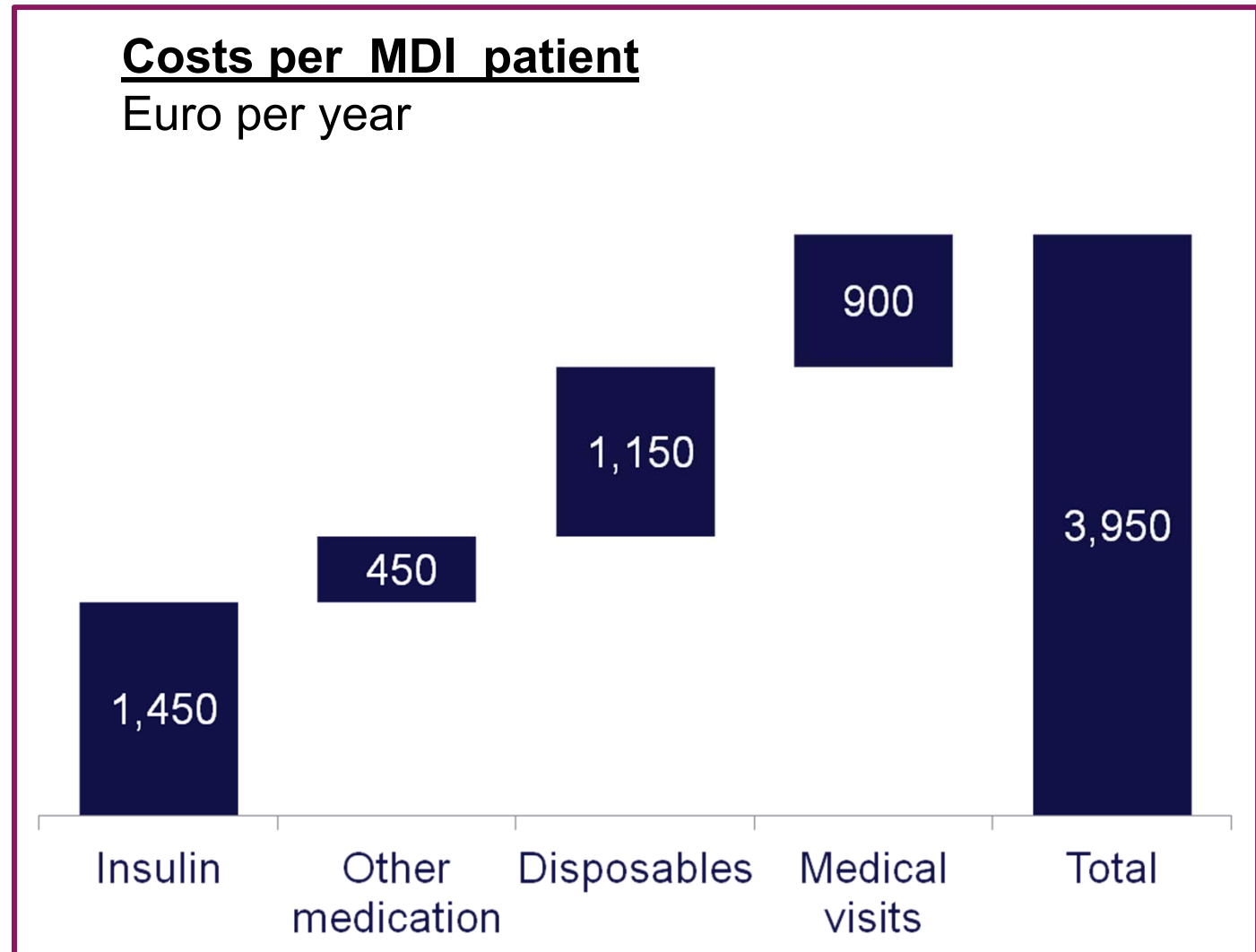
Reimbursement

- Performed Pricing study

- Will run a study to demonstrate economical benefit of the product.
- Received confirmation from leading health insurer about product reimbursement following positive study results

Possible Pricing in Germany

Based on a study* the company estimates that once economical benefit of the product is established, it can get reimbursement between 1.1 to 1.3 euros per day or about 400 to 470 Euros per patient per year



Estimates made by the company .

* Study performed by SIMON KUCHER & PARTNERS

Potential Revenues (after 2012 –Germany Only)

25% of the market	5% of the market	
225,000	45,000 (about 20 centers moving 50% of potential patients to use the product)	Number of Patients
90-105 m Euros	18-21m Euros	Annual revenues (1.1 to 1.3 Euro per patient per day)
45-52 m Euros	9-10.5 m Euros	Gross Profit (50%)

Remarks

- Usage depends on positive result in marketing & reimbursement study as well as achieving Key Opinion Leader (KOL) support .
- Reimbursement can be in the low range but it will increase product use faster.

Activity in 2011 – Study for FDA Approval & First Steps in Germany

Task	Planned for 2011	Current Status
<p>FDA Approval for InsuPatch™</p>	<ul style="list-style-type: none"> • FDA Study: <ul style="list-style-type: none"> • Efficacy May 2011 (55 subjects) • Safety Oct. 2011 (100 subjects) • FDA submission Oct. 2011 	<ul style="list-style-type: none"> • Efficacy phase ended July 2011 • Efficacy results, published in December 2011, are good • Safety Phase expected to end in April 2012
<p>InsuPad™ Sales in Germany</p>	<ul style="list-style-type: none"> • First Production Q1 2011 • Start Sales small scale Q3 2011 	<ul style="list-style-type: none"> • Production to support studies Q1 2011 • Design for COGS reduction – expected to end in Q1 2012 • Getting health insurers' support by mutual design of study to receive reimbursement. This will facilitate wide & fast adoption of the product

Study for FDA approval of InsuPatch™

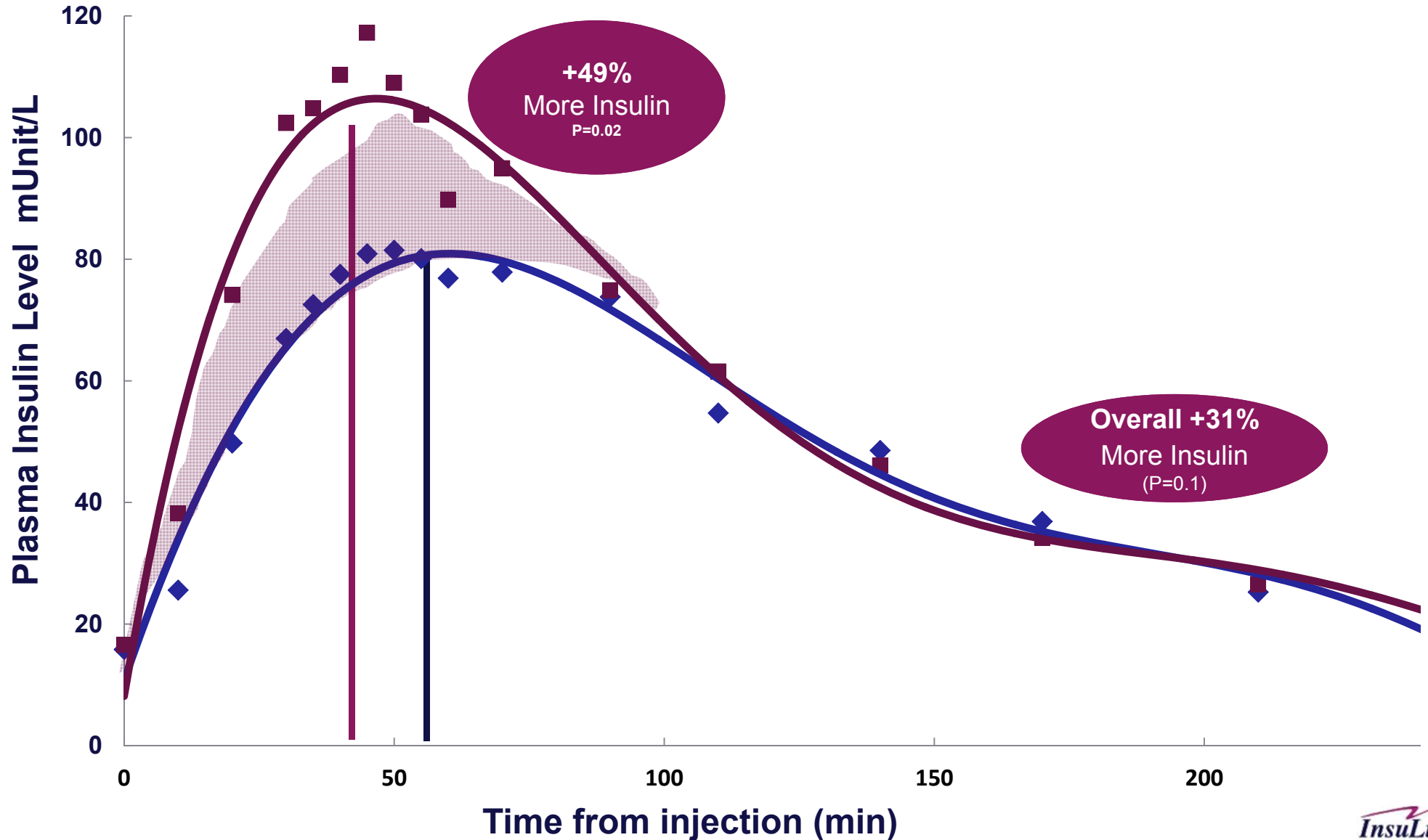
Study	Primary Endpoint	Status	Efficacy
<p>Crossover 55 subjects InsuPatch™ Clamp studies in clinical setting Study was performed at 1 site in the US & 2 sites in Israel</p>	<p>At least 10% increase in AUC (area under curve) of blood insulin level during 60 min after infusion</p>	<p>Ended – results show 29.7% increase (Median) in AUC (P<0.019)</p>	
<p>Crossover 100 patients using InsuPatch™ for 3 months at home comparing to 3 month without device Study performed at 1 site in the US & several sites in Israel</p>	<p>Demonstrate that there is no increase in the number of Hypoglycemia, Hyperglycemia or other adverse events when InsuPatch™ is used at home</p>	<p>Over 100 patients enrolled. Expected to end by April 2012 To date 92 subjects completed TEST phase of which 62 completed the study</p>	Safety
<p>Following the completion of the “safety” phase the company intends to apply for FDA approval of InsuPatch™</p>			

Clinical Evidence InsuPad™ (initial)

With InsuPad™

Without InsuPad™





n=5 T1&2 receiving 0.2U/Kg lispro & aspart (device operates in cycled heat profile)




Clinical studies – plan for 12 months

Objective

Protocol

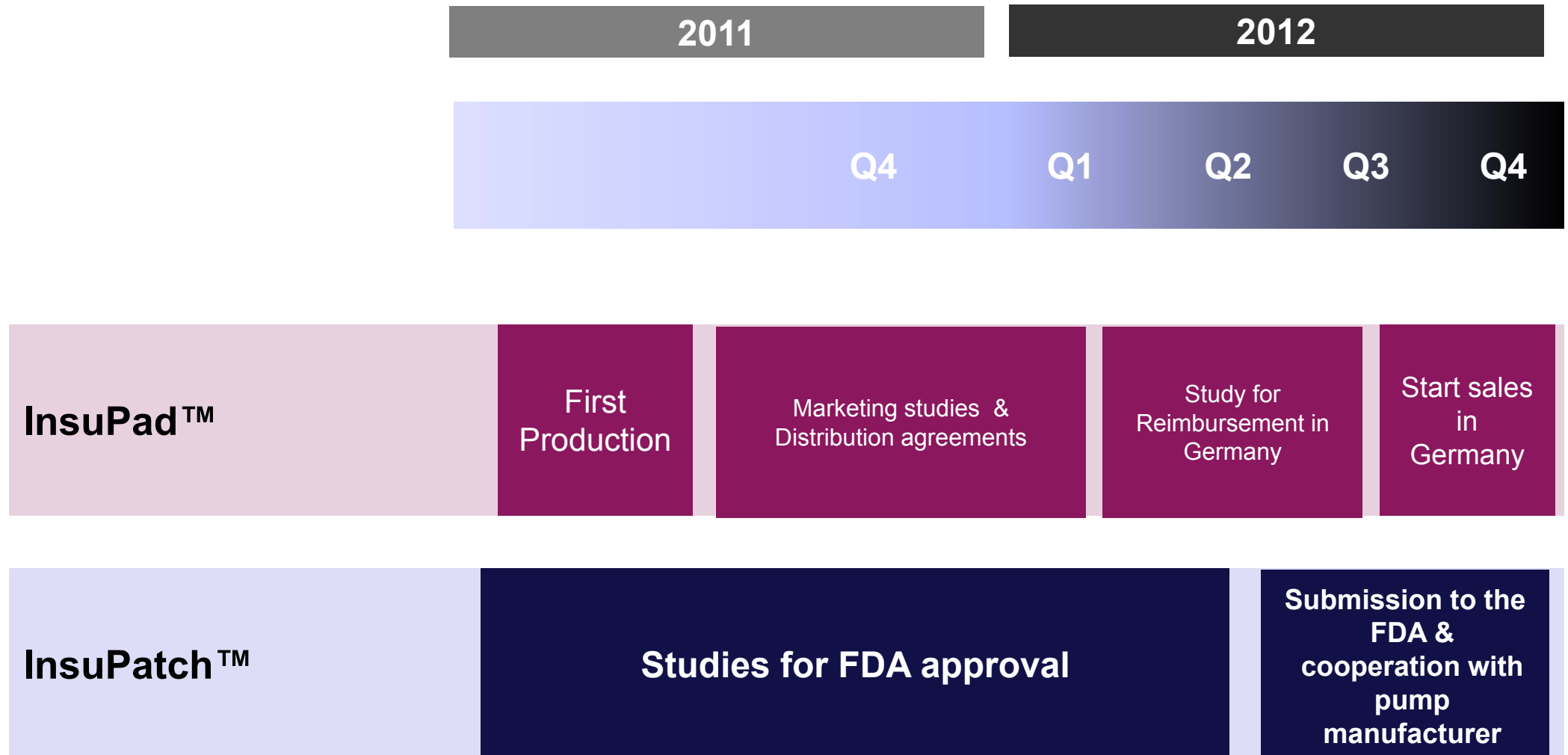
	<p>Safety during daily home use</p>	<p>Crossover 100 patients using InsuPatch™ for 3 months & comparing to 3 months without it, at home</p>
	<p>Lower postprandial glucose levels</p>	<p>Crossover InsuPad™ study up to 40 T1&T2 in clinical setting</p>
	<p>Safety during daily home use</p>	<p>Crossover InsuPad™ study up to 40 T1&T2 using InsuPad™ 4 weeks at home comparing to 4 weeks without it</p>
	<p>Faster insulin absorption</p>	<p>Crossover up to 40 T1 juveniles using improved InsuPatch™ in clamp & meal test studies</p>

Ongoing

	<p>Glycemic control superiority</p>	<p>InsuPad™ study up to 150 T1&T2 16 weeks at home</p>
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About to Start

Key Milestones



Achievements recognized by medical community

Publications & Conferences

November 2008 - DTM

May 2009 – Clinical Therapeutics

November 2009 - DTM

February 2010 - ATTD

September 2010 - EASD

October 2010 - ISPAD

November 2010 - DTM

February 2011- ATTD

June 2011- ADA

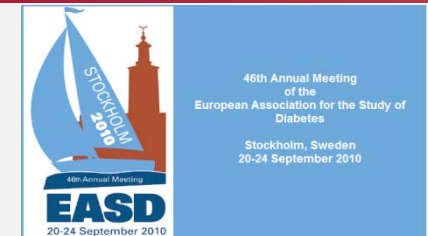
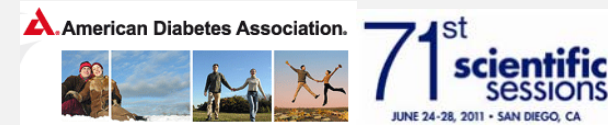
November 2011- DTM

February 2012 – ATTD

Clinical Therapeutics/Volume 31, Number 5, 2009

Effect of a Local Heating Device on Insulin and Glucose Pharmacokinetic Profiles in an Open-Label, Randomized, Two-Period, One-Way Crossover Study in Patients With Type 1 Diabetes Using Continuous Subcutaneous Insulin Infusion

Itamar Raz, MD¹; Ram Weiss, MD, PhD¹; Yevgeny Yegorchikov, MD²; Gabriel Bitton, PhD²; Ron Nagar, MS²; and Benny Pesach, PhD²



Additional publications are expected for 2012

InsuLine Medical: an attractive partner for all market players



The Company is negotiating distribution agreement rights in several countries

InsuLine innovation on the critical path for the future



dedicated to finding a cure

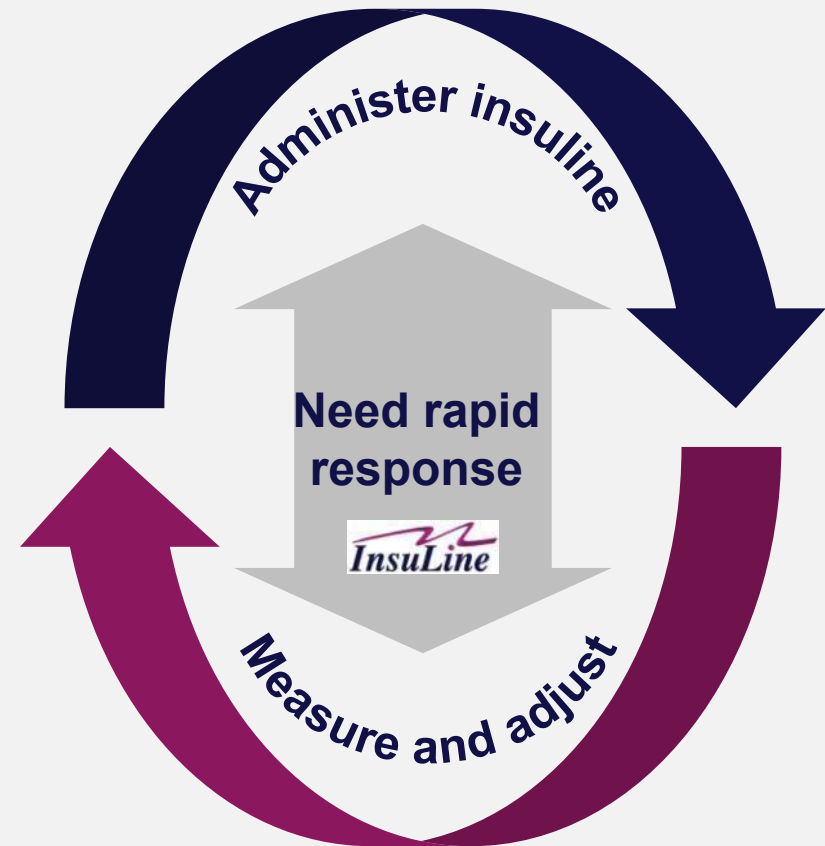
Foundation dedicated to provide solutions to diabetics including developing a “closed loop” system

It's Hot: Effect of Warming the Infusion Site on the Time Action Profiles of Aspart Insulin

William Tamborlane, MD
Yale School of Medicine




Closed system requires fast onset



The artificial pancreas initiative

Medical advisory team

USA


Prof. William Tamborlane
 Yale Research lead partner


Head of Pediatric Endocrinology and Diabetes,
 Yale University
 Pioneer of insulin pumps for children

Yale University


Prof. David Klonoff
 Principal investigator for the
 FDA study


Clinical Professor of Medicine, University of California SF
 Editor in Chief, Journal of Diabetes Science & Technology
 Medical Director, Mills-Peninsula Diabetes Research Inst.
 President of Diabetic Technology Society

UCSF


Prof. Stuart Weinzimmer
 Yale Research partner,
 artificial pancreas project

Associate Professor,
 Pediatric Endocrinology and Diabetes,
 Yale University


Yale University


Prof. Thomas Haak
 Bad Mergentheim

Chairman of the Diabetes Academy Bad Mergentheim
 Chairman of the Professional Association of German
 diabetologists (BDD)




Germany


Prof. Lutz Heinemann
 Profile Institute for clinical
 Research

Partner and Scientific Consultant Profil & Profil Institut for
 Clinical Research Inc.











Dr. Astrid Tombek
 Bad Mergentheim









Head of the Diabetes and Nutrition advice
 The diabetes clinic Bad Mergentheim



Management team

<p>Ron Nagar President & CEO</p> 	<p>Former co-founder & CEO of Glucon, 10years experience development of products for Diabetics</p>
<p>Elmar Schaefer Managing Director InsuLine Medical GmbH</p> 	<p>Former EVP Pharmexx, CEO BioGeneriX, Director BD GSK</p>
<p>Gabriel Bitton, Phd VP R&D</p> 	<p>Former CTO of Glucon, 10years experience development of products for Diabetics</p>
<p>Elisha Amir VP Operation & Manufacturing</p> 	<p>Former VP Operation Medingo (insulin pump company)</p>
<p>Eldad Yehieli CFO</p> 	<p>Experienced CFO in Public companies</p>
<p>Prof. Itamar Raz M.D Medical Director</p> 	<p>Head of Diabetes at Hadassah Medical Center Former president of the Israeli Diabetes Association</p>
<p>Prof. Andreas Pfutzner M.D Medical Director Europe</p> 	<p>Managing Director IKFE Former VP medical of Bidel , Former VP Medical Europe for Medtronic Minimed</p>

Board Of Directors

<p>Ilan Cohen Chairman</p> 	<p>Former Director General of Israel's Prime Minister office, Director at Discount Bank, Founder POC strategic consulting firm, entrepreneur</p>
<p>Prof. Marcelle Machluf External Director</p> 	<p>Associate Professor & Vice Dean Faculty of Biotechnology Technion – Israel institute of Technology</p>
<p>Arie Ben Yosef External Director Chairman Audit & Finance committees</p> 	<p>General Manager Teledata Networks Ltd.</p>
<p>Ronen Melnik Director</p> 	<p>Founder & Managing Partner, Wanaka Capital Partners. Former partner at Mckinsey & Co.</p>
<p>Udi Gilboa Director</p> 	<p>Founder & Managing Partner, Top Notch Capital – Investment Banking. Life Science companies entrepreneur</p>
<p>Yosef Agiv Director</p> 	<p>Strategic advisor in Telecommunication Former VP Engineering at GVT Brazil, Former VP Engineering & Operation at Bezeq</p>
<p>Ron Nagar Director</p> 	<p>Founder, President & CEO InsuLine Medical Ltd.</p>
<p>Dr. Gabriel Bitton Director</p> 	<p>Founder, VP R&D InsuLine Medical Ltd.</p>



Thank You

InsuLine