

P.L.E.A.S.E. transdermal protein delivery

DDP 2011, Miami




pantec
biosolutions

Pantec Biosolutions at a glance

- ✦ Breakthrough needle-less intraepidermal delivery system P.L.E.A.S.E.®
- ✦ P.L.E.A.S.E.® stands for Precise Laser EpidermAI SystEm
- ✦ P.L.E.A.S.E.® enables painless intraepidermal delivery of
 - Therapeutic peptides and proteins => first target infertility
 - Therapeutic proteins and antibodies => target immunology
 - Therapeutic proteins and small organics => target dermatology

P.L.E.A.S.E.[®] enables intraepidermal delivery

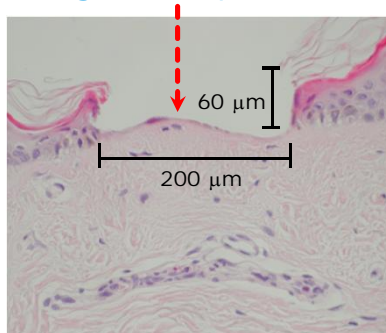
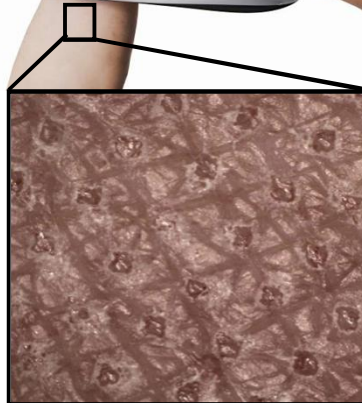
Delivery of large drug molecules using a hand-held laser device combined with an optimized patch formulation

- # Precise, reliable and painless drug delivery
- # Simple convenient use by patient or professional
- # Tailored and flexible dosing by variation of pore numbers
- # Accurate dose delivery or removal of drug
- # Independent of individual skin condition

Laser for skin microporation



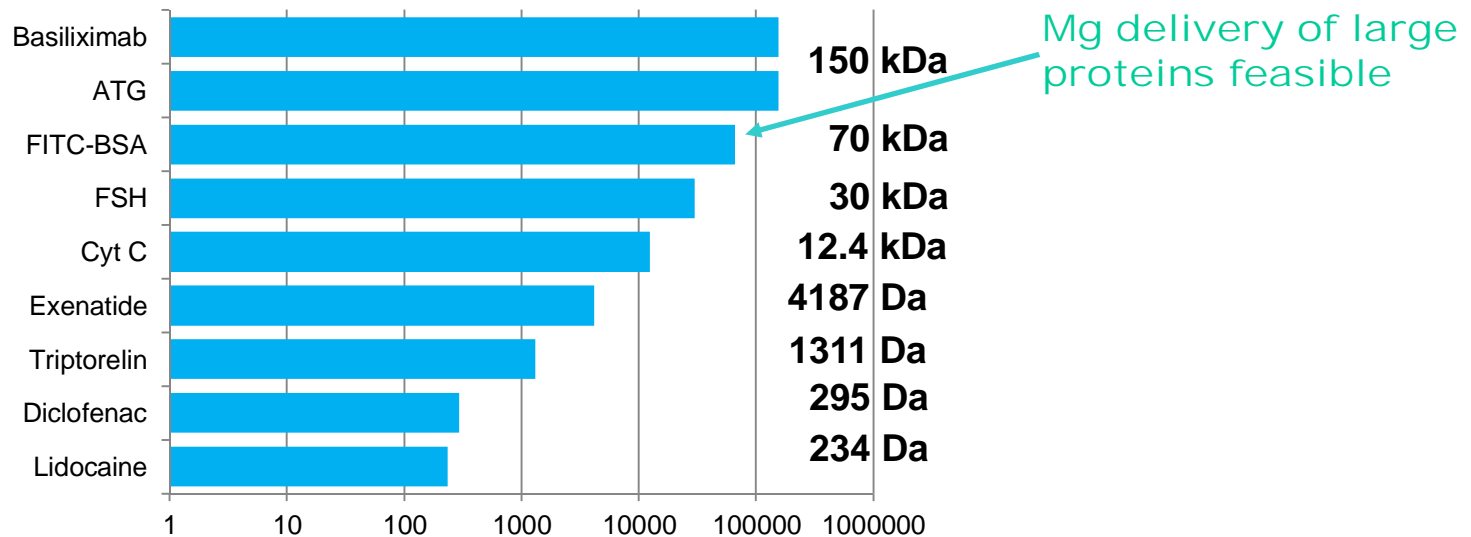
Target compartment



Drug patch onto microporated skin

P.L.E.A.S.E. [®] delivers drugs up to MW of 150,000 Da

Demonstrated intraepidermal delivery of small organic molecules, peptides, proteins, and functional antibodies *in vitro*



Two devices one platform

P.L.E.A.S.E.® Private

- Device for use at home, class 1 laser
- Easy to use by patients
- First generation has CE-mark

IVF therapy
Other applications



P.L.E.A.S.E.® Professional

- Device for medical professionals, class 1 laser
- Can run all day
- Multipurpose dermatology device
- CE-marked

Conventional dermatology
Aesthetic dermatology



You can buy it today
P.L.E.A.S.E. place your orders



Global *In Vitro* Fertilization (IVF) market

A premium product \$2 bn market growing at more than 10% p.a. depending on cumbersome and painful injections of infertility drugs



Currently used **injection therapy** for IVF
Takes 1 to 2 months of daily self-administration of drugs

Pantec's market research verifies

- ✦ 79.8% IVF patients have negative feelings about injections and their frequency
- ✦ Overwhelming proportion is ready for P.L.E.A.S.E.® based delivery:
 - 73.2% "very probable"
 - 15.5% "probable"
 - 11.3 % "it depends"

Pantec Biosolutions' novel IVF drug products

Painless, safe and accurate application using P.L.E.A.S.E.®

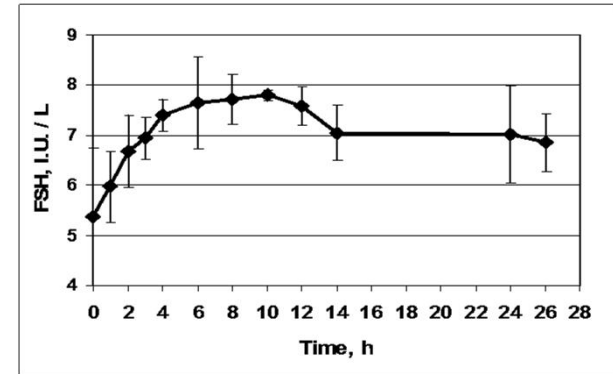
Product	Indication	Clinical Status
IVF001 Triptorelin patch	Infertility (IVF) Downregulation prior to stimulation	Phase I completed <ul style="list-style-type: none"> • Demonstrated safety, bioavailability, tolerability endpoints
IVF002 Follicle Stimulating Hormone	Infertility (IVF) Stimulation of follicle growth	Phase II ongoing, exploratory proof of concept successful <ul style="list-style-type: none"> • Demonstrated follicle stimulation • First pregnancy achieved



Demonstrating FSH delivery in man

Pharmacokinetics

- ✦ Delivered intact FSH across skin into systemic circulation
- ✦ Achieved therapeutic levels in circulation to induce follicle growth



Safety and tolerability

- ✦ Microporation and patch application well tolerated by all volunteers
- ✦ No adverse events reported

32 kDa protein delivered transdermally from a stable patch at therapeutic concentrations

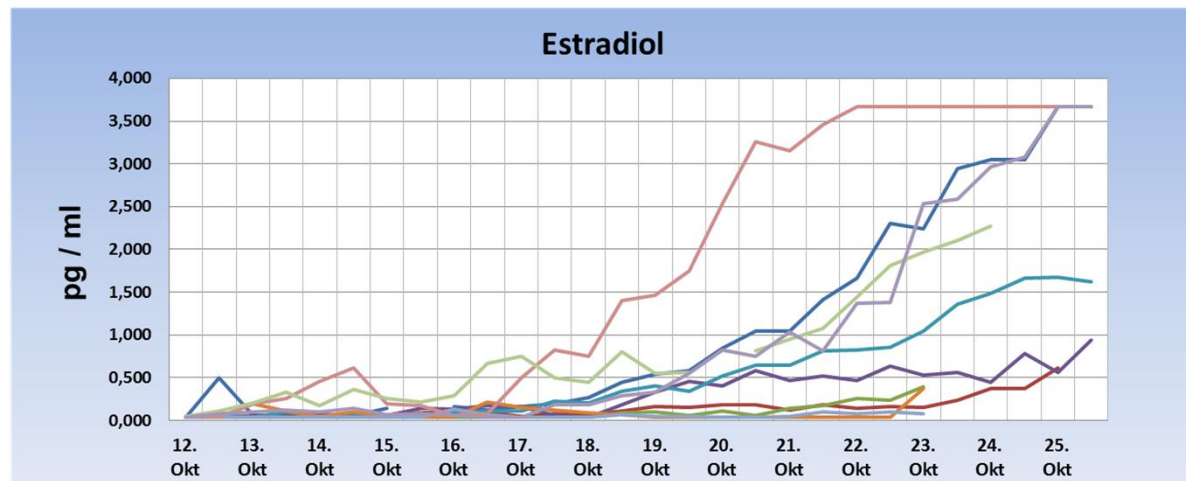
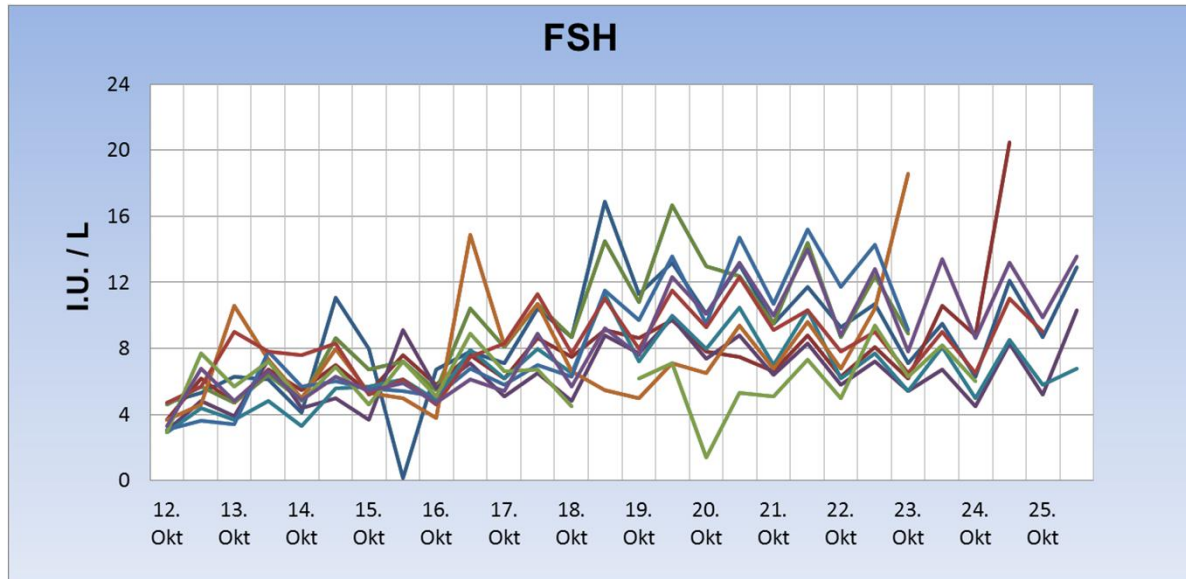
Demonstrating FSH activity in women

Showed follicle growth in 6 oocyte donors using P.L.E.A.S.E.® and a prototype FSH patch

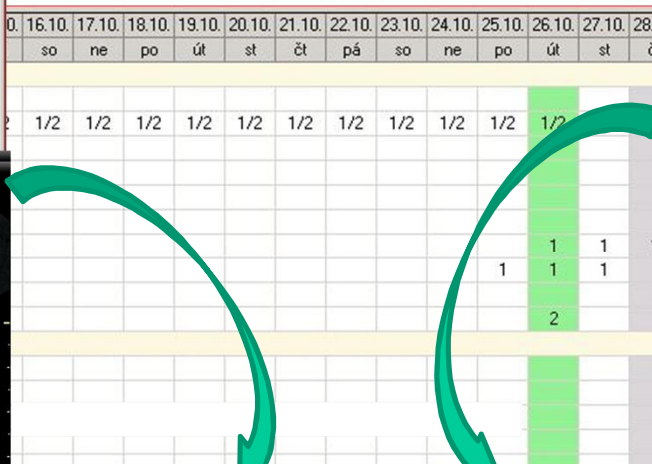
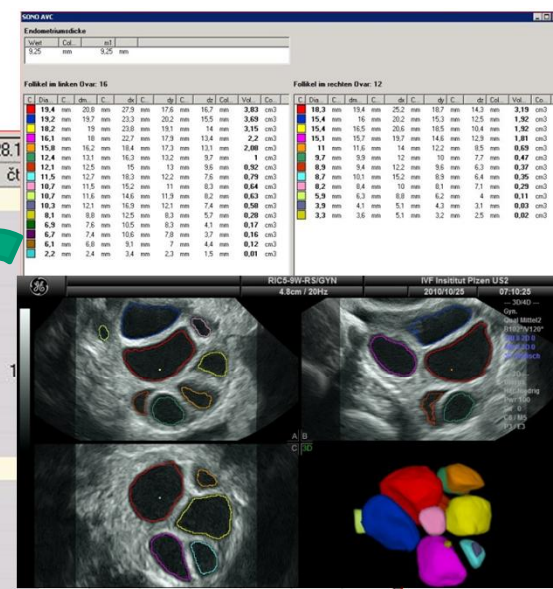
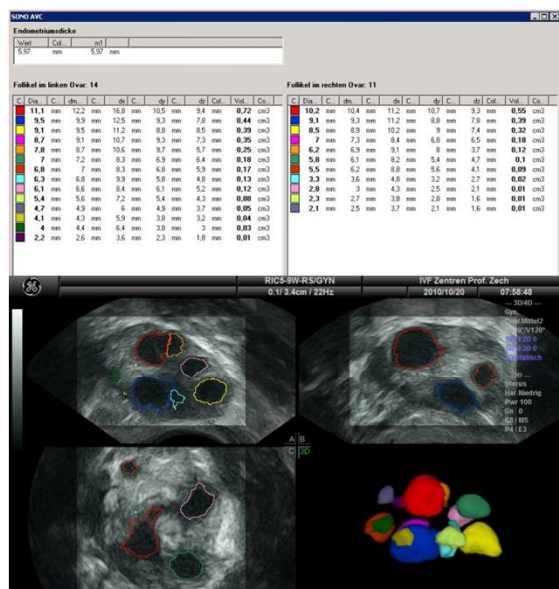
- ✦ Sufficient levels to induce follicle growth in a multiple dose standard In Vitro Fertilisation (IVF) protocol
- ✦ Achieved growth of a cohort of follicles in 6 oocyte donors
- ✦ Unexpected follicle recruitment – an approach for low responders ?

32 kDa protein delivered transdermally from a stable patch showing clinical pharmacodynamic activity

Multiple dose patch application shows typical increase of FSH and estradiol



Successful follicle stimulation by P.L.E.A.S.E. patch



US/Arzt																
Endometrium (mm):																
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- Standardised procedure with validated 3D intravaginal volume measurement
- Follicle growth shown

Clinical development strategy for IVF drug products

Rapid and straightforward clinical program

- ✦ Established GMP manufacture for stable peptide (triptorelin) and protein (follicle stimulating hormone) patches

- ✦ Phase I clinical program
 - ✦ IVF001 (triptorelin patch) completed
 - ✦ IVF002 (follicle stimulating hormone, FSH) completed

- ✦ Phase II clinical program
 - ✦ Exploratory PoC phase IIa with IVF002 completed
 - ✦ Further phase II studies planned for 2011/2012

- ✦ Pivotal studies for IVF001 & IVF002 planned for 2012/2013

- ✦ Registration and launch targeted in EU for 2015

Summary

- ✦ Pantec develops its product portfolio for infertility treatment and will prepare for commercialization
 - First proof of concept: therapeutic levels delivered from stable patches achieved
 - Second proof of concept: follicle growth and first pregnancy achieved from stable FSH (32kDa) patch

- ✦ Pantec partners P.L.E.A.S.E.[®] with companies with small molecule, peptide, or protein based products to address unmet medical needs (immunology, immunosuppression, allergy vaccines, orphan diseases)

- ✦ Pantec sells P.L.E.A.S.E. Professional directly or with partners for dermatology applications (conventional and aesthetic)

Partnering strategy

- ✦ Co-development / Co-marketing deals in our core indications
- ✦ Partnering including out-licensing for our non-core indications
- ✦ Distribution partners for P.L.E.A.S.E. Professional device



www.pantec-biosolutions.com



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the transdermal protein
delivery company

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P.L.E.A.S.E. visit us at booth # 200