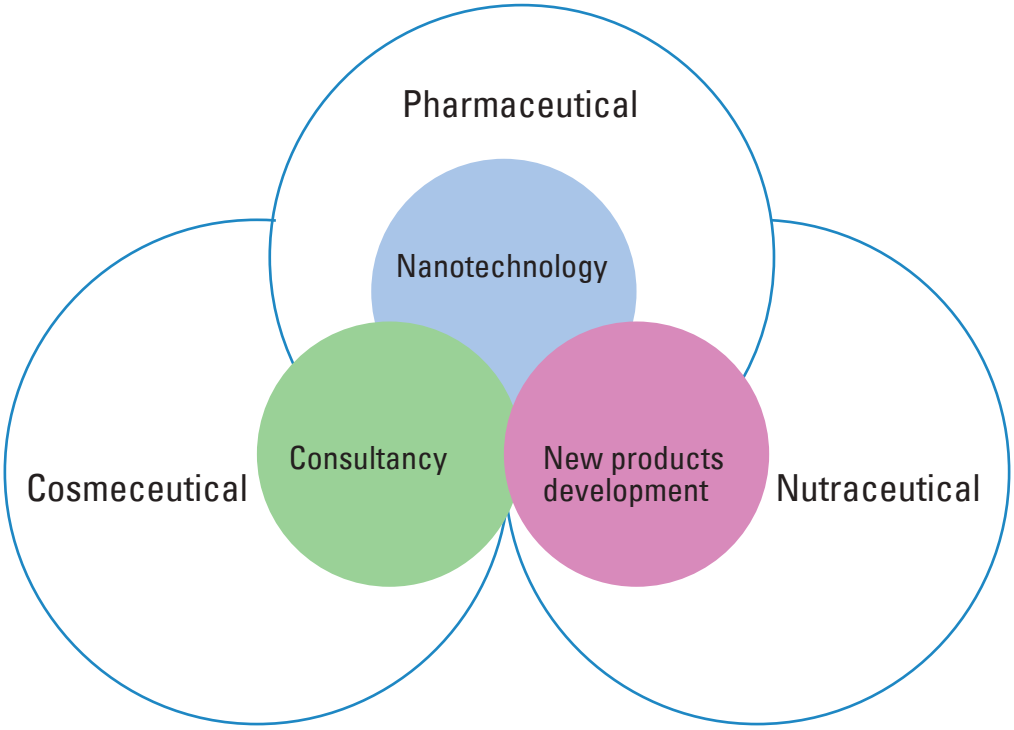
Nano & bio technologies

iDelivery
nano&bio technologies

Company Description



iDelivery is an innovative company operating in the field of nanotechnology for pharmaceutical, cosmetic and nutraceutical applications. The company activities and service revolve on three main areas:

- **Advanced Nanotech analysis**
- **Consultancy services**
  New product development (i.e. new formulations), nanotech product line upgrading, nano carrier delivery systems development.
- **Innovative products launch & technology transfer.**
  The company collaborates at different title with various Stakeholders (Universities, Research Centres, etc.) for the development, licensing and launch of innovative nanotech systems.

Mission

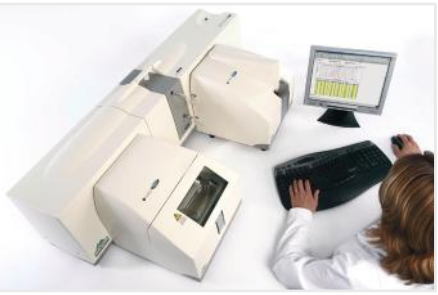
Our mission is to accelerate the up taking of nanotechnologies in the pharmaceutical, cosmetic and nutraceutical fields enhancing product efficiency and efficacy through the development of innovative tailored nano- systems that intelligently enable the delivery of adding value to both final customers and industrial players.

Vision

Our vision is to create a healthier world where all the products related to care & well-being are "free to express" their full and true potential without caring about any "barrier", achieving efficiently a long lasting and cost effective effects.

Tecnology

01 Rheological measurement to evaluate and improve product quality Kinexus Rotational Rheometer.



02 Dimensional analysis to evaluate the size of nanoparticles: Master - sizer 2000, equipped with Scirocco and Hydro systems.

03 Particle size and shape of microparticles: Morphologi G3.

04 Measurement of spray particle and spray droplet size for an efficient product development of sprays and aerosols: Spraytec_Nasal Spray System.

05 Microrheologic analysis to evaluate ageing and stability: Rheolaser Lab.

06 A technique able to obtain dry powders with micrometric mean sizes from solutions or suspensions: Spray dryer.

07 Molecular size and molecular weight measurement: Zetasizer Nano.

08 Proteins and polymers structure: Viscotek GPCmax.

09 Analytical chemistry, with the ability to separate, identify and quantitate the compounds: High pressure liquid chromatography (HPLC).

10 Separation of a broad range of different samples from the area of Biopharmaceuticals, Food-Agro-Cosmetics, Environmental, Chemicals and Nanotechnology Field: Flow Fractionation AF2000.

Consultancy Services

REALIZATION OF NANOSTRUCTURED SYSTEMS

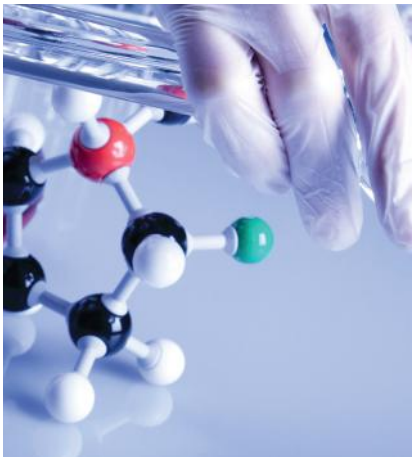
Our team is able to formulate and realize nanocarriers for biomedical, nutraceutical and cosmetic application. In particular our expertise is in the field of vesicular carriers (liposomes, ethosomes, ultradeformable vesicles), polymeric carriers (nano- and microparticles), lipidic (solid lipid nanoparticles) molecular (cyclodextrins) and emulsive systems (W/O, O/W, W/O/W, multiple emulsions, micro and nanoemulsions). Each formulation is developed, realized and characterized by a physic-chemical and technological perspective.

NEW PRODUCT DEVELOPMENT AND PRODUCT LINE UPGRADING

Our team is able to develop new formulations and to engineer new products in the reference sectors.
We are able to test the efficacy of different active ingredients using in vitro and in vivo tests. In particular cellular model are used in a preliminary phase to evaluate both the toxicity and the activity of the molecule. Different animal models have been developed and are daily used in our laboratories to test the toxicity and the efficacy of drugs. These experimental models are used both for free substances and for substances in conjunction with nano carrier.

ADVANCED TRAINING IN THE NANOTEHNOLOGY FIELD

Our know-how in the health field allow us to assist the buyers in the patenting new products in this field.
Moreover we are able to provide advanced and personalized coueses in the field of nano technology.



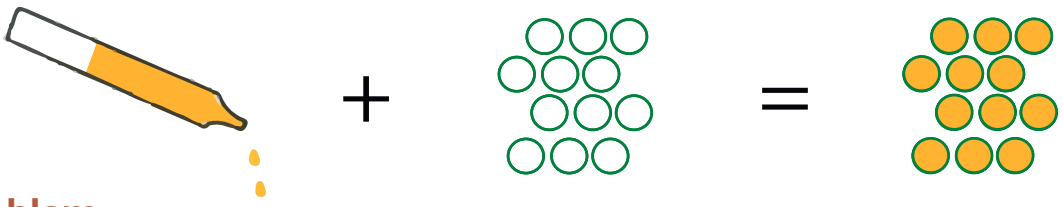
Innovative products and technology transfer

Bulbixin
nano delivery system

The product

iDelivery i.S.r.l. developed Bulbixin, a versatile nanocarrier able to go through the transfollicular barrier allowing the delivery of actives at full potential, for all the topical treatment related to the pilosebaceous unit (i.e. anti hair-loss, hair removal, anti acneic products).

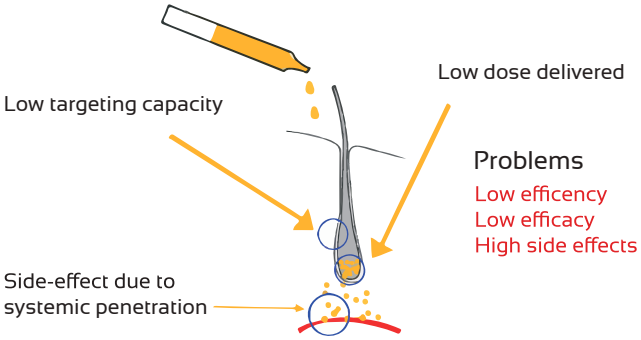
traditiona product	nano carrier Bulbixin	more efficient product

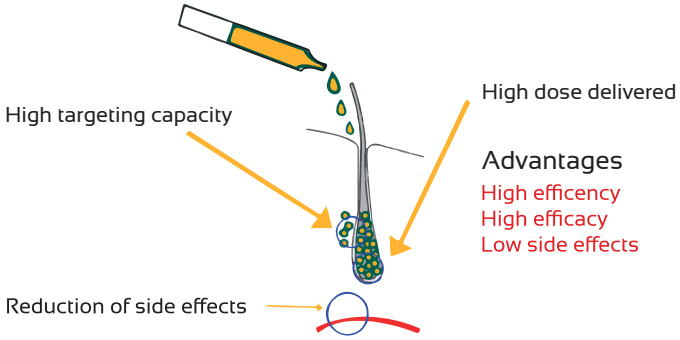


The problem

Currently actives for cosmetic and pharmaceutical use often suffer of low efficiency in terms of targeting the biological structures.

Traditional product vs Bulbixin





As shown in the figure above traditional products have low ability of targeting the pilosebaceous unit with low pilosebaceous unit with low level of permeability to the trans level of permeability to the trans follicular barrier

leading to:
- low efficacy
- low care efficiency
- increase probability of adverse effects

Bulbixin nonocarrier confers to traditional products the ability to convey the drug in the targeted biological structure.

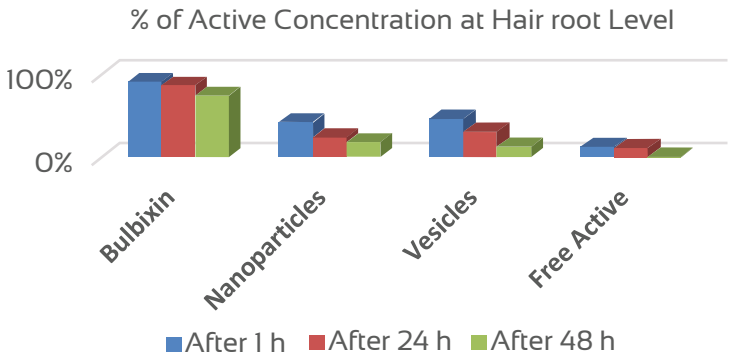
Minoxidil Concentration measurement at follicular level express as % of the initial topical applied dosage, using different nanocarriers and the "free" drug.

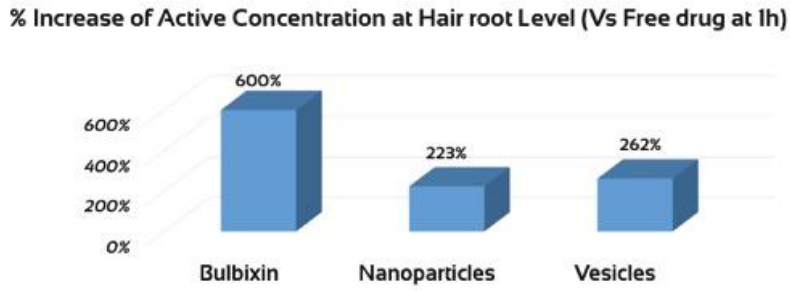
Striping Test (Active Minoxil)	Bulbixin	Nanoparticles	Vesicles	Free
After 1h	91%	42%	47%	13%
After 24h	86%	24%	31%	11%
After 48h	74%	18%	13%	1%

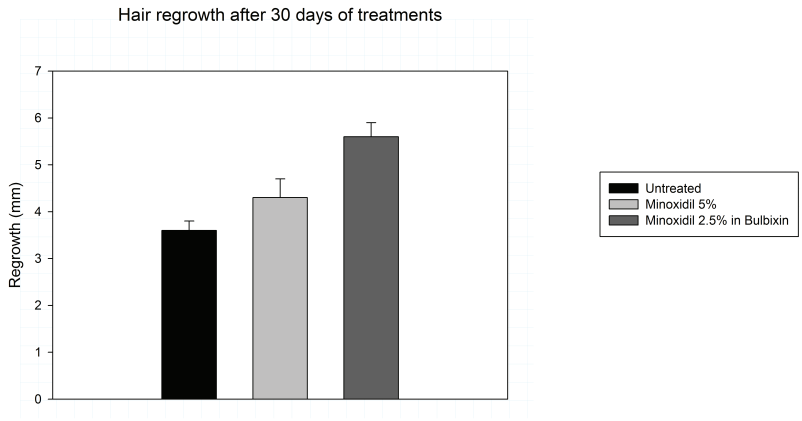
The main target market

The main reference market for Bulbixin is the one related to chemical anti hair loss treatments **(5,4 Billions yearly revenue industry, with 5% yearly growth rate)**. 1,5 billions people suffer of hairloss problems worldwide (65% of men have visible hairloss by the age of 60, 80% of women have visible hairloss by the age of 60). Numerous reports and statistic show how hairloss problems have a serious effect on person lifestyle and level of self-confidence.

- Consequent decrease of side effects due to the reduction of active compound dispersed at systemic level (safety increased 84%)







The Benefits

The proposed nanocarrier confers to the final customers the following benefits:

- Increase care efficiency, due to specific targeting (3,35 times from preliminary resting)
- Increase care efficacy, due to the amplification of compound delivery in follicular site (up to two times theoretical increase)
- Consequent decrease of side effects due to the reduction of active compound dispersed at systemic level (safety increased 84%)

The results

Our recent studies confirm the nanocarrier attitude to target the hair bulb, since the first hour of experiment test (figure 1 & table 1)

- Consequent decrease of side effects due to the reduction of active compound dispersed at systemic level (safety increased 84%)

Table 1 Main Experiment performed in order to assess the Bulbixin® nano carrier performances

	TYPE TESTING	EXPERIMENT AIM	RESULTS OBTAINED
A	Vitro bioassay in human cell	Bulbixin® un-loaded Toxicity assessment	Bulbixin® shown high level of tolerability
B	Toxicity in vivo human experiments	Bulbixin® un-loaded Toxicity assessment	Bulbixin® demonstrated high level of tolerability and safety.
C	Ex vivo (Franz Cells) experiments	Benchmarking with state of the art nanocarrier in terms of: -Percutaneous permeation -Dose Release -Physical- Chemical stability	Bulbixin® shown: -Good permeation capabilities - Optimal Releasing capabilities - High level of Physical- Chemical stability
D	In vivo experiments on mice benchmarking against three state of the art Nano carriers	Benchmarking Bulbixin® against the state of the art Nano carriers in terms of specific targeting capabilities for the hair hair root	Bulbixin® shows superior targeting capacity for the pilosabeceous unit.
E	In vivo experiments on mice	Benchmarking Bulbixin® capabilities with anti-hair loss / drugs (Minoxidil)	Better targeting capacity to pilosebaceus unit besides showing a long life time in situ and high dosage delivered.
F	Differential Stripping: Determination of the Amount Penetrated into the Hair Follicles	To determine the amount of topically applied substances penetrated into the hair follicles.	Bulbixin® showed a selective targeting for the pilosebaceus unit.
G	In vivo measurement of the stratification in the different skin layers of the drug	Evaluation of the disposition of the drug in the skin layers, when topically applied.	Bulbixin® disposes in the dermis, where pilosebaceus units are present.
H	Production process and encapsulation studies	Assessment of the cost related to Bulbixin® production process and raw materials.	The technology introduction cost are minimal for Bulbixin®: -Simple technological production process - Availability and low cost of raw materials

Lenipsor+

innovative care for psoriasis disease

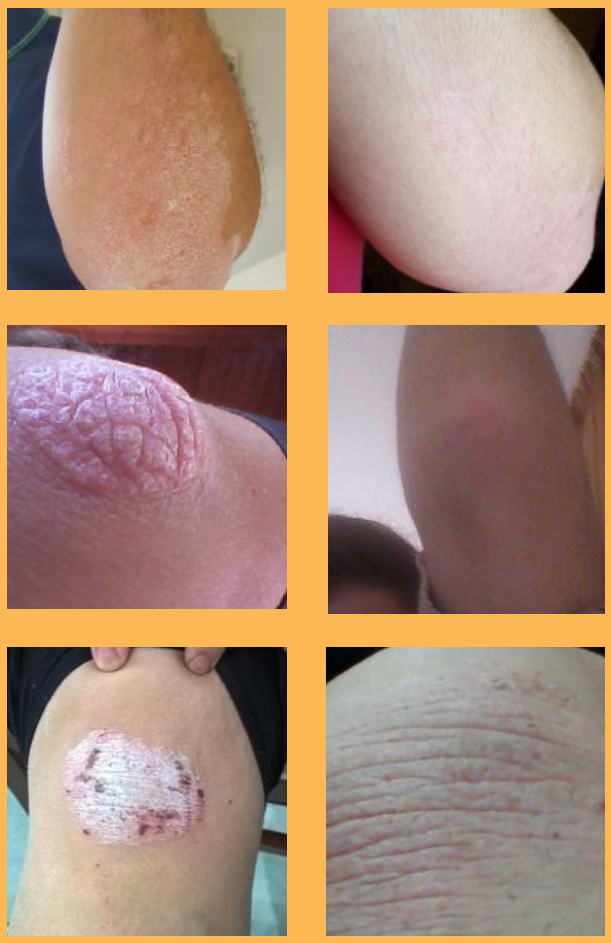
THE INNOVATION

iDelivery developed an innovative (patented) and efficient care for psoriasis disease. A topical low cost treatment to cure the psoriatic plaque with re-bound, average time of ten months. The treatment is derived by a plant phyto complex extract. At the moment, Idelivery has isolated the active molecules from the complex compound and is carrying out the validation studies.

PRELIMINAR RESULT

The in vitro tests were carried out on an experimental model of psoriasis stimulating a cell line of human keratinocytes with interleukin 6 (one of the pro-inflammatory factors present in psoriasis) and then treating with various concentrations of the freezedried decoction. The experimental results obtained have shown that the effect on growth inhibition produced by the solution of the decoction is both time and dose dependent, already after 48 h of treatment with the decoction to 0.1% , there is a reduction of the inhibition of growth equal to about 50% (the cell hyper proliferation is characteristic of psoriasis) .

The in vivo tests were performed on 50 volunteers suffering from psoriasis in different stages of the disease. All subjects were treated by applying the treatment directly on the psoriasis plaques, twice a day. The various parts of the body affected by psoriasis were rubbed for about 20 min with the compound. Subjects were evaluated at intervals of one week until remission of skin manifestations related to psoriasis. All subjects showed an improvement after just one week, and 100 % of subjects after one month showed complete remission of the disease rashes . The subjects were followed in the course of post - remission and 100% of the subjects showed an average lag-time before the reappearance of cutaneous manifestations of about 10 months. The subjects (38 %) in which have recurred symptoms of the disease, were treated with the same modalities of the first treatment and remission occurred for all subjects within 2 weeks.



The Benefits

The proposed treatment has several advantages:

- Increased efficacy of care;
- Low cost treatment;
- Short time regression of psoriatic plaque (one week);
- Last longing results for cycle of care (10 months);
- Absence of contraindication or side effect;

THE PROBLEM

Psoriasis is a serious inflammatory, non communicable autoimmune disease, which carries severe physical, psychological and socioeconomic burdens on over 125 million people worldwide. It is estimated that at least 10 percent of psoriasis sufferers have a severe form that causes disability and exclusion from a normal life. Economically, in the U.S. alone, impact is estimated that Americans with psoriasis lose approximately 56 million hours of work and spend $2 to $3 billion to treat the disease every year. Developing countries with less resources and healthcare have an even greater economic burden due to the lack of access to reliable diagnosis or risk for misdiagnosis of the disease, stigmatization and discrimination, and little-to-no access to affective treatments. Although there are numerous treatments for psoriasis, many still face a very poor quality of life because the treatments do not work, work poorly, are too expensive, or are not available to them. According to the National Psoriasis Foundation, in 2010 there were 34 drugs in the psoriasistreatment pipeline in various clinical stages of the approval process.
(1) Many of the new drugs are Biologics and inhibit the immune system from over-reacting or over-producing certain cells. Each Biologic product costs on average about $800 million U.S. dollars for pharmaceutical companies to produce, from conception-to-the-shelf, and once released to the public, cost on average around $11,000 to $18,000 a year, depending on the dose and the drug(2).
The extremely high cost of biologic medications for the national social security / health systems or the patients is one of the reasons why psoriasis is undertreated, yet many of the new treatments are biologic. Despite the dearth of medications available to treat psoriasis, a study by the National Psoriasis Foundation and Amgen reported that “nearly 40% of the 1,142 patients surveyed with chronic moderate or severe psoriasis are not currently receiving any treatment,” and more than half of the patients are not be treated as recommended by American Academy of Dermatology guidelines.(3) 73% were only using topical treatments.
Factors for lack or low treatment are health insurance issues, fear of the biologics (because the immune system is comprised), increased risk of side effects from the systemic and biologics, very high cost, low efficacy of the systemic, and lack of access to health care. The European Federation of Psoriasis Patient Associations (EUROPSO) undertook a Europe-wide survey(4) to examine the quality of life and patients’ perspectives on treatment and their disease and found that of the 17,990 respondents that had psoriasis. The greatest impact was on activities of daily living, especially affecting clothing choice, bathing routine and sporting activities. Overall, 77% replied that psoriasis was a problem or a significant problem. While patients were satisfied with the information and care from their dermatologist (40% highly satisfied), available treatment options were less satisfactory, with over 70% reporting only low to moderate satisfaction.

1) “Research Pipeline.” National Psoriasis Foundation. http://www.psoriasis.org/netcommunity/treating_psoriasis, Jan. 2011.

2) Morrow, Thomas, M.D. “Cost-E□ective Psoriasis Treatment May Demand Creative
Coverage Rules:, Managed Care, May 2006.
http://www.natbiocorp.com/pdfs/managed-care-May06.pdf

3) National Psoriasis Foundation. “Survey indicates people with chronic moderate
to severe plaque psoriasis may be under-treated.”
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4) L. Dubertret, L.; U. Mrowietz; A. Ranki; P.C.M. van de Kerkhof; S. Chimenti; T. Lotti;
G. Schäfer “European Patient Perspectives on the Impact of Psoriasis: the EUROPSO
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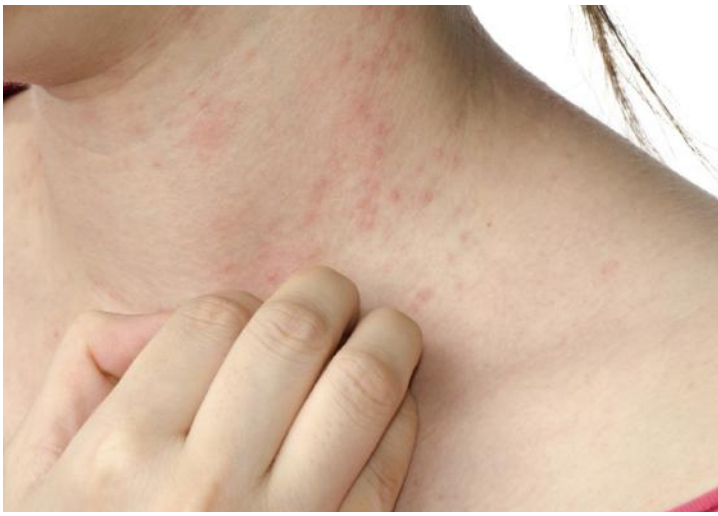

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