BIOTTS Profile

About Biotts

BIOTTS S.A. is a Polish biotechnological company that develops proprietary drug delivery technologies and drug formulas in the field of oncology, dermatology, and autoimmune diseases. With more than thirty years of experience, our Research and Development team is able to effectively create proprietary medicines, solve complex technological problems and create unique solutions to help people all over the world. The first technologies and formulas by the Biotts team have been developed to help our families and friends. In the treatment of hard-to-heal wounds and chronic diseases, Biotts formulas make it possible to achieve remarkable results compared to traditional drugs.

Biotts mission

Our mission is to improve the patients' comfort and quality of life thanks to innovative drug transport systems that will revolutionise the pharmaceutical market.

Our business model

Business is the art of sharing, which is why at Biotts we want to share knowledge, experience and profits. We are able to adapt our business model to the preferences and needs of our Business Partners.

Intellectual Property cloud

The strategy for building the corporate goodwill is based on the constant development of the Biotts patent cloud. We protect our patent applications in the EU, US, Canada, China, Japan and Brazil.

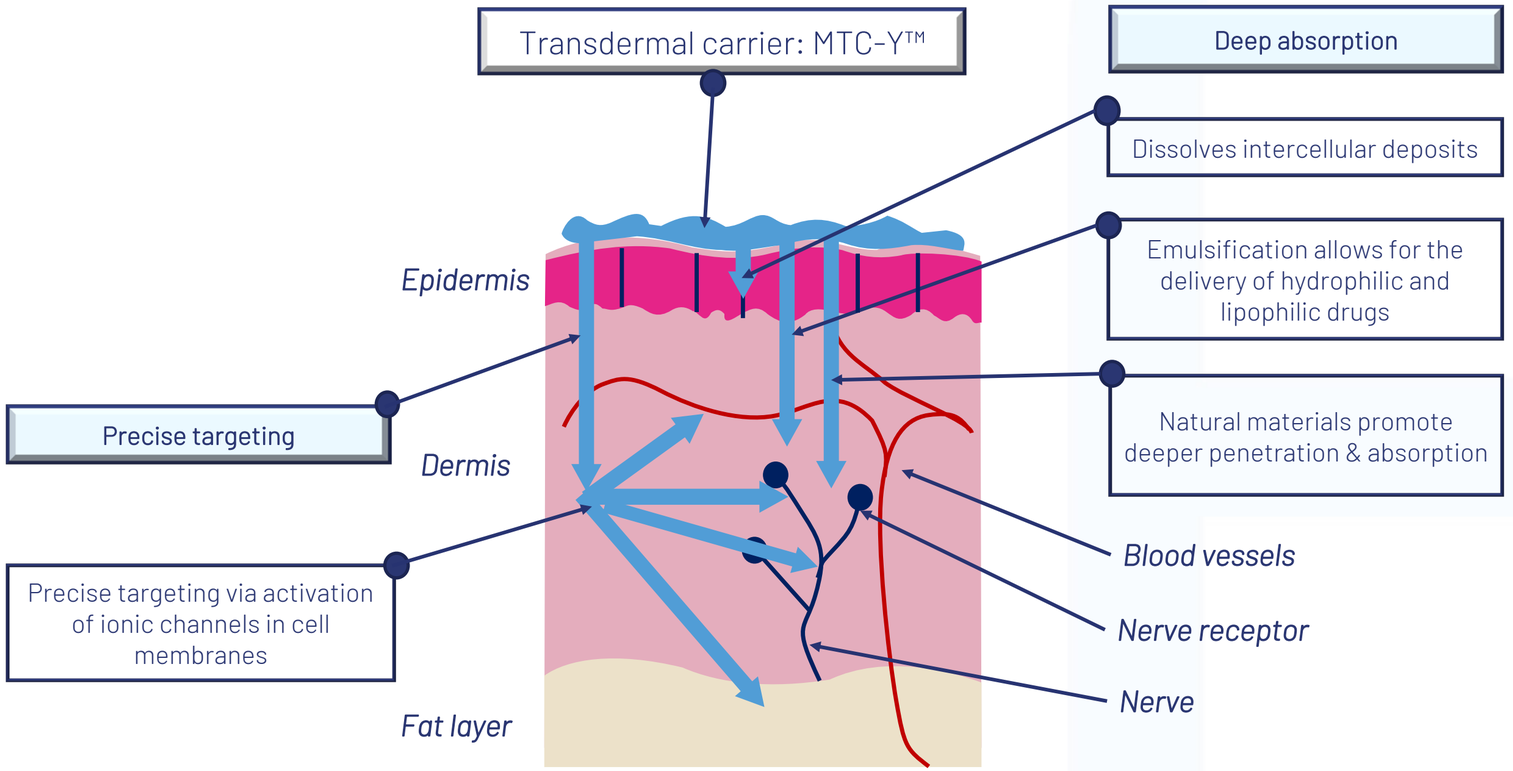
Biotts patent applications get the highest score from a patent office. Our submission of the transdermal MTC-Y technology with the Patent Office of the Republic of Poland scored A in all categories, which means that no invention has ever involved an inventive step or novelty comparable to those offered by our technology.

MTC-Y Technology

BIOTTS

MTC-Y is an original, universal, transdermal carrier of active substances, which increases their bioavailability. MTC-Y is **PATENTED GLOBAL REVULSION**. The mixture of excipients constituting the carrier of MTC-Y consists of components that ensure a simultaneous introduction of several active substances of different character and physicochemical properties into the body. MTC-Y transdermal carrier is 100% safe for people, because it is based on 4 substances with into the pharmacopoeia monographs.
Thanks to the unique properties of the system, it is possible to enable active substances to penetrate through skin barriers up to several centimetres. Due to MTC-Y carrier we are able to transport through the skin hydrophilic substances, big molecules and proteins.

How it works



Properties of the technology

- Design of multi-component drugs
- Therapeutic dose reduction
- Up to **10 times higher** bioavailability
- Penetration through the skin barriers to soft tissues and bones
- Simple implementation and **easy integration** with the production line
- Reduction of side effects **up to 5 times**
- Simple and quick modification of formulas
- Modified API release profile

MTC-Y Mechanism

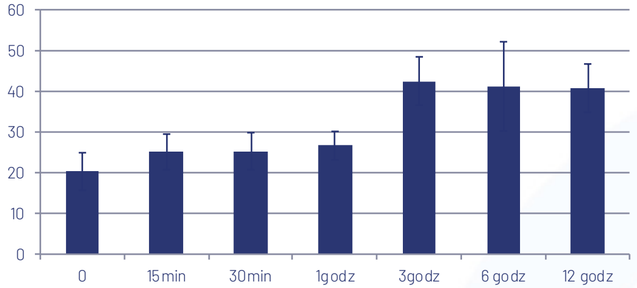
Mechanism of permeation

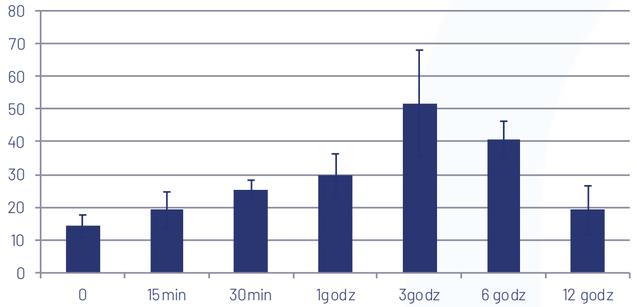
The pictures and graphs present the influence of various modifications of the MTC-Y carrier on the cellular structure of the skin and the relaxation of intercellular deposits that enable permeation of the MTC-Y carrier with hydrophilic molecules and macromolecular substances.

MTC-Y Medium activity

MTC-Y Deep activity

Diagram of the thickness of the keratinized epithelial layer

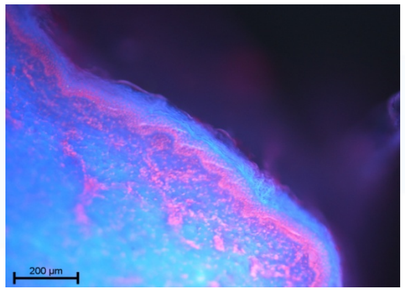


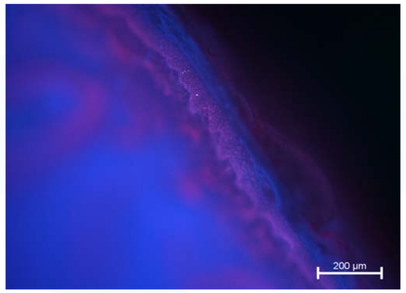


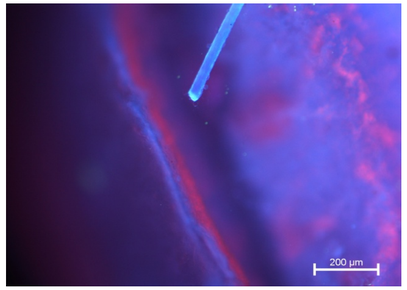
The observation of skin histological samples with a fluorescence microscope

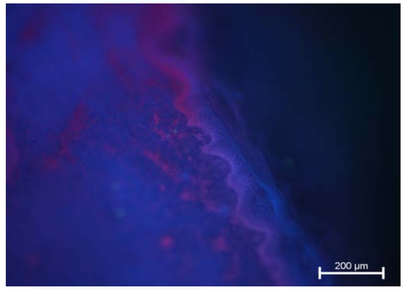
15 min.

12 hours









Full control

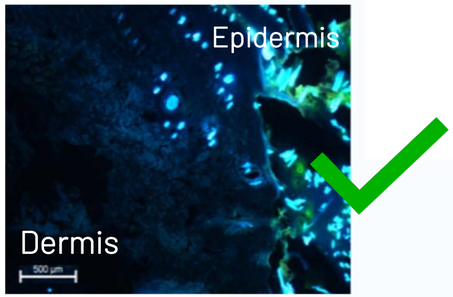
The pictures present the results of studies on the animal model of permeability of MTC-Y carrier combined with fluorescein. Depending on the simple quantitative modification of the carrier substances, we can control the depth of absorption from the skin surface, through tissues and muscles to the bloodstream and liver.

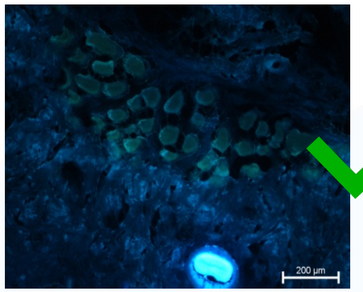
Surface&skin

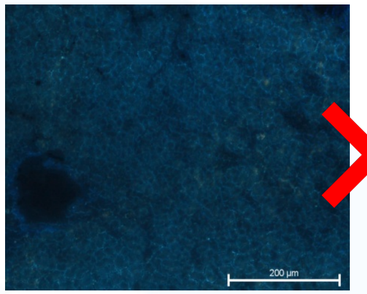
Muscles&tissues

Liver

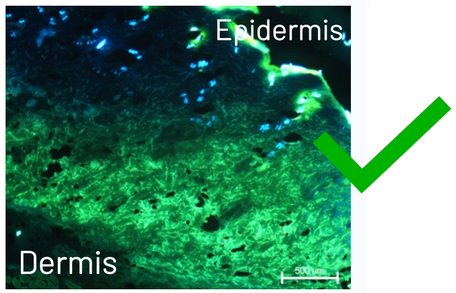
MTC-Y Medium activity

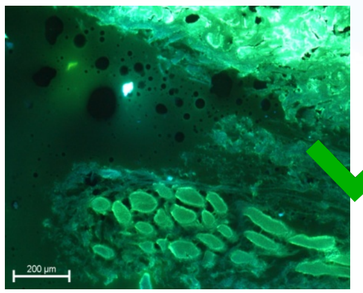


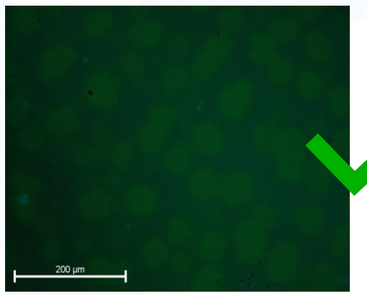




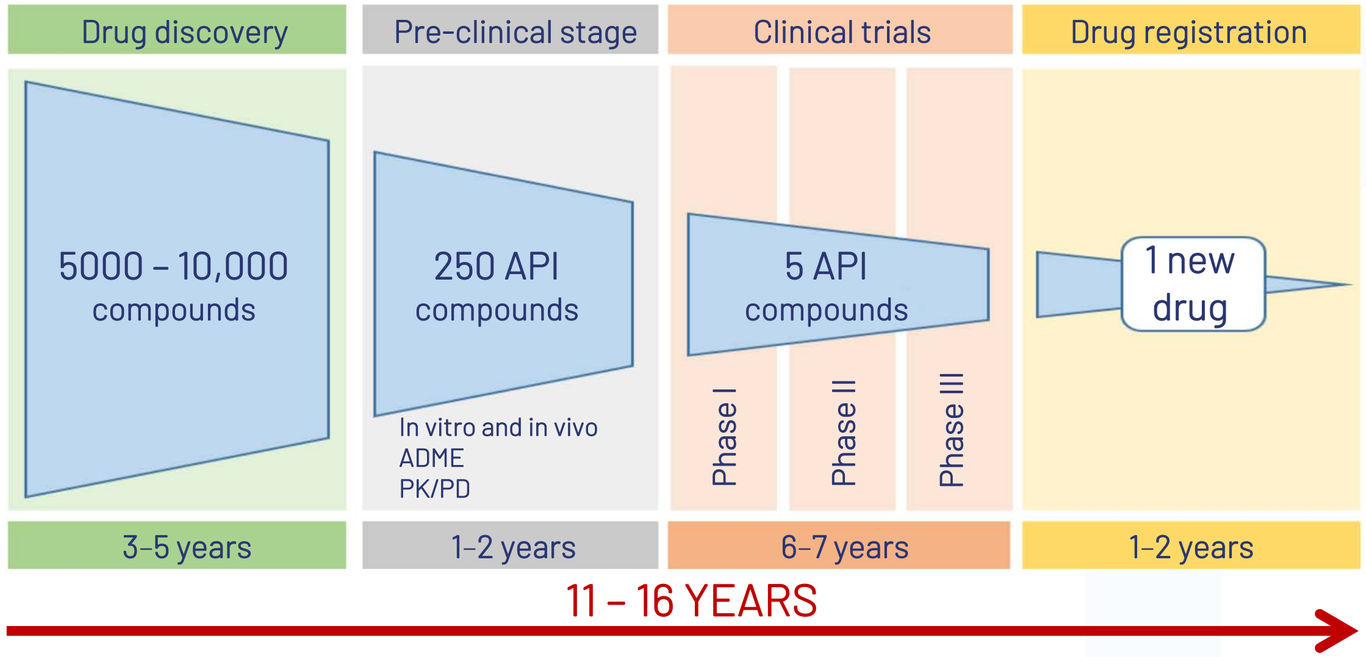
MTC-Y Deep activity







Quick registration process



New drug

The process of registration and testing of any new active pharmaceutical ingredient (API) requires huge financial outlays ranging from **500 million USD to 1.5 billion USD**, involves a very high risk, and requires an extended research process, even up to 16 years.

Biotts Technology + API

The technology developed by Biotts makes it possible to create new, more effective drug formulas based on the existing active substances in a faster and cheaper way at a reasonable cost. What is more, the risk of registering a new drug based on the Biotts technology is negligible, because both the carrier and active substances are already known, registered and come with extensive documentation of basic and clinical research.

Registration can be carried out in the "fast track" mode (FDA: 505(b)(2); EMA: Article 10 Directives 2001/83/WE). It allows to reduce research time to 2-5 years and costs to USD 10 M.

We transport drugs for the treatment of type II diabetes

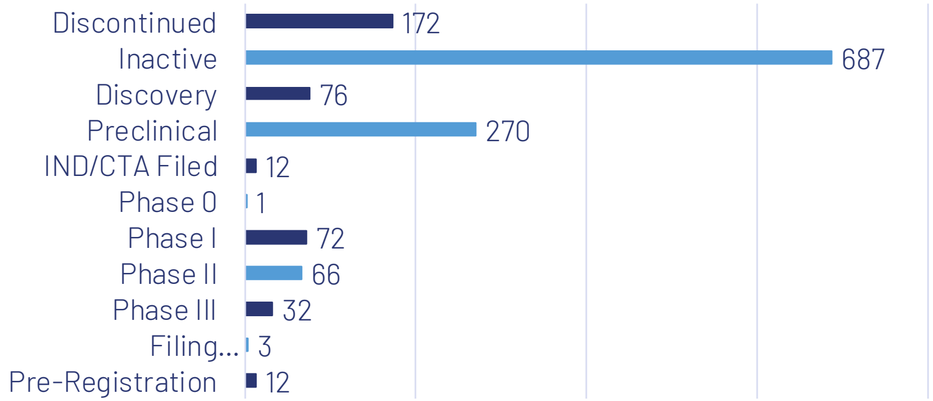
BIOTTS

Currently, the prevalence of diabetes exceeds 5% and is constantly increasing. It forecast that by 2030 there will be over 360 million people with diabetes in the world. The morbidity increases in all age groups, especially in middle- aged people (45-64 years), which is very well illustrated by the situation in developing countries.

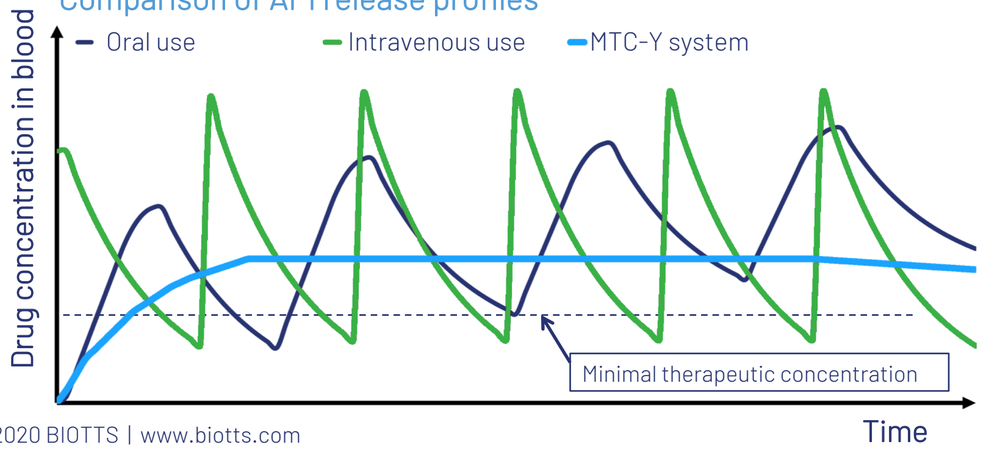
DIABETES TYPE 2

The disease sickness rate in Poland ranges from 1.6 to 4.7%, on average in Europe and the US a little over 6%. The morbidity rate (for 100,000 people per year) in Poland is estimated at 200, while in developed countries it is even 460. The age of onset is generally > 30 years of age.

Number of candidates in particular stages of development



Comparison of API release profiles



Patient benefits of trans dermal patch

Modification of the method of application of drugs administered orally or by injection into a transdermal form. The administration of drugs in a transdermal form significantly improves the well-being of the patient, enhances compliance and reduces side effects. The administration of drugs using the transdermal system, with MTC-Y carrier, allows to obtain a long- term constant effect of the drug, with the kinetics of release of the active substance similar to the zero order kinetics.

Increased bioavailability API

The transdermal form saves the manufacturer the cost of API use, especially for substances sensitive to external factors and digestive acids. The administration of the drug in the transdermal form is similar to that of an intravenous infusion, therefore, compared to the oral administration, the amount of the active substance may be even 10 times reduced, which translates significantly into the production cost of the active substance.

Key benefits for type 2 diabetes drug administration using MTC-Y

Change of form of application

Changing the form from oral to transdermal administration, allows to skip the intestinal absorption from the gastrointestinal tract and to eliminate side effects from this system, additionally we bypass the first pass effect, thanks to which we can reduce the concentration of the administered drug.

UE grant

3 million Euro – this is the amount of funding we have received from National
Centre for Research and Development (NCBR) to develop antidiabetic therapies and transport through the skin antidiabetic drugs and protins. The project is to end with the first phase of clinical trials for the selected antidiabetic API.

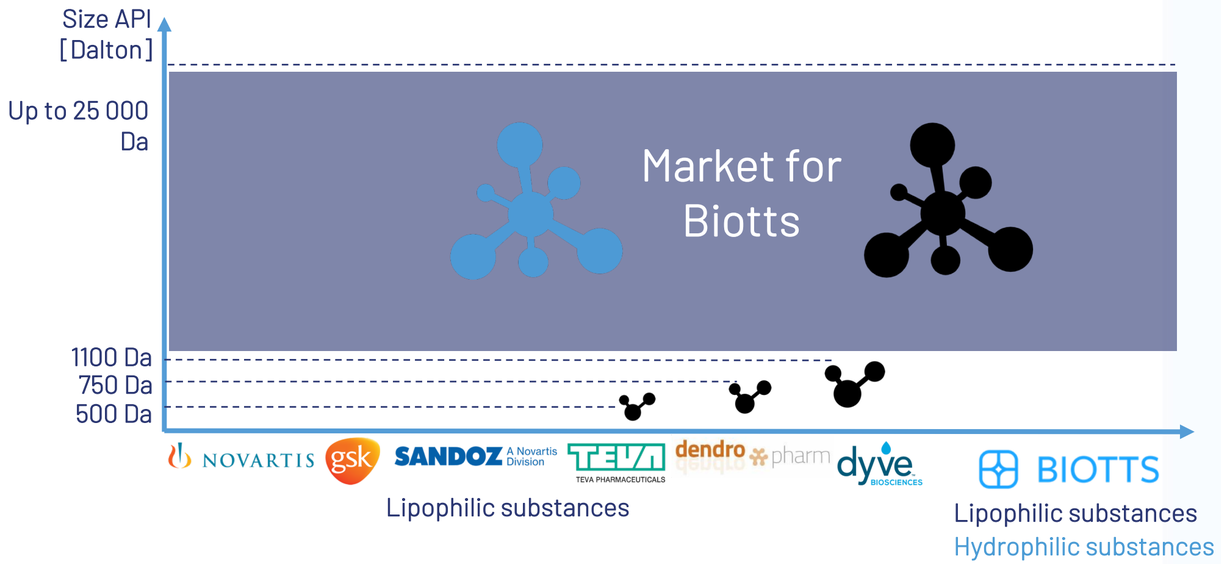
Intellectual property protection

Thanks to its unique technologies, Biotts is able to quickly and easily implement proprietary technologies for various therapeutic areas without the necessity to modify production lines.
The combination of Biotts technology with the existing solutions, formulas or active substances on the market creates a unique and unusual quality, which will be protected by a dedicated patent cloud securing the products of our partners.

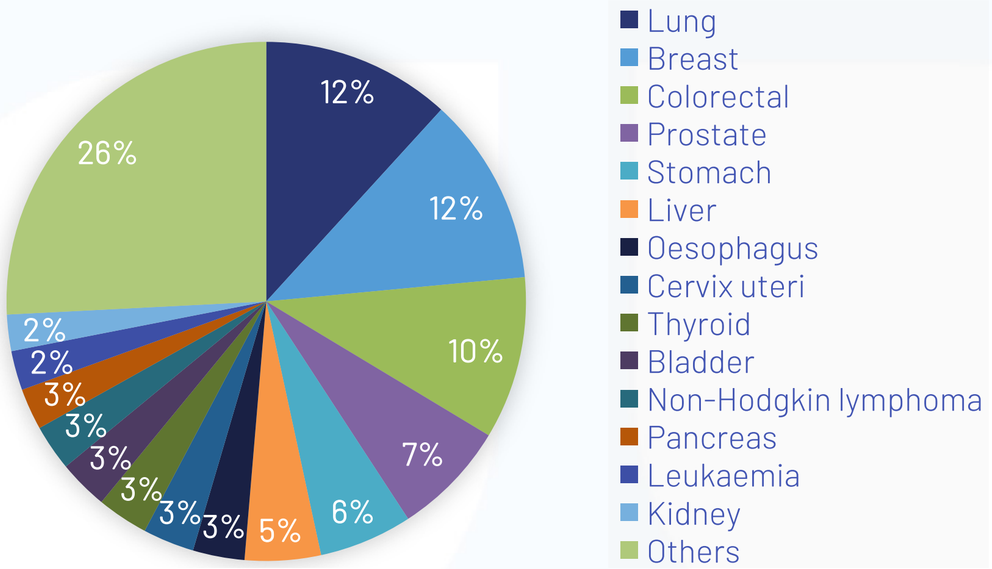
We transport oncological drugs

Cancer is the second cause of death in the world right after cardiovascular diseases. According to the WHO data, in 2018 18.1 million new cases and 9.6 million cancer-related deaths were recorded worldwide.
In 2017, the oncology drug market was worth 97,401,000 USD. In 2015, the market will already be worth 176,509,000 USD. Its average annual growth stands at 7.6%.
Over 90% of medicinal products are administered orally and intravenously. The first group includes hormone therapeutics (e.g. aromatase inhibitors), whereas the second group includes monoclonal antibodies and chemotherapeutics. The technology developed by Biotts makes it possible to transport most of common oncological drugs directly to tumour.

Revolution in TDDS: molecule and protein sizes of up to 25k Da



The most common types of cancer in the world in 2018



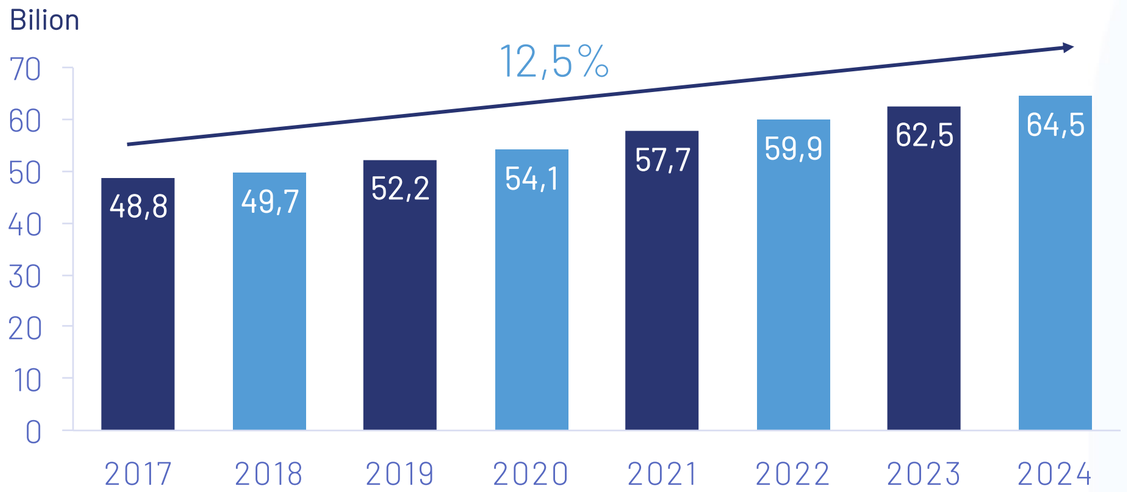
Benefits a new form of administration drugs using Biotts MTC-Y carrier

1. Improving patients quality of life.
2. Long-term drug release in transdermal form from 1 to 21 days.
3. Reduction of side effects.
4. Cost reduction thanks to use lower dose of active pharmaceutical ingredient (API).
5. Increasing bioavailability of API.
6. Extension of patent protection by new form of drug administration.

Candidate for a drug: MTC-A4

MTC-A4 is a proprietary local anaesthetic drug with increased bioavailability and permeability through skin folds. Thanks to the Biotts technology used in MTC-A4, it is possible to target local anaesthetics at nerve endings located in the spinous layer of the skin and nerves in the skin. The application of MTC-A4 is to result in a 10-times stronger local activity compared to the anaesthetic preparations currently available on the market and the reduction of active substances in blood plasma

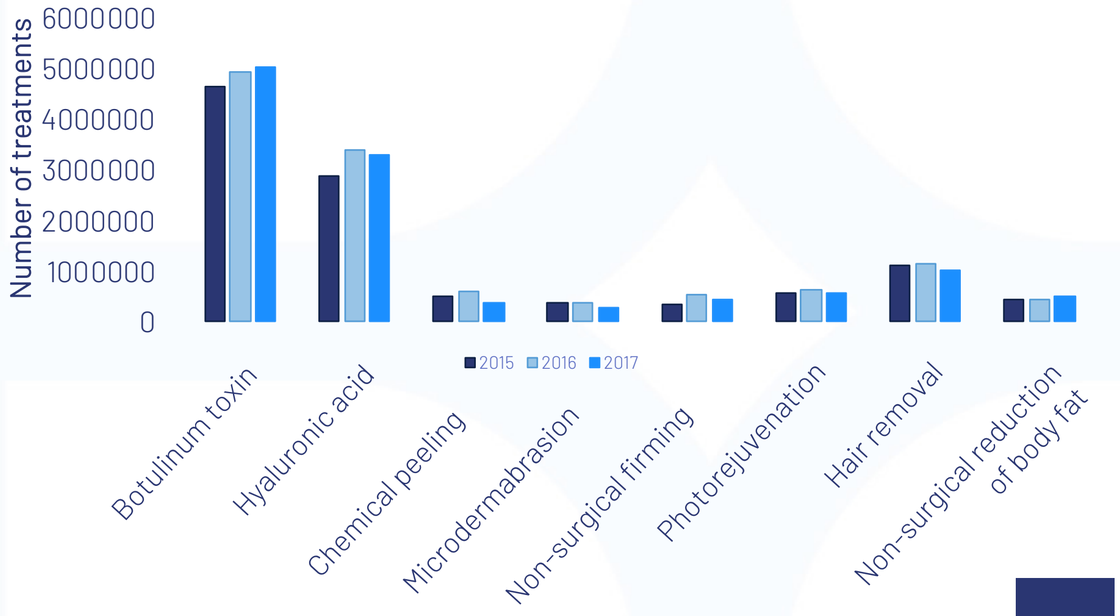
Global market for local anaesthesia



Leaders of the local anaesthetic sector

1. Aspen Pharmacare 29%
2. Grunenthal 9%
3. Aguettant 3%
4. Fresenius 1%
5. Gedeon Richter 1%
6. 67 companies with a 57% share in the market

Dynamics of the most popular aesthetic medicine procedures



Factors stimulating market development

Aesthetic medicine

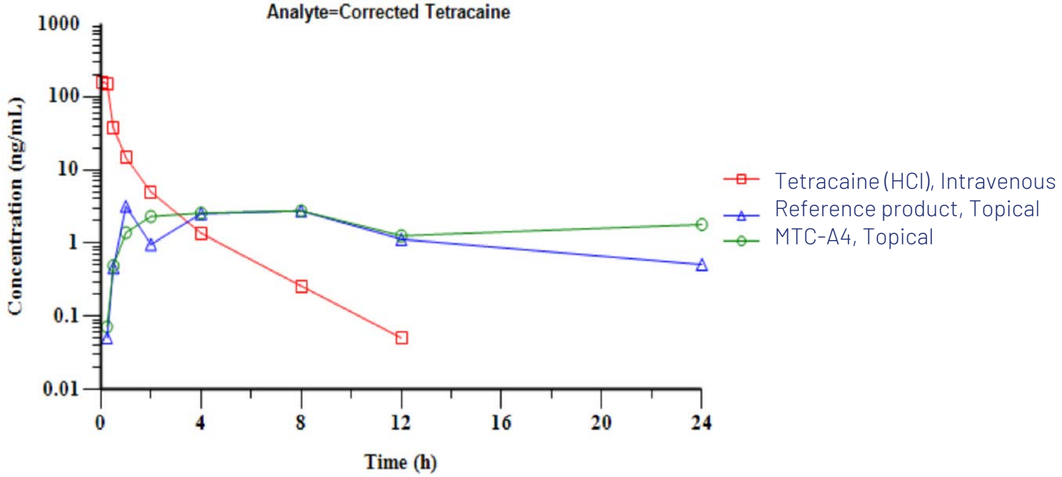
Local anesthetics, especially in the surface form, are most often used in aesthetic medicine procedures. Over the last decade, there has been a dramatic increase in both the number and spectrum of such treatments.
In 2017, the global value of the aesthetic medicine market was USD 9.2 billion, and by 2024 it may double. Almost 72% of revenues are generated by non-surgical procedures, such as injections from botulinum toxin or hyaluronic acid.

MTC-A4 Pharmacokinetics Study

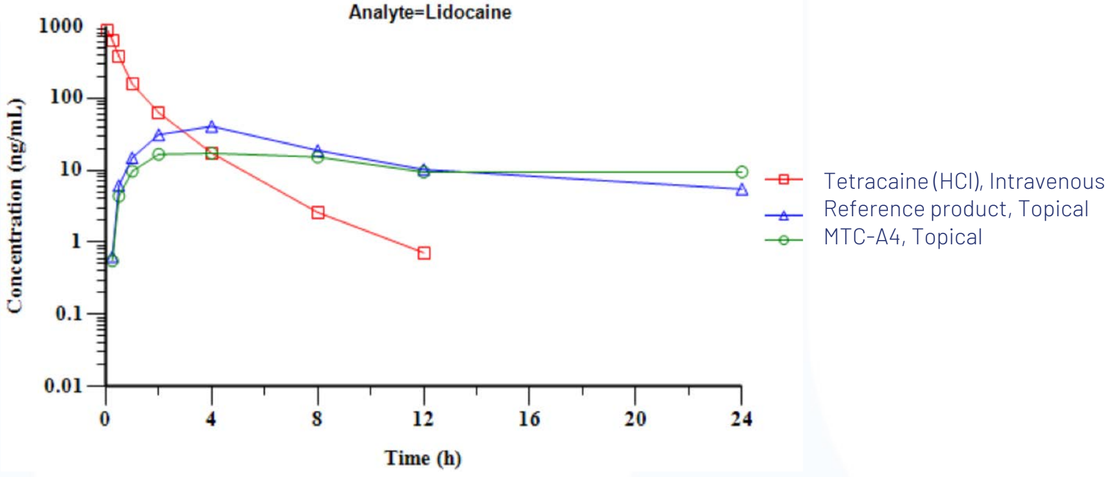
charles river

BIOTTS

The objective of this study was to investigate the pharmacokinetics and bioavailability after intravenous and topical administration of lidocaine hydrochloride and tetracaine hydrochloride to male Göttingen minipigs. The authorized results of the pharmacokinetic sample analyses were transferred to Charles River Den Bosch for pharmacokinetic evaluation. Individual and average plasma concentrations of tetracaine after intravenous dosing (Period 1), topical dosing of Reference product (Period 2) and MTC-A4 (Period 3).



Average Plasma Concentration – Time profiles of Corrected Tetracaine after Single Intravenous (1 mg/kg), and Topical (10 g/animal Reference product, MTC-A4) Administration



Average Plasma Concentration – Time profiles of Lidocaine after Single Intravenous (1 mg/kg), and Topical (10 g/animal Reference product, MTC-A4) Administration

The concentration of the active substances, i.e. lidocaine and tetracaine, in the product MTC-A4 is 4% each, while in the reference product it is 7% each. The result shows that using lower concentrations of active substances we obtained similar bioavailability of used API. Also the results obtained during the above study indicate that the active substances released from MTC-A4 show stable blood concentrations after 24 hours compared to the reference product.

Discussion and Conclusion

Göttingen minipigs were treated with lidocaine HCl and tetracaine HCl by single intravenous administration at 1 mg/kg (Period 1), single topical administration of 10 g/animal Reference product (Period 2) and 10 g/animal MTC-A4 (Period 3) with a wash-out period of one week between Periods 1 and 2 and of two weeks between Periods 2 and 3.

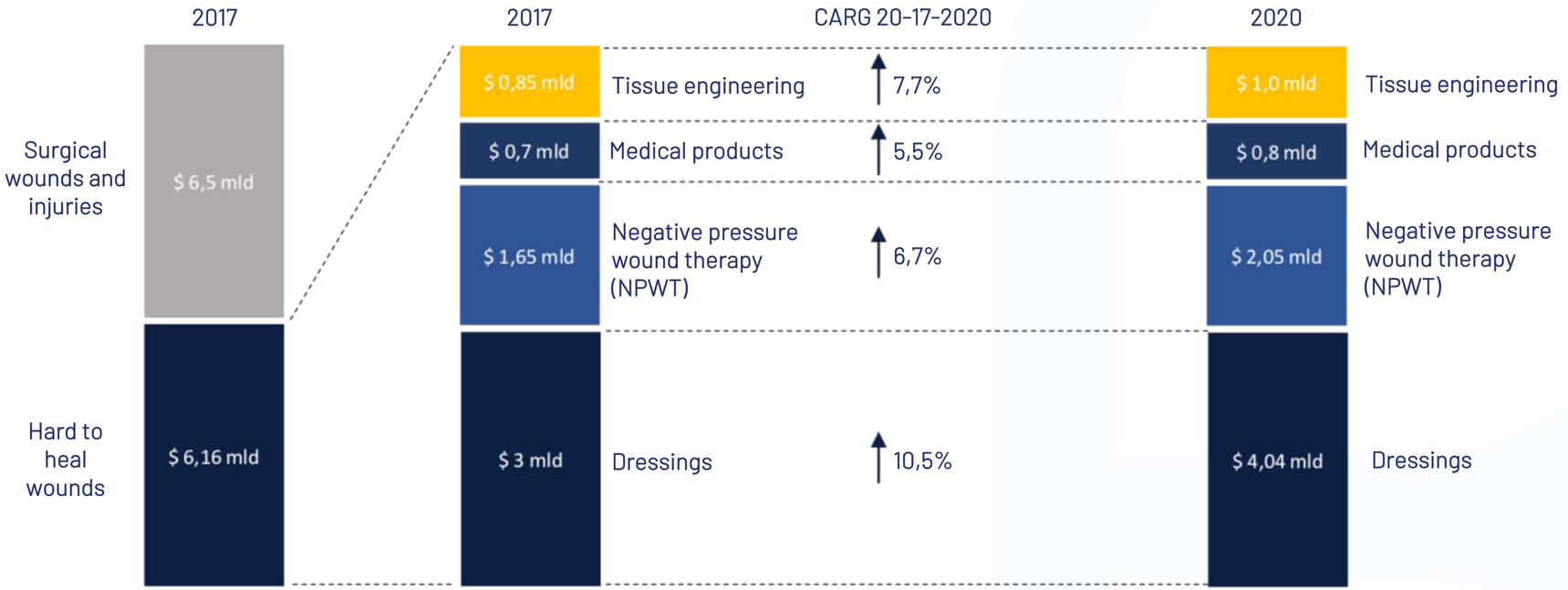
Intravenous administration of 1 mg/kg showed that tetracaine was a highly cleared and highly distributed compound. Following topical administration of 10 g/animal, t_{max} was 1 to 8 hours for Reference product and 2 to 8 hours for MTC-A4 and the average absolute topical bioavailability of tetracaine was 1.26% for Reference product and 3.34% for MTC-A4. After topical absorption, tetracaine was eliminated with a higher average half-life (6.37 hours) compared to intravenous administration (1.85 hours).

Intravenous administration of 1 mg/kg showed that lidocaine was a moderately cleared and highly distributed compound. Following topical administration of 10 g/animal, t_{max} was 2 to 4 hours for Reference product and 2 to 8 hours for MTC-A4 and the average absolute topical bioavailability of tetracaine was 1.41% for Reference product and 1.98% for MTC-A4. No regression analysis was possible after topical administration, consequently half-life could not be calculated.

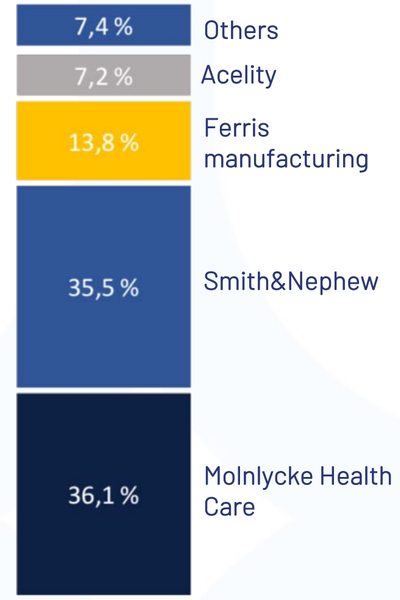
Candidate for a drug: MTC-U1

The MTC-U1 mixture is an original drug for the treatment of bedsores and ulcers of the lower extremities. With the therapeutic system thus developed it is possible to inhibit inflammatory conditions, stop local development of infections and support natural tissue regeneration processes. The MTC-U1 mixture is based on natural active substances, a multiphase, semi-solid form of the drug with an increased bioavailability and a modified release profile. The result of the solutions applied is a cheaply produced anti-inflammatory preparation, accelerating the regeneration of healthy tissues and having a wide range of applications, e.g. on skin inflammations, ulcers, decubitus ulcers, and wounds that are difficult to heal.

The global wound treatment market



Involvement of individual companies in the market



Factors stimulating market development

With age, the probability of morbidity is increasing for disease, such as diabetes, peripheral vascular disease, including venous hypertension and arterial insufficiency. The consequence of these diseases is the formation of chronic ulcers. Hard to heal ulcers and wounds are a global health care problem, affecting 0.3 to 6% of older people. The tendency of population aging, problems related to the ineffectiveness of traditional methods of treatment, the growing number of chronic wounds and the occurrence of diabetes, and the urgent need to develop effective and safe medical means are factors driving the market of advanced wound healing techniques.

Cooperation proposal to pharmaceutical industry

BIOTTS

Ready to use technologies

Business proposal: Licence / Exclusivity / IP and technologies for deal

MTC-Y

PATENTED GLOBAL REVULSION

A multifunctional, original and universal transdermal carrier of active substances, coming in various sizes and physicochemical properties

Proof of Concept (PoC) with your API

1. Biotts technology adaptation to your API: **up to 2 months**
2. Basic research and in vitro studies**: up to 3 months**
3. Animal studies: **3–6 months**

Drug candidates

Business proposal: IP and formulas for deal at the pre-clinical stage

MTC-A4

An original local anaesthetic drug with an increased bioavailability and permeability through skin folds

MTC-U1

An original drug to treat pressure sores, hard-to-heal wounds and diabetic foot

MTC-B7

An original drug to treat breast cancer

MTC-D1

Transdermal antidiabetic drug for type 2 diabetes

Business proposal

- SALE OF LICENSES FOR A SELECTED AREA, INDICATION, API
- IP AND FORMULAS SALE AT THE PRECLINICAL / CLINICAL STAGE
- DRUG DEVELOPMENT WITH A BUSINESS PARTNER
- CREATING DRUGS AND TECHNOLOGIES FOR YOUR BUSINESS NEEDS
- YOUR BUSINESS MODEL

We have won many awards

BIOTTS

MIT Enterprise Forum Poland
Finalist

Health Challenges Congress
Finalist

Akademia BioMed PFR
1st place

bioForum Central European
1st place
Category: Start-up

Forum Ekonomiczne
1st place

Med Trends
Europejskie Forum Nowoczesnej Ochrony Zdrowia
2st place

Akademia Efektywnych Badań Przedklinicznych
PACTT – Pfizer
Finalist

POWERED BY SEBASTIAN KULCZYK
INCREDIBLE INSPIRATIONS
Finalist

They trusted us

Balanced Biotech Inc.

Leonardo
Always be creating

Uniwersytet Medyczny im. Piastów Śląskich we Wrocławiu

MONTIS CAPITAL

TAPEMARK

PFR
Polish Development Fund Group

Team

Paweł Biernat, PhD

CEO & Transdermal Systems Specialist

Co-founder and co-author of BIOTTS patents and therapeutic systems. Graduate, lecturer and assistant professor of the Medical University of Wrocław, the Faculty of Pharmacy; for 14 years gaining experience in the Chair and Department of Drugs Form Technology. Drug Form Technician; expert in the field of designing: nanocarriers of active substances, as well as transdermal and sterile, parenteral drug delivery systems.

Karolina Buratyńska MBA

General Manager

Experienced leader in the pharmaceutical market for over 13 years. Expert strategist in management positions responsible in the largest pharmaceutical companies. She gained her experience in Teva Pharmaceuticals, Valeant Pharmaceuticals, Sandoz and Nutricia. The business strategies she has implemented have been very successful on the market.

Jan Meler PhD

Director of the Research & Development Department

Outstanding technologist in the area of dosage forms, for over 30 years associated with the Medical University of Wrocław in the Chair and Department of Drugs Form Technology. Specialist and technologist in the area of liquid and solid drug forms.Co-founder and co-author of patents and the BIOTTS therapy system.

Contact:
Konrad Krajewski | k.krajewski@biotts.com

Konrad Krajewski
Vice President & CBO

Anna Szczepanik
Operations & Finance Manager

Dominik Marciniak, PhD
Biostatistician

Hanna Dopierała-Bartczak
Senior Drugs Form Specialist & Laboratory Manager

Paulina Topolska
Drugs Form Specialist & HPLC Expert

Karolina Urban-Stojanowska
R&D Specialist

Dawid Bursy
Drugs Form Specialist

Aleksandra Pason
Junior Drugs Form Specialist

Kasia Romanowska
EU-Projektkoordinator