

Management

Dr. Walter Schmidt

Chief Executive Officer & Co-Founder

→ Biologist, entrepreneur, and business angel. Co-founded AFFiRiS (2003) and served as CEO (until Jan. 2015). Co-founded InterCell (now Valneva Austria), the first biotech company on the Austrian stock exchange

Dr. Frank Mattner

Chief Operating Officer & Co-Founder

→ Immunologist and entrepreneur. Co-founded AFFiRiS (2003) and served as CSO (until Jan. 2015) where he was in charge of research and development

Dr. Markus Mandler

Chief Scientific Officer

→ Molecular biologist. Successfully developed 5 vaccine candidates from the discovery to clinical stage while working at AFFiRiS. Responsible for company's patent strategy

Prof. Achim Schneeberger

Chief Medical Officer

→ Board-certified dermatologist with ample experience in drug development. As CMO of AFFiRiS, he was responsible for the planning, execution and analysis of 15 clinical studies including Phase I and Phase II studies

WHO WE ARE

ACCANIS is developing novel, mRNA-based therapeutics for local skin diseases and skin rejuvenation. Our mission is to pioneer mRNA-based blockbuster treatments for the skin.

WHAT WE BELIEVE

ACCANIS' clinical development strategy is focused on two highly relevant areas: non-melanoma skin cancer (NMSC including AK) and cosmetic dermatology (specifically atrophic scars, stretchmarks and wrinkles). Based on current proof-of-concept data in pigs and results in human skin explants, ACCANIS believes that its mRNA-based approach will revolutionize treatment of these two areas with significant potential in other fields in dermatology.

WHY IT MATTERS

mRNA is a new drug format offering unprecedented features and opportunities. It allows for the expression of fully human proteins generating distinct advantages over current treatment modalities. For AK/NMSC: tailored target dose and expression time maximizes efficacy (fast-track to marketing authorization in 2022 possible); for cosmetic applications: integration of the molecule of choice into the affected tissue, rather than simple deposition, is defining a new quality.

MARKET FOR mRNA THERAPEUTICS

mRNA therapeutics are one of the newest and fastest growing therapeutic areas. The advantages of using mRNA over conventional drugs have attracted billions of dollars in investment from the pharmaceutical industry and venture capitalists. Among the present industry players, Moderna Therapeutics (USA), CureVac and BioNTech (both Germany) have received the greatest support and currently maintain the broadest development pipelines. None of these companies are addressing skin-based indications or cosmetics offering **a unique market niche for ACCANIS and the opportunity in the field of dermatology**. ACCANIS is perfectly positioned to become one of the first companies to receive marketing authorization with mRNA-based therapy.

THERAPEUTIC PROGRAMS

ACCANIS has defined novel solutions for the expression of IVT mRNA in skin offering product candidates for several indications, relying exclusively on validated targets. Starting from proprietary mRNA constructs, suitable formulations and application techniques have been identified based on the company's ex vivo/in vivo paradigm (human and porcine skin explants compared to pig skin in vivo) to create a backbone for local mRNA expression in the dermis. **Proof-of-concept studies** in pigs have shown promising results, including strong expression data and excellent tolerance.

MEDICAL PROGRAM: AK/NMSC

ACCANIS' **lead candidate, NMSC01B, is based on a proprietary IFN α mRNA construct** and developed as lesional therapy of actinic keratosis (AK). ACCANIS aims to **enter a Phase I clinical trial early in 2020** with this lead candidate delivering within 9 months human POC for therapeutic mRNA expression in skin. Successful completion will pave the way for the developmental program of the lead and provide the opportunity to extend its indication (e.g., other forms of NMSC). NMSC01B is designed to overcome limitations of current treatment options (surgery: cost, scars; radiation: cost; topical therapies: extensive treatment period, decreasing compliance and limiting efficacy). Thus, NMSC01B is suited to fight the **high unmet medical need in AK/NMSC**.

Financing

Since its incorporation, ACCANIS has obtained **over €2.1m** from private investors and has secured **over €5.5m** in non-dilutive public funding

Key Company Data

Founded: 2015

Employees: 15

Location:

Vienna Biocenter, Karl-Farkas-Gasse 22, Vienna, Austria

Website:

www.accanis.com

To learn more about Accanis, call or email:

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AK program at a glance:

- Target: IFN α
- Product Candidate(s): lesional AK therapy (extension to other NMSCs)
- Stage of Development: late stage preclinical/clinical trial application
- Next Milestone: completion of clinical trial application
- Commercial Opportunity: Both, AK and NMSC markets are huge and growing: NMSC US\$5,365m. in 2015, currently: 3m patients (US, EU); AK US\$10,251m by 2026, currently 50-55m patients (US, EU)

SKIN REJUVENATION DEVELOPMENT PROGRAM

Targets here include growth factors and two structural elements of the extracellular matrix. The approach foresees single mRNA candidates and combinations thereof creating a product portfolio of increasing strength to address local states of tissue loss (e.g., atrophic scars, fine lines, wrinkles, stretch marks) and improving upon the standard of care in the field of soft tissue fillers. This also opens a unique market to ACCANIS as **skin rejuvenation remains unexplored by other mRNA developers** despite its significant market size and growth potential.

Skin rejuvenation program at a glance:

- Targets: growth factors and two components of the extracellular matrix
- Product Candidate(s): single mRNA products and combinations thereof yielding variable strengths to address atrophic scars, wrinkles, stretch marks
- Stage of Development: preclinical
- Next Milestone: POC studies in pigs in vivo, expansion of IP position
- Commercial Opportunity: Scar treatment market alone is expected to increase from US\$9,654m (2017) to US\$13,103m by 2025. Atrophic scars: 50% of all scars. Facial skin rejuvenation (global): US\$ 17,114m by 2018, soft filler market segment accounted for US\$ 3,478m (21.1%).

PLATFORM POTENTIAL

By focusing on two areas of expertise, ACCANIS is structured to yield a comprehensive platform covering mRNA expression in human skin. The algorithm established to optimize native human mRNAs was shown to yield constructs exceeding expression efficiency of native ones by a factor of 100. The ex vivo/in vivo paradigm set-up identified delivery formulations and devices enhancing expression >1000-fold. ACCANIS currently works on 5 molecular targets and screens and develops numerous delivery tools covering indications in all 3 skin layers to further expand its platform.

OFFERED TRANSACTION

ACCANIS is seeking to raise €9m in a series A financing. The following 3 key clinical milestones shall be achieved with the investment:

- **Completion of Phase IA study with lead candidate in AK yielding human POC for intradermal mRNA expression in general by end of 2020**
- **Start of Phase IB study (2020) with lead candidate in AK yielding first data on its clinical activity (by 2021)**
- **Start of first study addressing skin rejuvenation by 2021 (focus clinical activity)**