

Corporate Presentation APR Applied Pharma Research s.a.

at a glance

Developer of smart, differentiated products in niche therapeutic areas on a global basis

Swiss pharma company with a 25+ year track record of leveraging patented drug delivery technologies

What we do:

Identify, develop and commercialize known molecules engineered with drug delivery systems in niche diseases on a global basis

Use our core R&D competences to offer first-in-class contract development services to third party innovators

Vision: We Share Care

We want to make a real difference in the life of people living and dealing with debilitating diseases





Risk mitigated approach to R&D: making known medicines better

Proprietary Products

Identification, development and commercialization of patented products in niche indications

Focus in selected therapeutic areas on a global basis.



2 main Areas
Inherited Metabolic Diseases
Niche Disorders

C 2 Commercial Strategies

Direct Sales in EU and Distribution in RoW for Metabolic Products

Royalty bearing Licensing for all other Products

Third Party Products

Incubator and an accelerator of third party's innovation.

APR offers its core competencies in the development of third part's ideas and products on a flexible contract basis.



We do not simply execute what clients are asking for...

... we listen to them

and we do our best to enable and materialize innovations



Combining technical excellence in formulation development with deep expertise in regulatory path across multiple categories (Rx, OTC, MD, FS) in a lean organization



recent key milestones

1

Q1/2021

SENTINOX

COVID-19 and other airborne viruses

Received Marketing Authorization in Europe as Class III MD

Q4/2020

SetoFilm Oudspende film

CINV, RINV and PONV



Norgine acquires SetoFilm for EU, Australia and New Zealand

Q2/2020

GOLIKE

Phenylketonuria (PKU)



Launch of Shake & Drink on the International PKU Day (June 28)

Q1/2020

APR-OD031

Phenylketonuria (PKU)

FDA

US FDA granted Orphan Drug Designation

Q4/2019

APR-TD011

Epidermolysis Bullosa (EB)

FDA

US FDA granted Orphan Drug Designation





Product Portfolio & Pipeline

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	Areas
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Product	Indication	Preclinical	Clinical	Reg.	Market	Notes	
Inherited Metabolic R	ecessive Disorders						
G OLIKE	Phenylketonuria (PKU)					First FSMP engineered with delivery technology	
APR-OM032	Tyrosinemia (TYR)					Expected Launch as FSMP in 2023/2024	
APR-OM033	Maple Syrup Urine Disroder (MSUD)					Expected Launch as FSMP in 2023/2024	
APR-OM034	Homositinuria (HCU)					Expected Launch as FSMP in 2023/2024	
APR-OD031	Phenylketonuria (PKU)					ODD granted by FDA in Q1/2020	
Niche Disorders							
Acidoxidating Solution (ADS) NEX DDYN a THE WOUND CLOSURE CLEANSER	Chronic Wounds					Chronic Wounds	
SetoFilm Ondissolve ODF	CINV, RINV and PONV					First Rx Product approved with ODF Technology	
SENTINOX	Infectious Diseases (COVID-19)					First Nasal Spray indicated for SARS-CoV-2	
APR-TM011	Skin Toxicities in cancer Therapies					First Rx Product with a specific labeled indication	
APR-TD011	Epidermolysis Bullosa (EB)					ODD granted by FDA in Q4/2019	
APR-TD012	Haley Haley Disease (HHD)						
APR-TD013	Buruli Ulcer (BU)					Eligible for FDA Voucher (Working with WHO)	

Cash Cow Products

Other Therapeutic Areas				
CAMBIA' Doctoree Potessum to Oas Solution	Acute Migraine Attacks in Adults			First and only NSAID cleared by FDA for Migraine
eminocs	Acute Pain			
Voltadoľ	Local Pain and Strains			
HALY	Pediatric Line			
SwitzAGE€	Food Supplement Line			



Inherited Metabolic Diseases

Phenylketonuria (PKU)

G OLIKE	Phenylketonuria (PKU)			First FSMP engineered with a drug delivery technology
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APR-OM034	Homositinuria (HCU)			Expected Launch as FSMP in 2023/2024
APR-OD031	Phenylketonuria (PKU)			Orphan Drug Designation (ODD) granted by FDA in Q12020



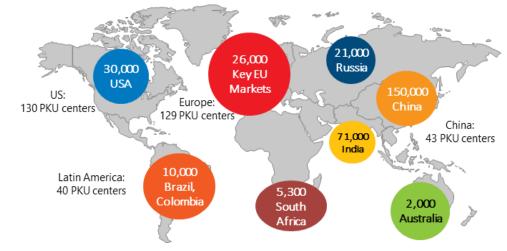
Leverage a patented drug delivery technology to develop and commercialize differentiated products in the most prevalent, rare, inherited metabolic diseases

The first and only technology able to control and prolong release of multiple active ingredients (19) simultaneously

Building a global presence with a combination of direct S&M and selected partners

Country	Partner	Notes
	APPLIED PHARMA RESEARCH	Direct S&M
+	APPLIED PHARMA RESEARCH	Direct S&M
•	d lifediet	Launched Q4/2019
**	RENDON EUROPE	Launch Q4/2020
	Synchrony Pharma	Launch Q4/2020
*)	以岭万洲国际制药有限公司 YILING PHARMACEUTICAL LTD	Launch Q2/2022
(MDM PHARMA BRASIL	Launch Q2/2021
\$	TrueMed	Launch Q2/2021
	PharmacarePlus	Launch Q4/2020

Enter the \sim \$ 1,0 billion inherited, metabolic disease market starting from the \sim \$ 0,5 billion PKU segment



More than 350,000 PKU patients across key geographies. Patients concentrated in small number of PKU centers that can be targeted with a small salesforce





The first FSMP* engineered with a drug delivery technology: a differentiated product offering an improved metabolic management and a better compliance

* FSMP: Food for Special Medical Purposes



Complete family of products covering main age groups and individual habits



Clear LCM Strategy through 2024

	2019	2020	2021	2022	2023	2024
Master SKUs	PKU GOLIKE sachets	GOLIKE Shake Shake Drink Drink	PKU GOLIKE and GOLIKE Sho to be merged in a Ready to l	ake & Drink unique SKU,	GOLIKE PRU GOLIKE GOLIKE Ready to drink	
Complementary SKUs			PKU GOLIKE Krunch	PKU GOLIKE Bar	PKU GOLIKE Krunch new flavors	PKU GOLIKE Bar new flavors
IEM SKUs						GOLIKE TYR GOLIKE RTD 34 Ready to drink

Our distribution Partners benefit from APR corporate support:

Marketing Support	Positioning, handout materials, videos
Training Sale Force	Training Sessions and Training Materials of the local Sale Force
Medical Affairs	Clinical Studies, Publications, local events
Advisory Board	Organization of local advisory boards with KOLs
R&D	Development of follow on and LCM products



SENTINOX

Saure oxidierende Lösung, enthält

Solution acide oxydante contenant

de l'acide hypochloreux (HCIO) AcidOxidizing Solution

hypochlorige Säure (HCIO)

AcidOxidizing Solution

50 ml **e**

Pompe 250 µl

for nasal care

AcidOxidizing Solution containing hypochlorous acid (HCIO) AcidOxidizing Solution

A new Product to block COVID-19

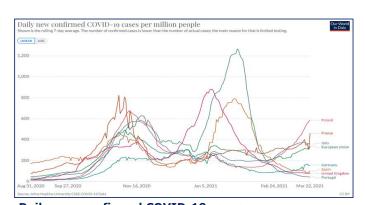
An additional protection to block airborne virus / bacterial infections and transmission (including SARS-CoV-2)

- SENTINOX is a ready to market,
 Class III Medical Device approved
 in EU on February 16th 2021.
- SENTINOX is an intranasal spray containing a well-known, safe and effective antiviral which can block transmission of the SARS-CoV-2 virus (including its mutations) from the respiratory tract and limit or reduce the effects of COVID-19.
- SENTINOX eliminates the virus directly at the site where the disease begins - the upper respiratory tract. Thanks to its safety profile, Sentinox can be marketed as a precautionary measure to a wide array of patients and consumers.
- SENTINOX is a long-term commercial opportunity: it can be initially commercialized as prophylactic/preventive measure against COVID-19 capitalizing on the strong approved claims. This positioning will allow product extension in the prevention of other respiratory viruses, extending the product lifecycle far and beyond COVID-19.

Approved Claims



- Prophylaxis/Prevention Claims: reducing the risk of infections caused by bacteria and viruses, including SARS-CoV-2 (etiologic agent at the basis of the pandemic COVID-19), by lowering the nasal microbial load
- Symptomatic Claims: symptomatic nasal care (to ease nasal symptoms, e.g. nasal congestion, typical of upper respiratory conditions such as cold, flu, sinusitis or rhinitis)
- General Claim: nasal care in case of minor lesions/alteration of the nasal mucosa (e.g. creates an ideal environment for an optimized resolution of irritation and lesions)



Daily new confirmed COVID-19 cases



Acute and Chronic Wounds



Nexodyn is a sprayable HCIO solution offering clinically proven efficacy with an excellent safety profile

Pathology Overview of Non-Healing Wounds

 Non-healing wounds may persist for months due to the build up of bioburden and biofilm and pro-inflammatory mediators



Non-healing wounds are a globally escalating problem primarily driven by an aging population and changes in lifestyle conditions that directly result in increased diabetic wounds and pressure ulcers

15 million

Estimated number of people who will develop a stalled wound during their lifetime in Europe and the US combined

\$41 billion

Pressure ulcer global expenditure in 2015

Average annual cost per patient

\$15,400

\$52 billion

Diabetic foot ulcer global expenditure in 2015

Average annual cost per patient

\$44,200

\$50 billion

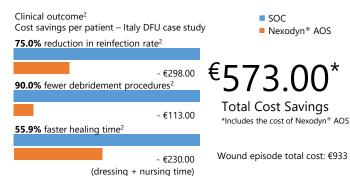
Venous leg ulcer global expenditure in 2015

Average annual cost per patient

\$11,000

Pharmaco/Economic Study in Italy

61% Cost Reduction vs. SOC1



Nexodyn is supported by a wealth of clinical data



- Internal APR data
- 2. Iacopini E. The Use of a Novel Super-Oxidized Solution on Top of Standard Treatment in the Home Care Management of Postsurgical Lesions of the Diabetic Foot Reduces Reinfections and Shortens Healing Time, Int J Low Extrem Wounds; 2018 Oct

A wealth of clinical evidence consistently supports Nexodyn's material impact on wound-related economic burden through accelerated wound closure, reduced infection rates, and reduced wound-associated pain



Acute and Chronic Wounds (cont.)

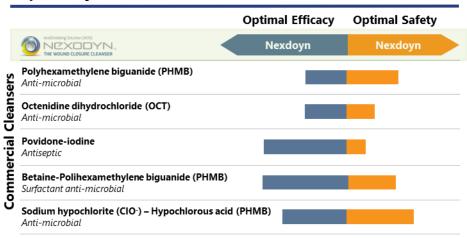


Nexodyn® AOS is proven to restart healing in stalled wounds, creating the ideal microenvironment to sustain the physiological healing process

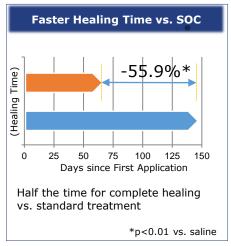


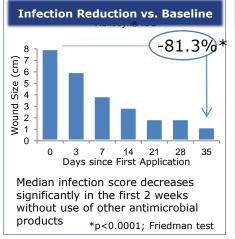
- Strong antimicrobial properties (against viruses and bacteria)
- Anti-inflammatory activity (irreversibly inhibits MMP-2 and MMP-9)
- Ability to remove Bio-film

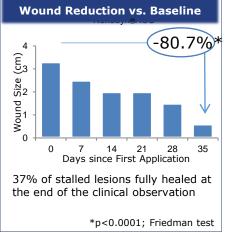
Superiority vs. Other Cleansers

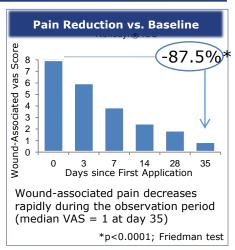


A Wealth of Clinical Evidence and Publications showing Nexodyn's Superiority vs. Standard of Care















First and only Ondansetron containing product approved as Oral Dispersible Film for the treatment of Chemotherapy and Radiotherapy induced nausea and vomiting (CINV, RINV and PONV) in children and adults.



FDA approved as 505(b)2 NDA

- Building a global presence with long term commercial partners
- Expand in still available territories

Country	Partner	Notes
	NORGINE	Launched in 2013
	NORGINE	Launched in 2013
	NORGINE	Launched in 2013
*	NORGINE	Launched in 2013
*	Takeda	Launched in 2015
	Mustice Printer	Partnership AQST
*	Gador 🏶	Under registration
	G Glenmark	Under registration
	<u>La Vasta</u>	Under registration

Approved for children (in EU only) with CINV and RINV thanks to the delivery system which avoid suffocation



How ODF Works

- ODF is an innovative oral dosage form that combines the convenience of a liquid with the stability and dosing accuracy of a tablet
- After the film is administered, the active ingredient is swallowed with saliva and is metabolized by the liver
- Polymers are used as film formers to hold the API and excipients in place while specific techniques are used to ensure that the API is uniformly distributed throughout the film

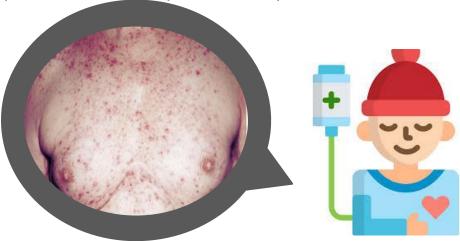


APR-TM011

First Class III Medical Device approved in EU in the prevention and treatment of skin lesions in cancer patients due to anti-EGFR inhibitors

Papulopustular Skin Rushes/Lesions

Induced by anti-EGFR Inhibitors (MABs and TKIs)



~200K Patients/Year*

Signs and Symptoms

Lesions usually develop within the first weeks of treatment and can last as late as 6 weeks after EGFR inhibitors have commenced.

Lesions are generally painful and itching

Prevalence and Incidence

With EGFR MABs ranges 45%–100% of patients (Cetuximab 88%–90%, Panitumumab 100%)

With EGFR TKIs ranges 47%–71% of patients (Erlotinib 60–99%, Afatinib 81–100%)

Radiodermatitis

Induced by cancer radiation therapy

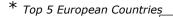


~1,7 Mio Patients/Year* Signs and Symptoms

They range from Erythema (Grade 1) to ulcerations and necrosis (Grade 4) Lesions are generally painful and itching

Prevalence and Incidence

In 2018, ~18,1 Mio newly diagnosed cancer patients Radiotherapy recommended in 50% of patients





Skin reactions/lesions in Cancer Patients (cont.)

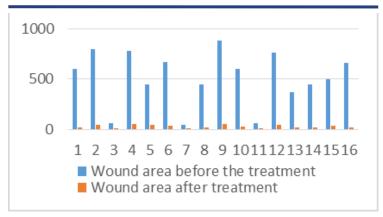
Product Overview

- APR-TM011 has the potential to be the first product indicated for the prevention and treatment of skin rashes associated with anti-EGFR mAb treatments
 - Result in substantial improvement in the quality of life of cancer patients
 - Positively impact survival rates due to improved compliance and adherence to the mAb treatment regimen

Clinical Study & Results

- Clinical Study: 15 cancer patients (10 men / 5 women) were treated for 3 months between October 2017 and March 2018 with cetuximab (Erbitux) and APR-TM011 was applied daily in conjunction with lenitive creams
- Clinical Results:
 - No patients developed any adverse skin events and 100% of patients completed their cancer treatment regimen

Wound Area Reduction



- In the 15 patients the widths measured ranged from 5 cm to 22 cm, while the lengths from 10 cm to 40 cm. The patient with the largest injured area was 22 cm x 40 cm lesion.
- Results: 93.3% of patients had a greater than 90% reduction in the area while 1 patient had a reduction of 88.9%

Development Pathway and Commercial Strategy

- APR-TM011 is approved as a Class III Medical Device in EU for the prevention and treatment of skin rashes associated with anti-EGFR mAb treatments
- APR is pursuing a label revision / extension for APR-TM011 in the EU based on the product's current clinical trial evidences
 - The label revision / extension will include skin reactions in cancer patients being treated with anti-EGFR mAbs
- APR-TM011 is patent protected until 2028
 - APR is in the process of filing an additional patent in the US claiming this additional indication, which could extend exclusivity well beyond 2028.



The US FDA granted to APR the Orphan Drug Status to the following early stage programs in two different rare disease settings



APR-TD011 (Epidermolysis Bullosa)

- EB is a group of rare, genetic, life-threatening connective tissue disorders characterized by skin blistering throughout the body and risk of severe impact to internal organs
 - It is estimated that EB affects ~250,000 EB patients worldwide, with ~30,000 patients in the EU and ~20,000 patients in the US
- There are three main types of EB: EB simplex (EBS), dystrophic EB (DEB) and junctional EB (JEB)
 - DEB and JEB are the most severe forms of EB representing about ~30% of all EB patients and are life threatening conditions

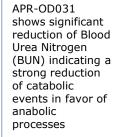
Product Overview

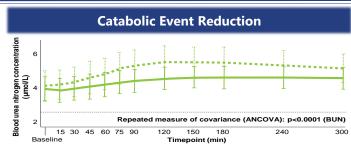
- APR-TD011 is a HCIO sprayable solution that combines a strong antimicrobial action with anti-inflammatory properties and has the potential to become one of the first products ever approved for EB
- In a preliminary proof of concept clinical trial, EB patient administered with APR-TD011 has demonstrated improvement in skin blistering and tissue repairing in just two weeks of treatment

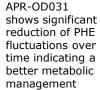
APR-OD031 (Phenylketonuria)

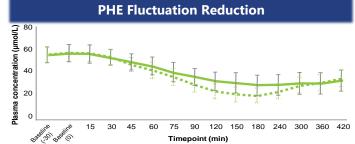
- Majority of the US PKU population diagnosed through Newborn Screening has no access (~46% or ~6,900 patients) or limited access (~33% or ~5,000 patients) to the only available treatment options (FSMPs)
- Currently available FSMPs show sub-optimal outcome and related side effects despite they represent up to 80%-85% of the daily protein intake for the entire life of majority of PKU patients

Strong Evidences of APR-OD031











Other Therapeutic Areas

Main royalty generating products

Dichirine Potesium for Oai Solidon	Acute Migraine Attacks in Adults		
Eminocs Dictorenac potassico	Acute Pain		
Voltadol	Local Pain and Strains		
HALY (©©	Pediatric Line		
SwitzAGE€	Food Supplement Line		

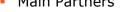


- The first and only FDA approved NSAID for the treatment of acute migraine attacks in adults (through 505(b)2 NDA)
 - Patent exclusivity until January 1st 2023
 - Working on Life Cycle Management to extend exclusivity until 2026
 - ~\$ 45 Mio/year in Net Sales in USA and Canada

Main Partners











- First Oral Drop formulation of Diclofenac for Acute Pain and Migraine
- Marketed in Italy and available for licensing in other territories

Main Partners





- Fast Acting, patent protected acute pain medication approved in various countries a Abbreviated New Drug **Application**
 - Marketed by Novartis in several countries worldwide
 - Patent exclusivity and royalty stream secured until 2024
 - ~\$ 35 Mio/year in Net Sales in Novartis territories

Main Partners





- First matrix pain patch marketed by GSK in several countries of EU
 - Indicated for local pain
 - ~\$ 20 Mio/year in Net Sales in **GSK** territories

Main Partners





OTC baby healthcare line of products



www.halykoo.com

The first and only OTC baby healthcare brand that matches formulations specifically focused on each of the unique ages and stages of children's growth with smart and innovative delivery systems intended to simplify their use for parents and reduce the hassle for babies.

- 27 Products developed and approved in EU in the 4 categories
- 4 Products close to completion
- 7 product under regulatory change
- Divestment and monetization process on going.

The Right Formula

INGREDIENTS: All products satisfy strict Efficacy and Safety criteria:



EFFICACY CRITERIA

Physiological compatibility Ingredients of natural origin

Proven efficacy

SAFETY CRITERIA

- Paraben Free
- Colorant Free
- Allergen Free Perfume

... in the Right Dosage Form

DELIVERY SYSTEMS: Tailored on the specific needs of each age group.







































Overview of Partnered Products

Technology Product **DDS** Overview/Benefit **Overview/Exclusivity** Product/Brand **Main Partners** First and still the only NSAID ASSERTIO= approved by FDA for acute Immediate Release migraine attacks in adults NUVO Technology offering an Diclofenac Potassium for Oral Solution Exclusivity until 2023/2026 increased rate of drug **Dynamic** absorption and faster **Buffering** Acute pain (rescue Rx medication) **NOVARTIS** peak plasma levels **Voltfast Technology** Exclusivity until 2024 Secures a fast and sustained pain relief in different pain settings Dr. Reddy's **ZONTIVA** ITAMI-ASI Acute local pain (OTC) Dicloreumdol Inflamac 50 rapid Exclusivity until 2026 **fidia** teva Transdermal patch Acute local pain (OTC) Voltadol 😮 technology for absorption Patent protection until 2027 GlaxoSmithKline of active substance **Matrix** through the skin **Patch Technology** Allows better adhesivity Cough & Cold (OTC) and flexibility especially Pediapharm 2 Patent protection until 2027 on joints Film-based technology Zuplenz. Chemotherapy Induced Nausea that can be tailored for and Vomiting (CINV) three delivery sites: Oral Radiotherapy Induced Nausea and buccal, sublingual and **Dispersible** Vomiting (RINV) lingual Film Allows for improved drug Post Operative Induced Nausea NORGINE **Technology** absorption combined with and Vomiting (PONV) Ondissolve ODF a better patient Exclusivity through 2031 Ondansetron Orally Disintegrating Film Ondansetron film à désintégration orale compliance



Structure, Governance and Locations



APR is a private corporation registered and operating under Swiss Law with two institutional investors as major shareholders





Management Team

Experienced and results driven Management Team with proven leadership



Paolo Galfetti Chief Executive Officer & cofounder



Giorgio ReinerCorporate Director R&D & co-founder



Giulia Recalcati Corporate Director Finance



Alessia Bettinelli Corporate Director Marketing & Sales Metabolic



Marco Marotta Corporate Director Partnering and BD



Sara MazzuoccoloCorporate Director Operations & Sales

Board of Directors



Thomas RinderknechtChairman of the Board
Biotech advisor/investor, lawyer



Enrico BragliaNon-executive member
Biotech investor and fund manager



Alexander AsamNon-executive member
Biotech investment fund manager



Jacques Gonella Independent member Serial entrepreneur



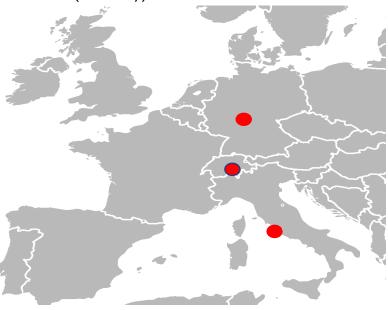
Paolo Galfetti Executive member CFO



Giorgio Reiner Executive member Corporate Director R&D

Locations

APR is headquartered in Balerna, Switzerland with its own Sale & Marketing subsidiaries in Rome (Italy) and Offenbach (Germany)



People



R&D Capabilities and Organization

Track Record

Developed 5 unique, proprietary technology platforms and leveraged these platforms to develop over 50 products over time in multiple categories

Proven, Long-Standing R&D Expertise

25+ years of R&D experience in developing innovative products

- Managing product development from formulation development through the regulatory approval process
- Expertise extends across multiple categories (Rx, OTC, nutraceuticals, dermo-cosmetic and medical device)

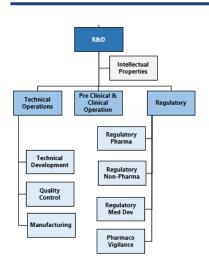
R&D team manages all aspects of product development

- Lean and flexible in-house team of professionals with deep industry experience coupled with an extensive network of clinical advisors and Key Opinion Leaders
- Leverage outsourced providers for functions such as commercial manufacturing and clinical trial management

Core competencies in oral and topical dosage forms

- Technical know-how to develop tablets, granules, buccal and sublingual oral films, gels, creams, ointments, liquids, and sprays
- Current infrastructure consists of in-house labs working under strict applicable guidelines
- 10-member Advisory Board comprising international experts in genetic metabolic diseases consults with APR throughout the R&D process
 - APR also leverages the expertise of 3 board members who are recognized pioneers and leaders in the drug delivery market

R&D Organization



(1) Director of R&D also serves as Head of Intellectual Property

Selected Contract Dev. Clients



APR stands as a trusted formulator and developer validated by the breadth and quality of its contract development partners and products developed over time under flexible fee for service agreements.



Wide range of Added Value Services

Across multiple categories

Intellectual Property

Technical Development

R&D and QC Analytical

Rx Drugs

OTC Drugs

Medical Device

Industrial Upscaling

Regulatory Compliance

Project Management

Medical Food

Nutraceuticals

Cosmetics

Adding Value to your Projects and Development Strategy



Intellectual Property	 IP proved experience to maximize your Innovation value Revamp an old or weak Patent to a wider and more effective one
Technical Development	 Catch the brief, figure out the Product beyond an Idea Feasibility study, Gap Analysis, Project management Formulation, delivery system, analytical methods, manufacturing process Prototypes manufacturing and pre-clinical studies, target product profile, Tech Transfer from lab scale to industrial manufacturing, to the Market
Control	 Set up, Validation and Transfer of Analytical Methods Product quality profile and Stability Studies R&D and GMP Contract Analytical Services
Small Lab batches manufacture	 Design of Experiment – Quality by Design Approach Proof of Concept batches for feasibility studies and patent scope Small lab batches to assess raw materials, formulation or process changes Pre-clinical batches manufacturing
Compliance Innovation Creativity	 Reformulation, repositioning, repurposing and new delivery Improvement of Product Design, User Experience and Usability Technical and regulatory know how in different Healthcare areas Multitasking Approach: formulative, analytical, industrial, regulatory
Finding viable Solutions	 Heuristics experience, out of the box mindset An extensive Network of best in class and trusted Partners We make it happen and keep it simple



Headquarters and Employees

Headquarters

Location Via Giuseppe Corti 5 Balerna, Switzerland Executive Research and Development Business Development and Partnering Key Sales and Marketing **Functions** Medical Affairs Finance Logistics Own / Lease Leased ~15,000 sf **Square Feet** 34 FTEs at Corporate Headquarters **Employees** 8 FTEs at Subsidiary Level (FTEs) (4 FTEs in APR DE and 4 FTEs in APR IT)

CERTIFICATIONS

APR is a registered pharmaceutical company in Switzerland, licensed and regularly inspected by the local Health Authority (SwissMedic). In particular, APR is a licensed GDP (Good Distribution Practices) and GLP (Good Laboratory Practices) company.

In addition, APR owns the 13485 Certification issued by TUV for Medical Devices.



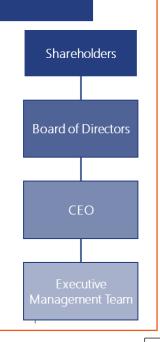




GOVERNANCE

The Company has adopted Corporate Governance Guidelines in order to provide the framework for the governance of APR and all the companies belonging to the APR Group.

- Corporate Governance Guidelines
- Code of Ethics
- Data Protection Policy (Privacy)
- Guideline on interactions with Healthcare Professionals (HCPs)
- Compliance Board





Paolo Galfetti

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