

# Corporate Presentation

Paolo Galfetti  
Founder & CEO



January 2018



# at a glance

---

Swiss, independent company focused to identify, develop and commercialize value added, science driven products designed to address patient needs in niche or rare therapeutic areas on a global basis.

## revenue stage company

- revenue stage, cash generating, profitable R&D company.
- products marketed in about 50 countries generating over USD 200 Mio in partners' net sales.

## proven B2B model

- improvement of existing molecules in selected therapeutic areas through proprietary delivery systems or novel dosage forms.
- solid B2B model with key partners in all major markets with focus in EU, USA and China.

## compelling pipeline

- focus in niche therapeutic areas and/or orphan indications where we can deliver significant value to patients, healthcare professionals and payers with highly differentiated products.
- strong patent estate for all the key products.

# board of directors and management team

## management team

### Paolo Galfetti, CEO

Founder of APR

### Giorgio Reiner, Corp. Dir. R&D

Founder of APR.

### Manolo Bellotto, Corp. Dir. Innovation Management

Former positions as Global Product Leader at Vifor, Head of Product Mgm at Helsinn, International Group Product Manager at DKSH

### Alessandro Bossi, Corp. Dir. Partnering & BD

Former Director Business Development & Licensing In at Helsinn Healthcare

### Massimo Poletti, Corp. Dir. Marketing

Former Marketing director and Country manager at Artsana Chicco Group.

### Paolo Tomasi, Corp. Dir. Finance

Former Finance Manager at Hewlett-Packard Europe and Italy.

## board of directors

### Alberto Reiner, Chairman of the Board

Founder of APR, REAL, Farma Resa; inventor or co-inventor of various patents in chemical synthesis and drug delivery systems.

### Thomas M. Rinderknecht, Vice Chairman

Senior Partner in the law firm Badertscher in Zurich; Vice Chairman of Basilea Pharmaceuticals; former Chairman of Ganymed Pharmaceuticals.

### Jacques Gonella, Independent Board Member

Founder of Jago Pharma, Permatec, former Board Member of SkyePharma, Board Member of Antares Pharma (ATRS).

### Enrico Braglia, non-executive Board Member

Former Helsinn CO-CEO, Onelife Founder and board member in several companies.

### Alexander Asam, non-executive Board Member











Partner at HBM Partners AG, former Managing Director of DVC; board member of Mika Pharma and Curetis.

### Paolo Galfetti, CEO

### Giorgio Reiner, Executive Board Member

# product portfolio

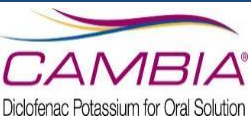





balanced mix of revenue generating products and development pipeline.

Product/Brand	Pre-Clinical	Clinical	Registration	Market	Indication
 Diclofenac Potassium for Oral Solution					Migraine Attacks
					Mild/Moderate Acute Pain
					Local Mild/Moderate Pain
  					CINV, RINV and PONV
					Baby Care Product Line
					Advanced Wound Management
					Tissue Transplantation
					PKU (Orphan/Rare)
APR-1204					Corneal Ulcers/Scarrings
APR-1205					Neurothrophic Keratitis (Orphan)
APR-1206					Epidermolysis Bullosa (Orphan)

The Brand names Cambia, Voltfast, Voltadol, Zuplenz, Ondissolve are property of our Commercial Partners

# main revenue generating products

marketed products contribute to organic growth.

product/brand	exclusivity	highlights
 Diclofenac Potassium for Oral Solution	2023 in USA 2026 Ex US	the first and still the only FDA approved NSAID specific for migraine. rated by the American Headache Society as level A migraine medication.
	2026	marketed by Novartis in over 50 countries as acute pain medication. more than 60 Million doses sold in 2017 globally.
	2024	drug in adhesive Matrix Technology approved in EU since 2015. IND Filed in the US and under registration in China.
 Oral Dispersible Film Ondansetron (ondansetron) oral soluble film	2027 in USA 2031 Ex US	the first Rx Oral Dispersible Film ever approved in EU and US. labeled pediatric indications. better compliance in CINV, RINV and
 RESEARCH WITH BABIES IN MIND	N/A	the first OTC baby line focused on each of the unique ages and stages of children's growth with tailored deliveries intended to simplify use.
 Wound Care Solutions (WCS)	2030	the first Active Wound Cleanser creating the ideal wound Microenvironment thus facilitating physiological wound healing process.

<sup>1</sup> Zuplenz and Voltadol are co-development projects

<sup>2</sup> Some of the Brands listed above are property of our Commercial Partners



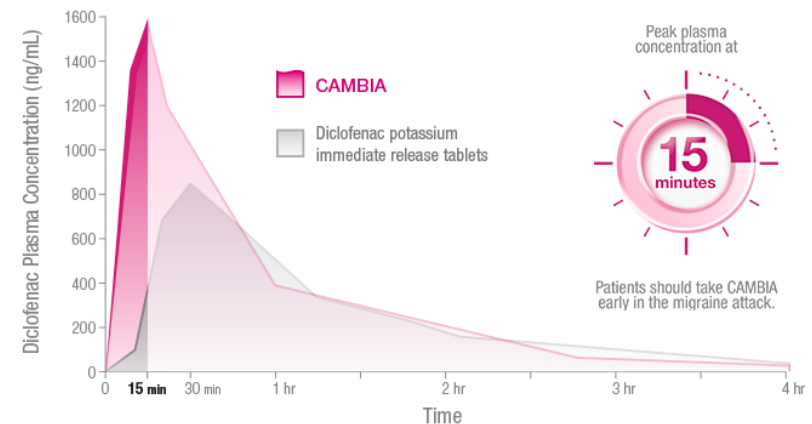
# Main Revenue Generating Products



The first and only NSAID specifically approved by the FDA for use in migraine and approved for Acute Pain indications outside the US.

- ✓ USD 78 Mio run rate as of Q4/2017 on a global basis.
- ✓ Strong Patent Estate with exclusivity until 2023 in USA (ANDA settlement) and 2026 outside USA.
- ✓ Rated as effective Level A Migraine Medication by the AHS. More than 60 Mio doses sold in 2017 globally.
- ✓ Life cycle management strategies ongoing.

Dynamic Buffering Technology allows CAMBIA to be rapidly absorbed

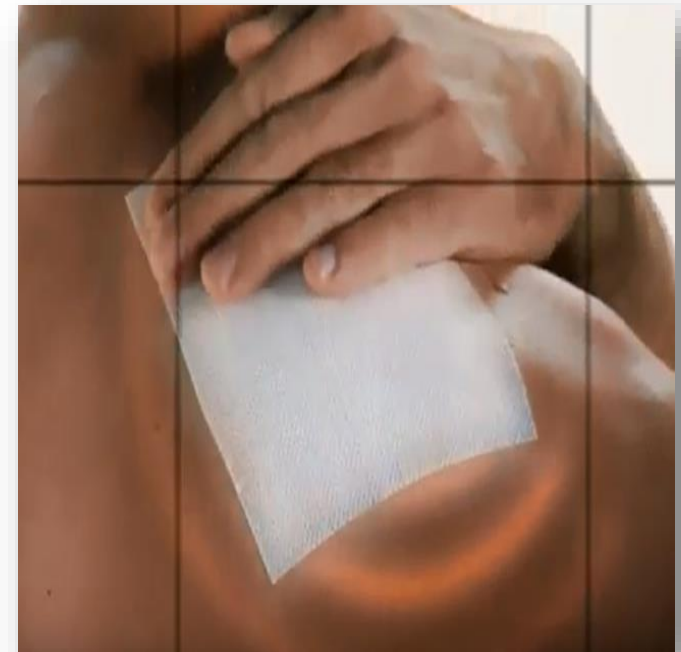


# Main Revenue Generating Products

<sup>1</sup> Product co-developed in partnership with Fidia (Italy)

A consumer friendly, transdermal, locally applied and locally acting matrix (drug in adhesive) topical patch<sup>1</sup> for the local treatment of acute strains and sprains

- ✓ Approved and marketed in Italy since 2005; approved and marketed in Europe since 2015.
- ✓ Poised to reach about USD 25 Mio in Sales in EU only.
- ✓ IND filed with the FDA in the USA and under registration in China.
- ✓ It could successfully compete in the USD 700 Mio and fast growing topical NSAID market in the US.
- ✓ Geographical expansion strategy is ongoing.



<sup>1</sup> The Brands Voltadol and Itami are owned by our Commercial Partners

# Main Revenue Generating Products

<sup>1</sup> Product co-developed in partnership with Monosol Rx, USA

The first Rx Oral Dispersible Film<sup>1</sup> approved in EU and US offering better compliance and better safety than oral dispersible tablets in the treatment of CINV, RINV and PONV.

- ✓ Expected to reach about USD 60 Mio in Sales by 2020.
- ✓ Strong Patent Estate with exclusivity granted until 2029 in USA and 2030 outside USA; non substitutable.
- ✓ Bioequivalent to Ondansetron ODT, with proven, non-sedating efficacy in both fast and fed conditions.
- ✓ Geographical expansion strategy is ongoing.



Approved for pediatric populations outside the US, thanks to its total safety (no risks of suffocation compared to ODTs).

**Ondissolve<sup>®</sup> ODF**  
Ondansétron film à désintégration orale



**SetoFilm**  
Orodispersible film  
Ondansetron



**Zuplenz<sup>®</sup>**  
(ondansetron) oral soluble film  
**m** MIDATECH PHARMA





# Main Revenue Generating Products

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 deliveries intended to simplify their use for parents and reduce the hassle for babies.

## Key Insight



*...it happens that the treatment of even a simple health problem of my child, quite often hides a little but bad family drama.*

*For him, it becomes like a "torture" added on top of the health problem, and for me, it becomes an overwhelming concern about **right** products, efficacy, **right** doses, **right** mode of actions and **right** delivery methods...*

## Brand Purpose

To transform the moments of child health caring in a time of relation peaceful, simple and safe.

(...for you, mom and for your kids)



## Positioning

Research with babies in mind

HalyKoo provides the **right** formula and the **right** delivery for the **right** age



- Delivers products with formulas and dosage forms tailored for specific age groups
- Uses "State of the Art" formulations and delivery systems
- Focuses on reassuring a mother and providing relief to the child



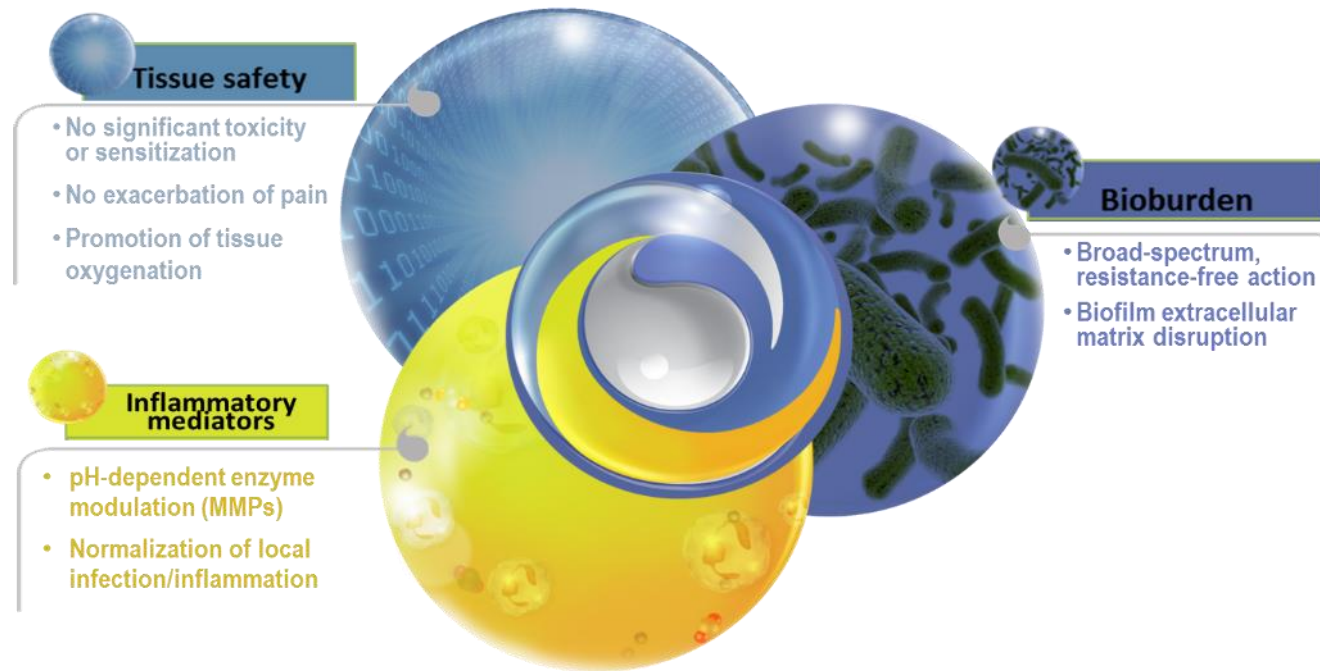
- ✓ Licensed in 7 countries (Canada, Russia, Ukraine, China, Italy, Australia, Central America and Balkan region).

- ✓ Roll-out strategy ongoing
- ✓ Potential to become a global recognized brand in baby healthcare.

# Main Revenue Generating Products



Nexodyn is the first Active Wound Cleanser that creates the ideal wound Microenvironment, managing simultaneously three main components, thus facilitating physiological wound healing process.



- ✓ Substantial Post-Approval Clinical supporting program ongoing.
- ✓ The Product competes in the USD 200 Mio wound cleansing market.
- ✓ Recently approved in EU and USA (under registration in China).



# diversified partner network





# product pipeline



## Soft Tissue Transplant

A non antibiotic, super-oxidizing solution for the effective cleansing and decontamination of soft tissues intended for transplantation while securing optimal biocompatibility.

- ✓ The cleansing, decontamination and preservation process aims at reducing the risk of contamination from the procurement to transplantation.
- ✓ Gemiax is the first product in its category specifically developed and approved in EU for the treatment of allografts by providing an ideal biocompatible profile.



# product pipeline

---



## Inherited Metabolic Diseases

APR-1301 is the first controlled release, phenylalanine free formula developed using proprietary patented Technology which secures physiological absorption of amino-acids mix, mimicking absorption profile of natural proteins.

- ✓ Control of phenylalanine levels and fluctuations and improving phenylalanine tolerance (relaxing diet);
- ✓ Prevention of long term side effects connected to a non physiological absorption (i.e. bone density, anabolism/catabolism, etc.);
- ✓ Currently in clinical development. Anticipate market entry in 2018.



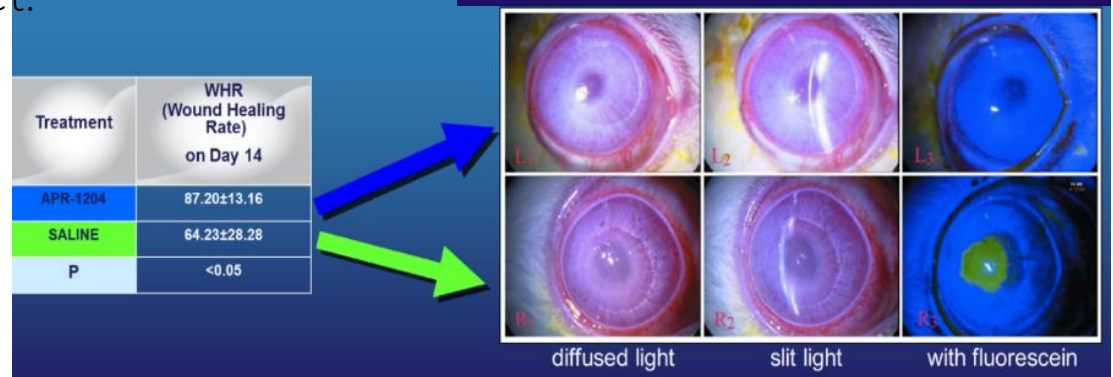
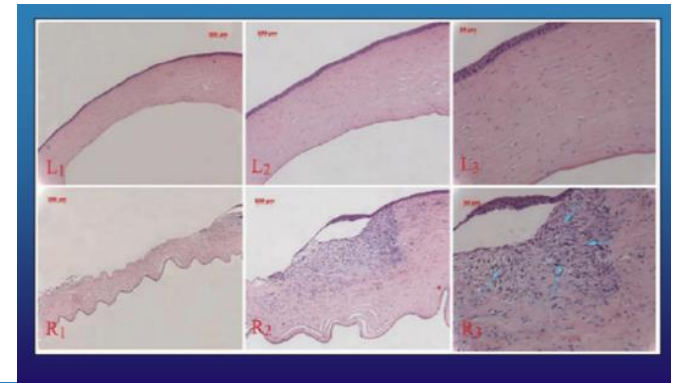


# product pipeline

## Corneal Ulcers/Scarring

APR-1204 is a proprietary ophthalmic solution able to modulate the eye microenvironment, thanks to its chemical-physical properties and ancillary anti-microbial properties and to effectively treat corneal scarring.

- ✓ There are no effective treatments available.
- ✓ Proof of concept studies conducted in validated animal models
- ✓ Niche but fast growing market.



## Neurotrophic Keratitis ("NK")

APR-1205 is an orphan drug candidate in pre-clinical development able to contribute to corneal wound healing and inflammation modulation thanks to its specific corneal and ocular surface mechanism of action

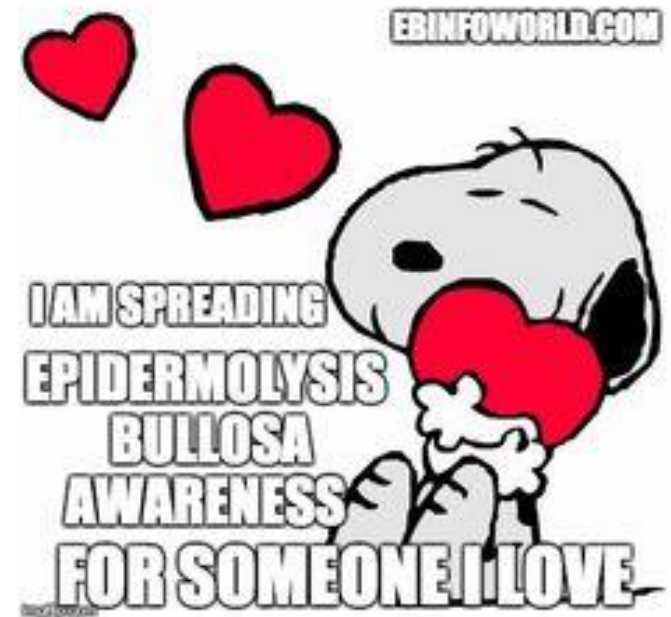
- ✓ NK is a corneal degenerative disease characterized by a reduction or absence of corneal sensitivity.
- ✓ NK is characterized by thinning/disruption of the epithelial layer, cytoplasmic swelling of epithelial cells, loss of microvilli, disorganization of Bowman's membrane, stromal melting/scarring and corneal neovascularization.
- ✓ The epidemiology of NK is still uncertain. As a rare disease, its estimated prevalence is less than 50/100.000 individuals



## Epidermolysis Bullosa ("EB")

APR-1206 is an orphan drug candidate in pre-clinical stage targeting EB and able to modulate the skin microenvironment thus contributing to skin integrity, thanks to the chemical-physical properties of the proprietary Tehclo<sup>®</sup> technology.

- ✓ EB is a rare genetic connective tissue disorder that affects 1 out of every 20,000 births in the United States (approximately 200 children a year are born with EB).
- ✓ EB is characterized by extremely fragile skin that blisters and tears from minor friction or trauma.
- ✓ EB is always painful, often pervasive and debilitating, and is in some cases lethal before the age of 30



# conclusions

---

positioned to deliver growth by leveraging its know-how and infrastructure.

building  
brands

differentiated  
product portfolio  
with patent  
exclusivity in key  
therapeutic areas.

service  
business

leveraging internal  
Know How to offer  
value added  
development  
services to mitigate  
overall risks and  
optimize research  
& development  
capacity.

partner  
network

track record in  
securing strong  
commercial  
partners in all key  
strategic markets.

growth  
strategy

positive cash flow  
to fuel pipeline  
development and  
execute  
acquisitions of  
synergic assets or  
companies.



# Many Thanks!

**Paolo Galfetti, CEO**  
[paolo.galfetti@apr.ch](mailto:paolo.galfetti@apr.ch)

**APR APPLIED PHARMA RESEARCH S.A.**  
Via Corti, 5 - 6828 Balerna CH  
Ph. +41 91 695 70 20  
[info@apr.ch](mailto:info@apr.ch) [www.apr.ch](http://www.apr.ch)