

# INVESTOR PRESENTATION

Thomas Schaffer, CFO  
NYC | September 2019

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COLLECTIVELY MORE THAN 75 YEARS OF EXPERIENCE

## EXECUTIVE MANAGEMENT TEAM



**Prof. Hermann Lübbert, PhD**  
CEO & Founder

- Founded Biofrontera in 1997
- Extensive experience in academic research in the U.S. and Europe
- 10 years in research management at Sandoz Pharma and Novartis Pharma



**Christoph Dünwald**  
CCO

- 25 years of healthcare sales and marketing commercial expertise in the U.S., Europe and Asia Pacific
- Previous employments at Bayer Healthcare and Allergan



**Thomas Schaffer**  
CFO

- 25 years of experience in finance and venture capital
- CFO positions in small and multi-billion dollar businesses

**Biofrontera is uniquely positioned to exploit the growing global market of photodynamic therapy (PDT) for non-melanoma skin cancer and other dermatological conditions as well as revolutionize the topical antibiotics market in the U.S.**

- 1.** Two commercial prescription drugs: Ameluz® & Xepi®
- 2.** Innovative clinical research
- 3.** Industry renowned customer service

# BIOFRONTERA AT-A-GLANCE

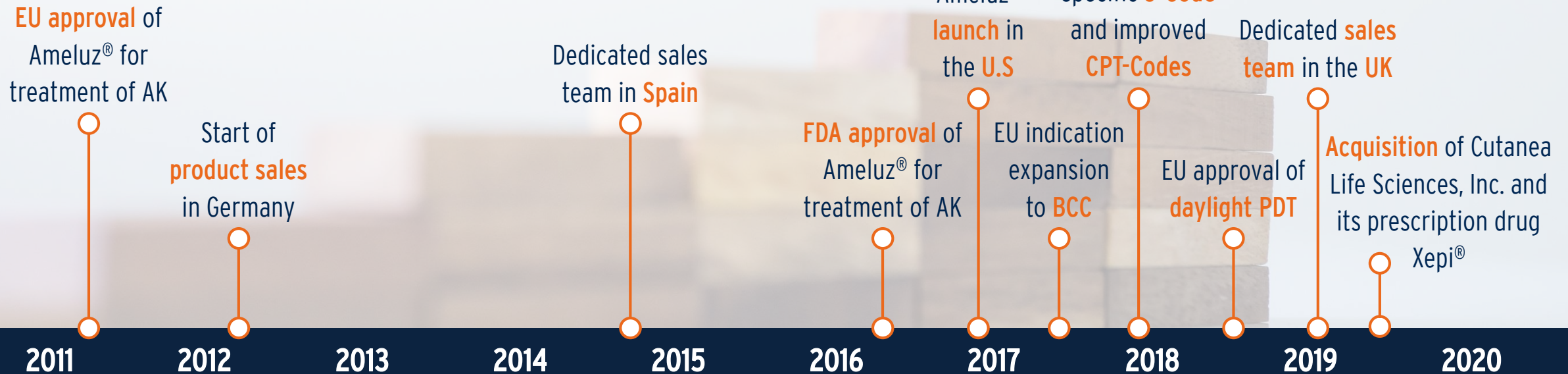


HEADQUARTER	PRODUCTS	SALES FORCE	FINANCIAL PERFORMANCE	STOCK MARKET
Headquartered in Leverkusen, Germany; US-headquarter in Woburn, MA	Biofrontera's PDT drug Ameluz® is approved in the U.S., EU, Switzerland and Israel  In the U.S. Biofrontera also markets the new topical antibiotic Xepi®	Dedicated sales teams in the U.S., Germany, Spain and the UK	Strong revenue growth: doubling of revenue year-over-year for the past 3 years  Anticipated operational break-even in Q4 2019	Listed on the Frankfurt Exchange (B8F) and Nasdaq (BFRA)

## Corporate strategy

Optimizing the market potential of Ameluz® and Xepi®, positioning Biofrontera amongst the most innovative specialty pharmaceutical companies in dermatology.

# OUR MILESTONES



- Strong U.S. commercial infrastructure now complemented by an additional FDA-approved product and enlarged sales force through the acquisition of Cutanea Life Sciences, Inc.
- High efficacy of Ameluz® is supported by favorable reimbursement in the U.S. through new CPT-codes for PDT.
- Xepi®, a novel topical antibiotic for treatment of impetigo, supplements product portfolio in the U.S.
- Approval of daylight PDT in combination with Ameluz® in March 2018 fueled the European PDT market.

# NON-MELANOMA SKIN CANCER

## Epidemiology<sup>1</sup>

- **BCC:** >4 million BCC treatments annually in the U.S.
- **AK:** >58 million patients in the U.S., particularly the elderly population
- **SCC:** second most dangerous skin cancer after melanoma

## Progression<sup>2,3,4</sup>

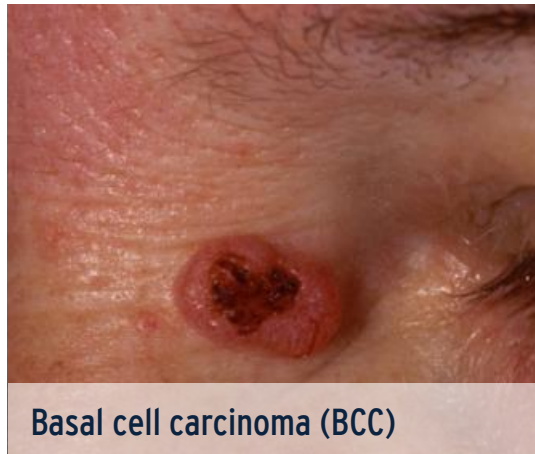
- Recent data show that mild or even invisible AK has a higher chance of progression to SCC than severe (with strong hyperkeratosis) AK
- If an AK lesion progresses to SCC, it does so in about 2 years on average



Actinic keratosis (AK)



Squamous cell carcinoma (SCC)



Basal cell carcinoma (BCC)

## Sources:

1. <http://www.skincancer.org/skin-cancer-information>
2. Schmitz et al., J EurAcadDermatolVenereol. 2016 Aug;30(8):1303-7
3. Fernández-Figueraset al., J EurAcadDermatolVenereol. 2015 May;29(5):991-7
4. Fuchs & Marmur, DermatolSurg. 2007 Sep;33(9):1099-101



# AMELUZ® IS A GEL FORMULATION FOR TOPICAL USE

## EU Approval\*

Basal Cell Carcinoma (BCC)  
Actinic Keratosis (AK)  
Field Cancerization  
Daylight PDT

## US Approval\*\*

Lesion- and field-directed  
treatment of AK

## IP

IP protection until 2027



## EU/US

Medical device in the EU;  
Approved for PDT with  
Ameluz® in the U.S.

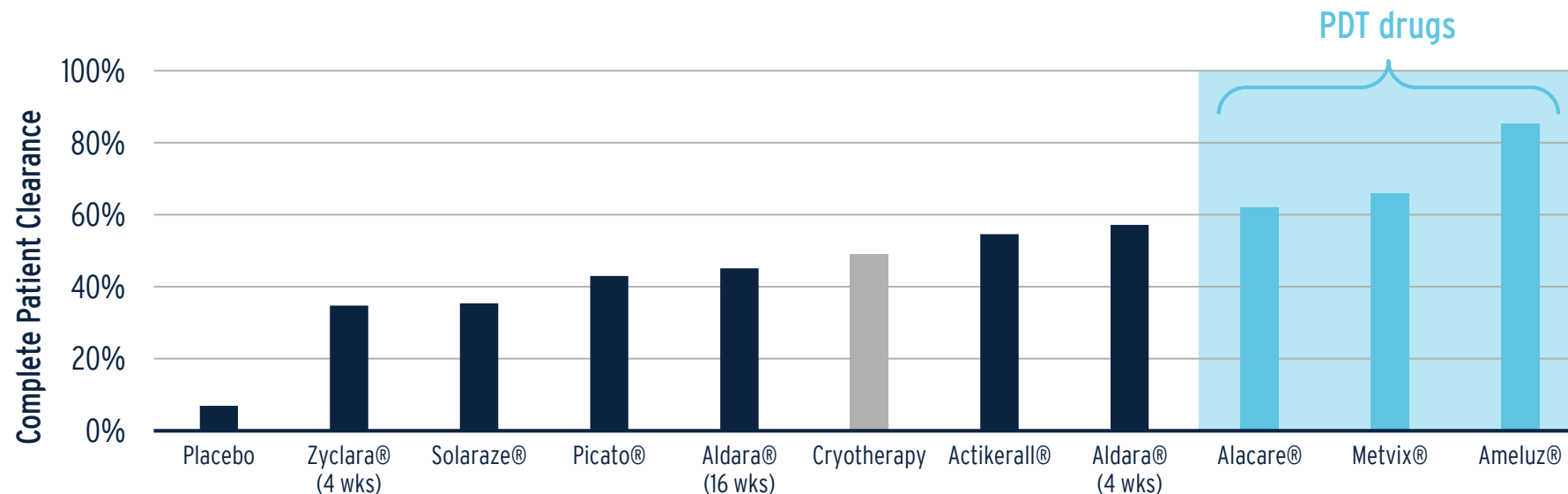
- Treatment of actinic keratosis of mild to moderate severity on the face and scalp (Olsen grade 1 to 2) and of field cancerization in adults. Treatment of superficial and/or nodular basal cell carcinoma unsuitable for surgical treatment due to possible treatment-related morbidity and/or poor cosmetic outcome in adults. Full EU SmPC can be found at [http://www.ema.europa.eu/docs/en\\_GB/document\\_library/EPAR\\_-\\_Product\\_Information/human/002204/WC500120044.pdf](http://www.ema.europa.eu/docs/en_GB/document_library/EPAR_-_Product_Information/human/002204/WC500120044.pdf)

- \*\* Ameluz® gel, a porphyrin precursor, in combination with photodynamic therapy using BF-RhodoLED® lamp, is indicated for the lesion-directed and field-directed treatment of actinic keratoses of mild-to-moderate severity on the face and scalp. Full US prescribing information for Ameluz® and the U.S. User manual for BF-RhodoLED® can be found at [https://www.accessdata.fda.gov/drugsatfda\\_docs/nda/2016/208081Orig1s000LBL.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/nda/2016/208081Orig1s000LBL.pdf)



# META-ANALYSIS OF ALL AK TREATMENT OPTIONS AVAILABLE IN EUROPE

Significant superiority of Ameluz<sup>®</sup> over Metvix<sup>®</sup> was proven in phase III trials and is documented in the EMA approved Ameluz<sup>®</sup> SmPC (PI)



- European meta-analysis included 25 randomized, controlled studies (5,562 patients)
- Clinical endpoint: total patient clearance rates in mild to moderate AK on face or scalp
- All included PDTs were performed with LED lamps

- The relative efficacy of different treatment options for mild to moderate actinic keratosis (including cryotherapy, topicals and PDT options) was analyzed in a European meta-analysis (Vegter & Tolley 2014).
- Although this study was a meta-analysis of placebo-controlled trials, rather than a head-to-head comparison of treatments, we believe this data shows significant support for Ameluz<sup>®</sup> PDT as the best available treatment for mild to moderate actinic keratosis on the face and scalp.

Source: Vegter & Tolley, PlosOne 2014, June, Vol. 9, Issue 6

AMELUZ<sup>®</sup> VS. LEVULAN<sup>®</sup>

FDA-approved prescribing information of both drugs		Ameluz <sup>®</sup> / LED lamps (ITT)*	Levulan <sup>®</sup> / Blu-U <sup>®</sup> (ITT)**
<b>Efficacy</b>	Patient clearance: 3 months after last of 1 or 2 PDTs	84-91%	66-69%
	Patient clearance scalp	65-82%	50%
	Patient clearance: 12 (Ameluz) or 10-12 (Levulan) months after last of 1 or 2 PDTs	53-69%	31%
<b>Convenience</b>	Formulation (easier and faster application of gel)	Gel (tube)	Liquid (stick)
	Illumination time	10 min	16 min + 40 sec
	Incubation time	3 hrs	14-18 hrs
<b>Indications &amp; potential</b>	Skin rejuvenation	Phase III data	No phase III data
	Approved treatment area	Field and lesion	Lesion
	Superficial and nodular BCC	High efficacy in phase III	no data

\* three phase III studies

\*\* two phase III studies and one open-label study

# EXTENDED US-PRODUCT PORTFOLIO THROUGH ACQUISITION OF CUTANEA LIFE SCIENCES IN MARCH 2019

## LICENSED FROM FERRER

Xepi® offers a brief five-day treatment course with only two daily doses

## FDA approved in 2018

Topical antibiotic used to treat impetigo

## IP

IP protection until 2032

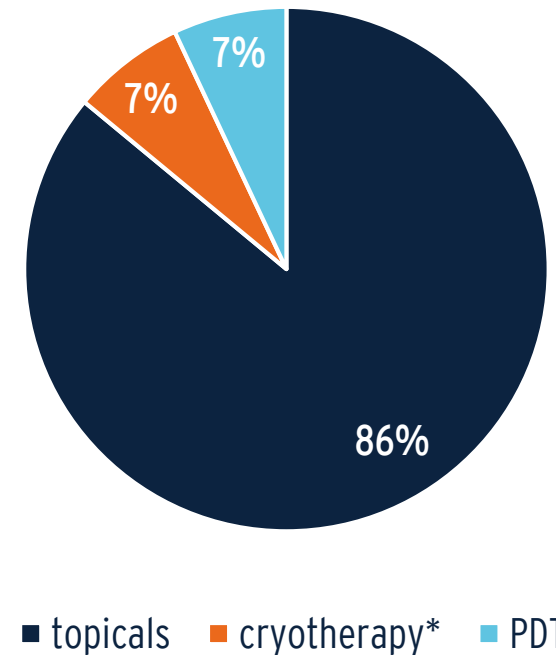


- First new topical antibiotic to enter the US-market in over 10 years
- Activity on and FDA-approval for drug resistant strains (MRSA)
- Advantageous side effect profile

# POSITION AMELUZ® AS THE #1 PDT DRUG AND EXPAND THE PDT MARKET

## EU - Strategy

- Position Ameluz® as the **#1 PDT drug**
- **Expand the PDT market through daylight PDT** to compete with topical drugs
  - Average ex-factory price per tube of Ameluz®: EUR 150
  - Dermatologists in Europe have favored topical prescriptions due to lack of reimbursement for procedures such as PDT
  - Recent approval to market Ameluz® for use in combination with daylight PDT enables patients to obtain reimbursement more easily
  - Cryotherapy is unpopular due to perceived poor efficacy, high recurrence rates, bad cosmetic outcome and lack of reimbursement



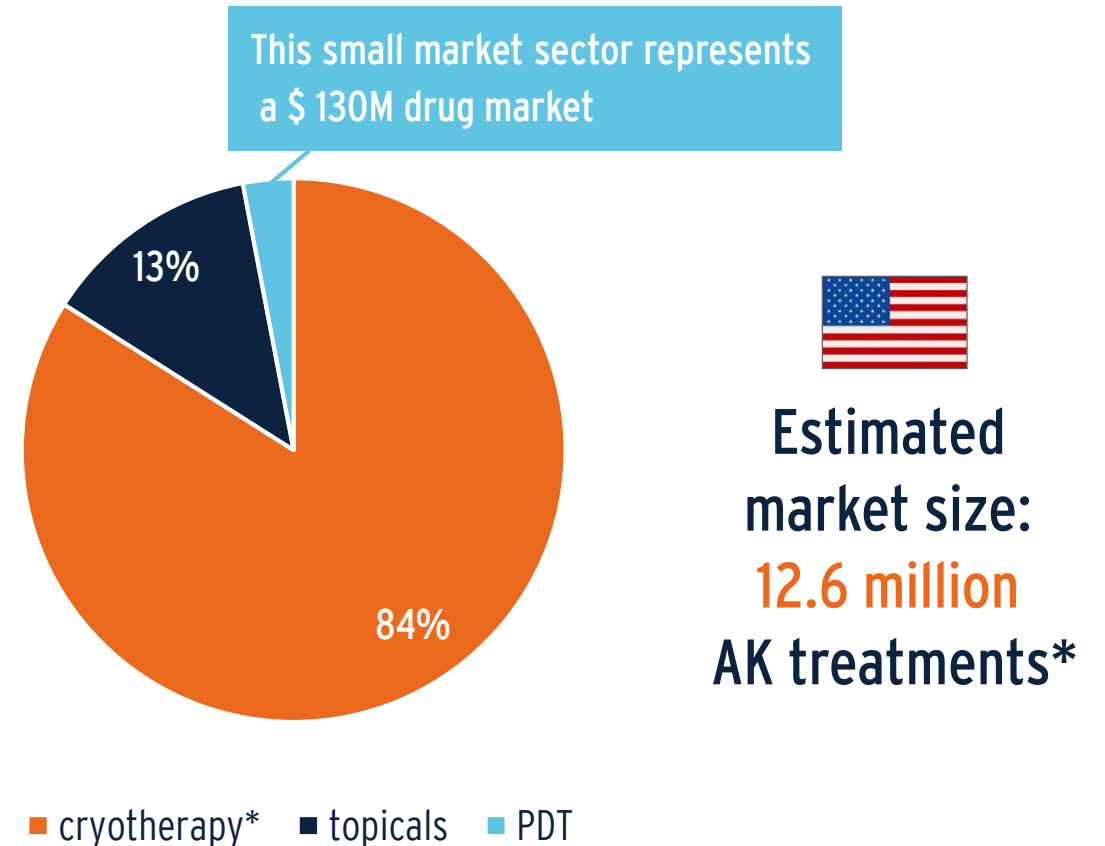
Estimated  
market size:  
**2.1 million**  
prescriptions  
for AK p.a.

\* Share of cryotherapy estimated since no reliable data available

# POSITION AMELUZ® AS THE #1 PDT DRUG AND EXPAND THE PDT MARKET

## US - Strategy

- Position Ameluz® as the **#1 PDT drug**
- **Expand PDT market by taking away market share** from topicals and cryotherapy
  - List price per tube of Ameluz®: US\$ 285
  - 3% PDT treatments of the AK market represent annual PDT drug sales of estimated US\$ 130 million
  - Most U.S. dermatologists have traditionally preferred cryotherapy due to more favorable reimbursement
  - New CPT codes and medical need for field therapy is now more favorable for PDT



\* based on Biofrontera review of 2016 publicly available information

# REIMBURSEMENT OF AMELUZ<sup>®</sup> - NEW CPT-CODES

## CPT-codes (Jan 2019)

Avg. payment to dermatologist in USD

Efficacy rates	Avg. payment to dermatologist
PDT performed by other health care workers	\$126
PDT without debridement, by qualified health care professional (corresponding to USPI of Levulan)	\$205
PDT with debridement (i.e. targeted curettage, abrasion), by qualified health care professional (USPI of Ameluz <sup>®</sup> )	\$261
Cryotherapy capped at >14 lesions	\$155

Qualified health care professionals are MDs, PAs, and NPs

The Centers for Medicare and Medicaid Services (CMS) have assigned new CPT-codes, which make the use of PDT **financially more rewarding for doctors**



# MEDICAL BENEFITS OF PDT



High efficacy  
with better  
clearance and  
recurrence rates

- Field treatment (selective killing of tumor cells) vs. spot treatment (no selectivity for tumor cells)
- General skin rejuvenating effect of PDT, as documented in phase III trials
- Good esthetic result: no visible signs left after PDT vs. white spots or scars after cryotherapy

# XEPI®: TOPICAL ANTIBIOTICS MARKET IN THE U.S.

## Short-term strategy:

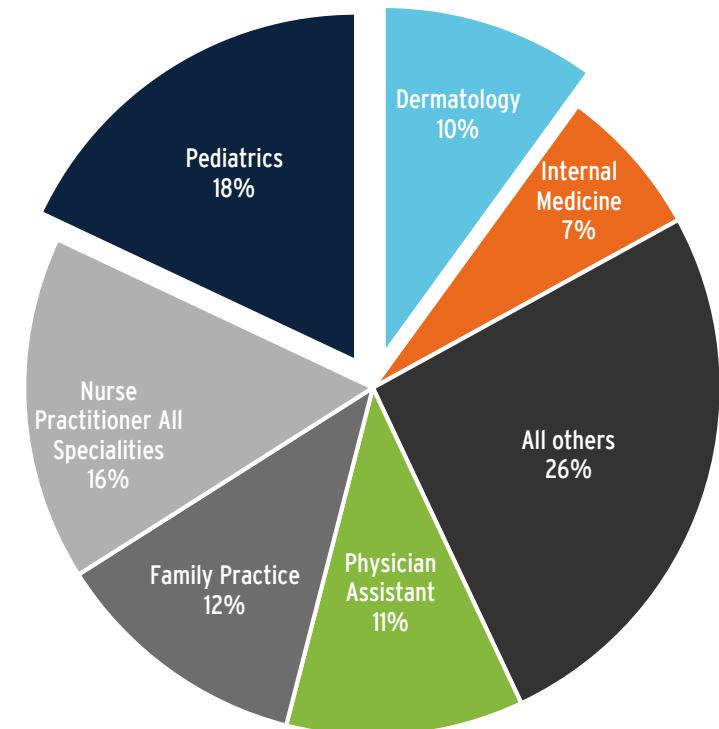
- 1) Position Xepi® as the #1 choice for topical antibiotic prescribed by dermatologists
- 2) Take away market share from generic Mupirocin
  - Dermatologists write 10% of all prescriptions for generic Mupirocin.
  - Dermatologists issue ~ 1 million prescriptions annually; most prescriptions per patient among all specialty physicians.

## Long-term strategy:

- 1) Focus on pediatricians with ~ 1.7 MM prescriptions annually
- 2) Establish Xepi® as the first choice in skin and soft tissue infections
- 3) Expand Xepi® label beyond Impetigo through clinical program

Estimated market size:  
10.8 million prescriptions annually

Generic Mupirocin prescription share by specialty



Data Source: IMS - NPA MAT July 2018

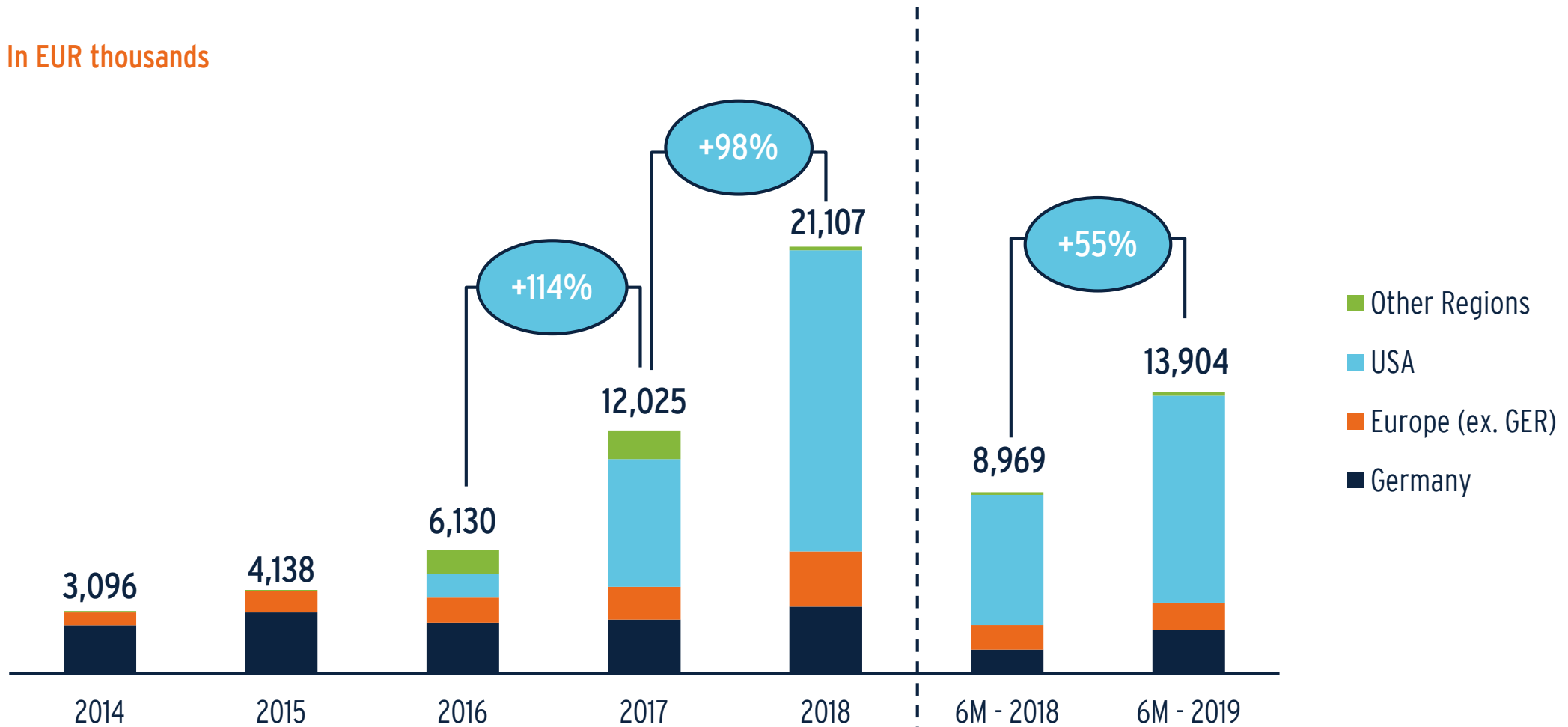
# DEVELOPMENT PIPELINE

Biofrontera's strategy is to optimize the market potential and market positioning of Ameluz<sup>®</sup> before investing in the development of additional products.

Product	Indication / comments	Territory	Pre-clinical	Clinical Phase			Submitted	Status
				I	II	III		
Ameluz <sup>®</sup>	Actinic keratosis (AK), field cancerization	EU, CH, IL	●	●	●	●	●	On market
Ameluz <sup>®</sup>	AK, lesion- and field-directed	US	●	●	●	●	●	On market
Ameluz <sup>®</sup>	Basal cell carcinoma	EU	●	●	●	●	●	On market
Ameluz <sup>®</sup>	AK: Daylight PDT	EU/CH	●	●	●	●	●	On market
Ameluz <sup>®</sup>	AK: Trunk & extremities	EU/US	●	●	●	●	●	Phase III completed
Ameluz <sup>®</sup>	Basal cell carcinoma	US	●	●	●	●		Phase III ongoing
Ameluz <sup>®</sup>	Squamous cell carcinoma in situ	EU/US	●	●	●			Phase III in preparation
Ameluz <sup>®</sup>	Acne	EU/US	●	●	●			Phase II in preparation

## PRODUCT SALES

In EUR thousands



# BIOFRONTERA GROUP FINANCIAL RESULTS

In million EUR (IFRS)

	2014	2015	2016	2017	2018	6M 2018	6M 2019	FY 2019 Revenue Guidance
Total revenue	3.1	4.1	6.1	12.0	21.1	9.0	13.9	32.0 - 35.0
Product sales	3.1	4.1	5.0	10.6	21.0	8.8	13.7	
thereof U.S .revenues	0	0	1.2	6.3	14.9	6.4	10.2	
Operating income	(9.6)	(10.2)	(11.8)	(13.9)	(18.5)	(7.3)	(12.9)	(7.0) - (9.0)
Net income before tax	(10,721)	(11,203)	(10,579)	(16,102)	(19,269)	(7,685)	9,027	(10.0) - (13.0)*
Cash & cash equivalents	8.5	4.0	15.1	11.1	(19.5)	26.3	21.6	
Permanent loss carry forward	98.6	109.8	120.4	136.5	145.4	144.2	136.3	
Financial debt	10.8	11.2	3.6	12.4	13.5	13.6	22.7	

\*adjusted for expenses/income from Maruho due to Cutanea acquisition

# BIOFRONTERA SHARES

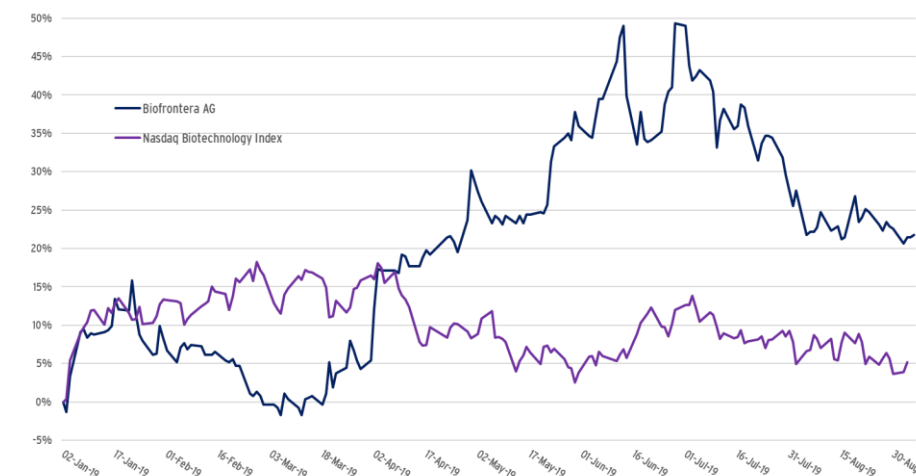
## Key stock information

Listing	Frankfurt	Nasdaq
Ticker Symbol	B8F	BFRA
Price per Share (as of Sep 5, 2019) 1 ADS = 2 common shares	€6.54 per share	US\$ 14.09 per ADS
52 Week High-Low	€8.07 - €4.78	\$18.32 - \$11.04
Shares Outstanding	44,815,815	
Market Cap (as of Sep 5, 2019)	~US\$ 320M	

## Analyst coverage

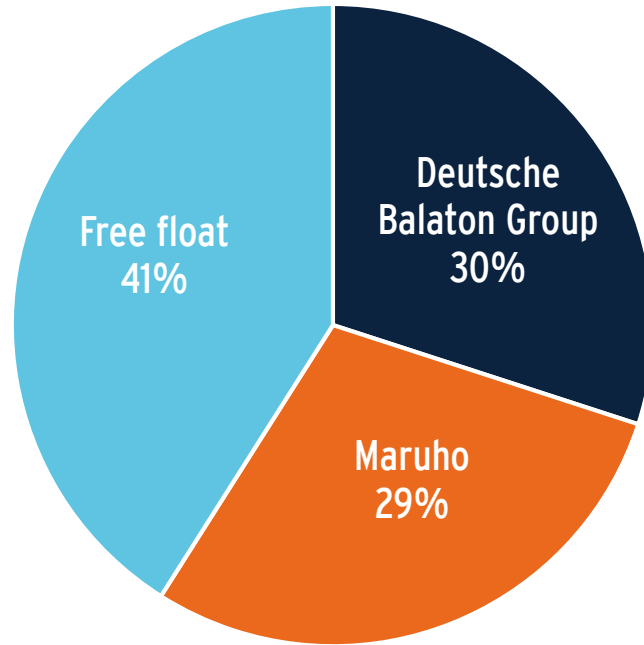
Financial Institution	Analyst
Benchmark & Co	Bruce Jackson
Lake Street Capital	Thomas Flaten
sc-consult GmbH	Holger Steffen

## YTD share price development: B8F





# SHAREHOLDER STRUCTURE



Shares outstanding: 44,815,815

Shareholder structure:

- Two major investors, each holding about 30%
- About 41% free float, including institutional investors and family offices in Europe and the U.S.

# INVESTMENT OPPORTUNITY

Our goal is to optimize the positioning and market potentials of Ameluz® and Xepi®, becoming a leading specialty pharmaceutical multi-product company in dermatology.

PRODUCTS	PIPELINE	COMMERCIALIZATION	FINANCIAL PERFORMANCE	STOCK MARKET
Ameluz®: superior PDT drug for non-melanoma skin cancer	Very low development risk due to approved products	Commercialization of Ameluz® in major pharmaceutical markets	Strong revenue growth and healthy balance sheet	Solid share price development
Xepi®: first new topical antibiotic on the US-market in over 10 years	Additional indications with similarly high market potentials possible	Multi-billion \$ market opportunity with Ameluz® and Xepi® in the U.S. alone	Anticipated operational break-even in Q4/2019	Listings on major global stock markets

# Your skin health is our concern

## CONTACT DETAILS



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THANK YOU!