#### **OUTPERFORM**

\_ .

Reason for report: INITIATION

Seamus Fernandez

(617) 918-4011

Seamus.Fernandez@Leerink.com

Aneesh Kapur

617 918 4576

Aneesh.Kapur@Leerink.com

**Ario Arabi** (617) 918-4568

Ario.Arabi@Leerink.com



#### **DERMIRA, INC.**

Advancing the Next Wave in Dermatology with Big Pot'l in Acne; Initiating at OP

- Bottom Line: We are initiating coverage of Dermira (DERM) with an Outperform rating and a \$32 price target based on our DCF analysis. DERM is a development stage specialty pharmaceutical company exclusively focused on advancing therapeutics used by dermatologists to treat skin-related conditions. DERM's business development strategy is validated, with 5 in-licensed products, 3 of which have positive Ph II data. With two Ph III ready assets in development for psoriasis and axillary hyperhidrosis (HH; excessive underarm sweating), a major pot'l advance for acne in Ph II, and a focused management team with deep dermatology & business development expertise, we believe DERM is well positioned to become a leader in medical dermatology. We believe the current valuation is justified by DERM's partnership with UCB to develop Cimzia for psoriasis and a first-in-class topical pharmaceutical wipe for HH alone. However, our excitement is keyed to DRM01, a first-in-class agent that could be the "holy grail" of topical acne therapy, potentially driving share price >\$50/shr in 18 mos.
- DRM01: Uncovering the "holy grail" of acne. MEDACorp KOLs call DERM's topical sebum inhibitor a potentially transformative therapy for acne. KOLs note that statistically significant and clinically meaningful improvements on all three of the FDA's co-primary endpoint evaluations in its 108-pt Ph IIa data is "unparalleled." These early results compare favorably to the efficacy of the leading branded acne therapy, Epiduo. We believe that a similar result when the planned Ph IIb study reads out in 1H16 would position DERM to be a long-term leader in medical dermatology or a major strategic acquisition target.
- DRM04: First-in-class topical treatment for severe sweating with topical Botox-like efficacy. Originally in-licensed from GSK's (MP) Stiefel, DRM04 is a novel salt formulation of glycopyrrolate, in development for reducing sweat production under the arms. Ph IIb data on the reference agent in 198 pts demonstrated a clear dose response benefit with efficacy that appears comparable to Botox. While we believe DRM04's pot'l could be best optimized by large pharma, we believe DERM can successfully build it into a \$300M+ product over time.
- Cimzia & UCB: Strong biologic asset with partnership synergies. In our view, DERM's partnership to develop Cimzia for the treatment of psoriasis provides an oppt'y for DERM to "hit the ground running" with a 2018 launch. Despite a highly competitive market, access to a pot'l best-in-class anti-TNF for treatment of psoriasis should help put DERM on the map with medical dermatologists. While there is pot'l upside to our \$250M forecast of dermatology end-user sales, we view the Cimzia partnership as a foot in the door with payers and dermatologists to help fund commercial development ahead of the DRM04 & DRM01 launches.

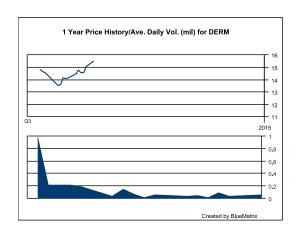
Key Stats: (NASDAQ:DERM)

S&P 600 Health Care Index: 1,342.30
Price: \$15.50
Price Target: \$32.00
Methodology: DCF with 12% discount rate & 2%
terminal growth rate

52 Week High: \$18.50 52 Week Low: \$12.68 Shares Outstanding (mil): 24.6 Market Capitalization (mil): \$381.3 Book Value/Share: \$6.80 Cash Per Share: \$7.30 Net Debt to Total Capital: 0% Dividend (ann): \$0.00 Dividend Yield: 0.0% Est LT EPS Growth: NM

Book Value/Share: Pro Forma including proceeds from recent stock offering.

Cash Per Share: Pro Forma including proceeds from recent stock offering.



Dec Yr	1Q	2Q	3Q	4Q	FY Rev	1Q	2Q	3Q	4Q	FY EPS	P/E
2013A	0.0	0.0	0.0	0.0	0.0	(\$1.33)	(\$1.07)	(\$1.00)	(\$1.47)	(\$2.31)	NM
2014E	0.0A	0.0A	0.0	0.0	0.0	(\$0.88)A	(\$0.80)A	(\$0.67)	(\$0.59)	(\$2.78)	NM
2015E					\$9.0					(\$2.80)	NM

Source: Company Information and Leerink Partners LLC Research Revenues in \$MM.

GAAP EPS.

Please refer to Pages 66 - 68 for Analyst Certification and important disclosures. Price charts and disclosures specific to covered companies and statements of valuation and risk are available at <a href="https://leerink2.bluematrix.com/bluematrix/Disclosure2">https://leerink2.bluematrix.com/bluematrix/Disclosure2</a> or by contacting Leerink Partners Editorial Department, One Federal Street, 37th Floor, Boston, MA 02110. Rx trends derived from IMS Health.

A description of the benchmarks is available by contacting the Leerink Partners Publishing Department.

DERMIRA, INC. October 28, 2014



## **DERMIRA (NASDAQ: DERM)**

## **Advancing the Next Wave in Dermatology**

#### SEAMUS FERNANDEZ

MANAGING DIRECTOR SEAMUS.FERNANDEZ@LEERINK.COM 617.918.4011

#### **ANEESH KAPUR**

ASSOCIATE, MAJOR PHARMACEUTICALS

ANEESH.KAPUR@LEERINK.COM

#### **ARIO ARABI**

ASSOCIATE, MAJOR PHARMACEUTICALS ARIO.ARABI@LEERINK.COM



### **Dermira (DERM): Investment Summary**

## Dermira

**We rate DERM Outperform.** DERM represents an unique investment opportunity, with a highly experienced and proven management team developing three late-stage dermatology assets, each with robust, positive Phase II data and multi-hundred million dollar commercial potential.

## **Investment Thesis**

- Cimzia is an extremely high probability psoriasis biologic partnered with UCB and likely to provide profits and milestones sufficient to fund Dermira's standalone operations
- DRM04 represents the first topical pharmaceutical wipe for hyperhidrosis with a high probability of success given a well-characterized mechanism, positive Phase II data, in an area of high unmet need
- DRM01 is a first-in-class topical sebum inhibitor with an on-target mechanism that acne KOLs have called the "holy grail" of topical acne treatment

#### Valuation

We value DERM at \$32/share. Our price target is based on a DCF valuation which assumes a 12% discount rate on probability-adjusted sales and profits through 2026E and applies a 2% terminal growth rate. Our valuation assumes late-stage assets Cimzia, DRM04, and DRM01 have 90%, 75%, and 50% probabilities of success, respectively, and each contributes \$10-12 per share. This price target equates to 18x 2021E EPS of \$3.56 discounted back 6 years at 12%. Fully valued, with 100% probability for all three programs, we arrive at a DCF-based price target of \$49/share with Cimzia and DRM04 contributing \$10/share and \$12/share, respectively, and DRM01 contributing \$27/share.

## Risks to Valuation

An investment in DERM involves a pooling of different risks including technical, regulatory, and commercial risk for three fundamentally different pipeline products. Most significant to DERM's overall valuation, in our opinion, is clinical success of DRM01 in acne. Important for Cimzia and DRM04 is commercial execution associated with launches into the highly competitive psoriasis and the underdeveloped hyperhidrosis markets, respectively. There are also competitive risks from other pipeline therapies. Finally, DERM may face financing risk beyond mid-2017.

DERMIRA, INC. October 28, 2014

## LEERINK

## **Management:** Experienced Leadership Behind Multiple Successful Dermatology Companies

## **Tom Wiggans** *Chairman & CEO*

- Chairman & CEO, Connetics, Peplin
- Chairman, Excaliard; director, Abgenix, Onyx
- 25 years in specialty pharma, 18 years in dermatology

## Gene Bauer, MD CMO

- · Co-Founder, Connetics; CMO, Peplin
- Chairman, Dermatology, and Dean, Stanford Medical School
- Internationally recognized leader in dermatology
- Chairman & CEO Tom Wiggans and CMO Gene Bauer have been the key mgmt behind multiple successful dermatology companies. Wiggans was Chairman and CEO of Peplin through its ~\$300M acquisition by LEO Pharma A/S in 2009 as well as of Connetics until its ~\$650M acquisition by Stiefel Laboratories, Inc. in 2006. Bauer was President and CMO at Connetics as well as CEO of Neosil, and a co-founder of Peplin. The unique combination of their expertise and years of collaboration gives us confidence in their ability to execute and bring value to shareholders.
- KOLs highlight mgmt team as solid scientists who are "uniquely good listeners." KOL commentary not only confirmed the scientific leadership and executional prowess of DERM's management team, but highlighted Wiggans and Bauer's genuinely aligned interests and unique attentiveness to their scientific advisory board. KOLs across multiple areas of dermatologic medicine cite that Bauer's scientific leadership in dermatology and previous role as the Dean of Stanford Medical School bring him undeniable credibility in the field. Wiggans is equally recognized, even among dermatologists, for his track record of executing from early stage assets through to their sales, particularly with "grass roots" dermatology therapeutics.

## LEERINK

## **Dermira (DERM):** DRM01 (Acne) Is the Primary Long-Term Value Driver, in Our View

• Our analysis highlights DERM's acne program as the primary valuation catalyst. Our sum of the parts DCF valuation is based on probability of success, expected launch timing, and peak net sales contribution of each of DERM's three programs to the company's overall valuation. While we view each of the programs as relatively equal contributors in the near term, at "full value" we view the DRM01 acne program as the most critical valuation driver based on high gross margins and peak sales to DERM expected to be ~2x that of the other two programs.

Product	Launch (LOE)	Peak Net Sales (\$M)	\$/Share Contribution at 100% POS	Assigned POS	\$/shr contribution at Assigned POS	
Cimzia (psoriasis)	2018 (2024)	\$330M, (\$250M to Derms)	\$10/shr	90%	\$10/shr	
DRM04 (hyperhidrosis)	2018 (2029)	\$300M	\$12/shr	75%	\$10/shr	
DRM01 (acne)	2019(2030)	\$540M	\$27/shr	50%	\$12/shr	
DERM			\$ 49/shr		\$ 32/shr	

DERMIRA, INC. October 28, 2014

## LEERINK III

## **DRM01:** First-in-Class Topical Sebum Inhibitor Could Be the "Holy Grail" of Topical Acne Treatment

- Topical, on-target sebum inhibition has been described as the "hoy grail" of acne treatment. Inhibiting sebum is akin to turning off one of the major drivers of acne. Two oral drugs, Accutane (isotretinoin) and spironolactone, have the best efficacy against the worst forms of acne, yet are severely limited by safety risks. Topical agents offer the opportunity for significantly better tolerability and lower risk of systemic side effects. DRM01's inhibition of acetyl coenzyme-A carboxylase (ACC) is a novel approach to turn off the synthesis of lipids as opposed to blocking the male hormone. DRM01 also appears to penetrate the skin sufficiently to directly inhibit sebum production at the sebaceous gland. Others have failed to accomplish this with topical Accutane and only one other pipeline agent, Novan's nitrous oxide releasing gel, has shown promising early results, to our knowledge.
- KOLs highlight "strikingly good" Ph 2 data which suggest DRM01 monotherapy can potentially rival combination therapy with Epiduo. Noting that acne drugs rarely reach significance on any endpoint in Phase 2 studies, KOLs argue DRM01's highly significant and clinically meaningful reductions on both lesion counts and Investigator's Global Assessment (IGA) in a 108-patient, placebo-controlled study make it extremely likely that the drug will advance to Phase 3. With Phase 2 endpoints that are directly aligned with the FDA's guidance for the approval of acne agents, we echo specialists' confidence that DRM01 results will be corroborated in larger studies. Though cautioning against cross-trial comparisons, KOLs highlight that DRM01 as a single agent looks even better than Epiduo Galderma's combination of adapalene and benzoyl peroxide which has the most branded scripts on the market and took a much larger study to demonstrate significance.
- We view DRM01's Ph 2b readout, estimated for 1H16, as a critical valuation inflection point for DERM. Given the novel mechanism of action and limited number of successful new single agents launched in acne, we apply a 50% probability of success to DRM01. The company plans to initiate a Ph 2b 300-patient dose selection study in 1H15. Confirmatory Ph 2b results, which we estimate will be available in 1H16 would significantly bolster our confidence in the compound's probability of success. Following Ph 3 and an assumed 2019 launch, we model unrisk-adjusted revenues at ~\$540 million by 2026E based on 7% penetration of overall scripts and Epiduo-like pricing. Success in acne trials would, in our opinion, make DERM a highly attractive takeout target for one of the large strategics in this promotion-sensitive market, where innovation has been severely lacking, in our view.

# **DRM04:** First Topical Pharmaceutical Wipe for Axillary Hyperhidrosis (Excessive Underarm Sweating) with a Well-Characterized Mechanism & Strong Phase II Data

- Our KOL checks confirm a vast hyperhidrosis market where treatment options are limited to ineffective antiperspirants or burdensome Botox injections. Hyperhidrosis (HH) is an area of severe unmet need where patients' excessive sweating can carry significant psychosocial burden and most noninvasive treatments provide little relief. We estimate that of the nearly 9 million Americans estimated to have hyperhidrosis (HH), only one in five are on treatment. Though we expect inexpensive industrial strength deodorants and anticholinergic orals to remain fist-line treatments, KOLs note significant need for noninvasive second-line treatment options to challenge the effective but burdensome use of every-6-month Botox injections.
- Well-characterized glycopyrrolate mechanism and clear dose-response curve give us confidence in DRM04's clinical effect headed into 1H15 data from DRM04's Ph 2b bridging study. DRM04 a convenient, easy to use glycopyrrolate wipe is initially intended to inhibit axillary sweat production by blocking acetylcholine neurotransmission. Phase 2b data from DERM's 200 patient HH01 dose-finding study demonstrated a dose-dependent, statistically significant impact on sweat production measured via gravimetry as well as the widely used patient-reported outcome (PRO) score (Hyperhidrosis Disease Severity Scale or HDSS) with the reference agent. The demonstrated -76% change in sweat production and 52% improvement in HDSS response rate with the 3% dose are both clinically meaningful and comparable to data for standard-of-care Botox injections. The data remove much of the technical risk in KOLs' opinions. The 2 & 3% doses, while highly active, appear to have a low incidence of dry mouth and blurred vision data from HH01 together with the bridging study data will determine the likely goforward dose(s).
- Potential competition from topical botulin toxins is factored into our assumptions, although there are significantly more questions and fewer patients exposed via this approach. Commercial risk is expected to be much greater in the hyperhidrosis market where we note that underreporting by patients and under-diagnosis by providers underlies the challenges of market growth. In fact, the potential introduction of topical Botox options from Anterios (ANT-1207) and RVNC (RT001) in a similar 2018-19 timeframe could be positive for increasing overall HH awareness and investment. We forecast peak sales estimates of ~\$300M based on relatively modest mid-to-high teens percent penetration of the overall market and similar monthly pricing to Botox. We apply a 75% probability of technical success as we look forward to confirmatory data with the wipes in the Phase 2b dataset.

DERMIRA, INC. October 28, 2014

## LEERINK

## **Cimzia:** High Probability of Success with Partner UCB Should Provide Resources to Fund Dermira's Operations Over Time

- We expect branded tumor necrosis factor (TNF) inhibitors to remain a pillar of psoriasis treatment as increasing biologic penetration expands the US market. Despite expected competitive pressure from the 2015 launch of IL-17 antibodies, our checks with KOLs validate the favorable long-term prospects for TNFs to remain the first-line agent for the majority of patients based on: (a) years of safety experience, (b) preferential effects in the third of psoriasis (PsO) patients with joint pain. We further assume the introduction of biosimilar Humira ~2018 yet believe, as corroborated by payer discussions, that that branded contracting and discounts will likely keep biosimilar penetration in check for these broadly-indicated agents.
- Cimzia has the potential to demonstrate Humira-like or better efficacy, with a potentially better safety profile. In a class where ABBV's Humira is rapidly becoming the first-line agent of choice, Cimzia's Phase 2 data suggest skin clearance at least as good as Humira at standard doses and possibly better at higher doses. KOLs familiar with the data suggest Cimzia could become the preferred 2<sup>nd</sup> line TNF in Humira failures over AMGN's (MP) Enbrel, where they continue to look for an another anti-TNF option with 70%+ skin clearance and Q2W dosing, as opposed to <50% clearance on QW dosing with Enbrel. DERM will initiate its Phase 3 in 1H15. The program will include two placebo-controlled and one active comparator (vs. Enbrel) study which, together, we expect to: (a) satisfy US and EU regulatory requirements, (b) confirm and expand skin clearance data at 12 & 16 weeks while demonstrating superiority to Enbrel, and (c) support lower maintenance dosing from 12 & 16 through 52 weeks of treatment.
- <10% penetration into the anti-TNF market and ~5% of all psoriasis biologics for Cimzia assumes only modest differentiation vs. existing agents. We expect Cimzia to launch in PsO in 2018, following completion of Phase 3 trials in mid-2017. While we believe 1-2% penetration of the anti-TNF market is achievable based on off-label dermatologist prescribing prior to the PsO indication, we expect dermatologist-focused promotion and improved reimbursement/formulary access to increase uptake from 2019 to 2022, with loss of exclusivity (LOE) currently expected in 2024. We apply a 90% probability of success on peak potential US sales of ~\$250M among dermatologists.</p>



## Cimzia cont'd: UCB Partnership Provides >\$89M in Pot'l Milestones as Well as US Managed Care Infrastructure

• UCB's strategic support and an attractive collaboration agreement solidify our conviction that these high-probability revenues can help fund DERM's early operating expenses. UCB's efforts to further Cimzia's benefits in joint pain, contracting position and expertise, and equity investment bolster DERM's strategic interests while allowing the company to retain promotional control to dermatologists. Financially, we view the collaboration structure as favorable given DERM's disproportionate share of early gross margins and oppt'y for a "running start."

#### **Psoriasis-Indication Royalties Psoriasis Program Milestones** 140 (Figures are probability adjusted based on our assumed 90% probability of success) 120 100 80 \$102M \$120M 60 \$117M \$112M \$112M \$109M \$79M \$52M 40 20 \$25M \$22M \$18M \$10M \$10M \$9M \$9M

2020E

2021E

2019E

2018E

#### Up to...

2015E

 \$36M development milestone payments

2016E

2017E

- \$13.5M EU approval milestone payment
- \$40M commercial milestone payments

 Dermira receives share of gross margin from Cimzia sales attributed to dermatologists for all indications in US, Canada

2022E

 Share tiered based upon increasing levels of annual net sales attributed to dermatologists in a given year, retaining a higher share of gross margin initial sales dollars

2023E

2024E

2025E

2026E

 Dermira is likely to have a "running start" in 2018 as current IMS scripts among derms show some adoption likely to occur prior to PsO indication

Source: Company Information; Leerink Partners Estimates



### Catalysts: Estimated Timing of Key Catalysts

Timing	Event / Description							
2015 Events								
1H15	Initiate Phase 3 program for Cimzia (psoriasis)							
1H15	Phase 2b data for DRM04 (hyperhydrosis)							
1H15	Initiate Phase 2b program for DRM01 (acne)							
2H15	Initiate Phase 3 program for DRM04 (hyperhydrosis)							
2015	Preclinical data for DRM02 (inflammatory diseases)							
2015	Preclinical data for DRM05 (acne)							

#### 2016-2018 Events

1H16	Phase 2b data for DRM01 (acne)
2H16	Phase 3 data for DRM04 (hyperhydrosis)
mid-2017	Phase 3 data for Cimzia (psoriasis)
2018	Phase 3 data for DRM01 (acne)

Source: Leerink Partners LLC estimates & company information

- 2015 is an execution year for DERM; major data catalysts likely will be limited. 1H15 data from a Ph 2b hyperhidrosis bridging study should help confirm the ultimate commercial potential of the glycopyrrolate wipes and should boost our current 75% probability of success for the compound. Beyond this, 2015 will largely be focused on planning and execution as DERM initiates Ph 3 programs for Cimzia and DRM04 as well as it's Ph 2b in acne. Any acceleration of timelines, particularly in acne, would be meaningful in our opinion. An earlier-than-expected Ph 2b start could mitigate headline risk associated with the slight current lead for Novan's SB204 development program, which investigates topical nitrous-oxide gel for acne.
- Value inflection keyed to Phase 2b acne data expected in 1H16. Given the novel mechanism of action and limited number of successful new topical monotherapy treatments launched in acne during the last two decades, we conservatively apply a 50% probability of success to DRM01. Confirmatory Ph 2b results, which we estimate will be available in 1H16 would significantly bolster our confidence in the compound's probability of success. With the delta between the probability weighted \$12/shr contribution of DRM01 vs. a peak contribution of \$27/shr, we expect the confirmatory Ph IIb data to be the major valuation driver for DERM in the next 18 months. On its own, we believe that success in later-stage acne trials would make DERM a compelling acquisition target.



## Revenues: We Forecast Probability-Weighted Total Revenues of ~\$430M by 2022

Dermira – Income Statement Analysis 2013-2022E

(\$ in Millions, Except EPS)												
(Year Ended December 31)			2013A	2014E	2015E	2016E	2017E	2018E	2019E	2020E	2021E	2022E
	POS	LOE										
Product Revenue (POS adj.)			-	-	-	-	-	9	61	147	232	319
DRM04	75%	2029	-	-	-	-	-	9	23	61	102	148
DRM01	50%	2030	-	-	-	-	-	-	38	86	131	171
Other DRM Pipeline	0%		-	-	-							
Royalty Revenue (POS adj.)			-	-	-	-	-	25	52	79	102	112
Cimzia End User Sales	90%	2024	-	-	-	-	-	42	85	133	185	206
Cimzia Royalty (from UCB)	90%		-	-	-	-	-	25	52	79	102	112
Other Revenue (POS adj.)			-	-	9	9	18	-	22	10	10	_
Cimzia Development Milestones	*				9	9	18					
Cimzia Regulatory Milestones	90%								12			
Cimzia Commercialization Milestones	*					-	-	-	10	10	10	-
Total Revenue Incl 1x Milestones			-	-	9	9	18	34	135	236	345	431
Total Revenue			-	-	-	-	-	34	113	226	335	431
Growth (% y/y)										100%	48%	29%

	Launch <i>(LOE)</i>	Peak Net Sales (\$M)	Assigned POS	Pot'l Probability of Success Inflection Milestones
Cimzia	2018 <i>(2024)</i>	\$330M, (\$250M to Derms)	90%	Phase III Data, Mid-2017
DRM04	2018 <i>(2029)</i>	\$300M	75%	Phase IIb Data, 1H15 Phase III Data, 2H16
DRM01	2019 <i>(</i> 2 <i>0</i> 3 <i>0</i> )	\$540M	50%	Phase IIb Data, 1H16 Ph III Data, 2018

Source: Leerink Partners and Company Reports



### P&L: We Expect Dermira to Become Profitable in 2020E

Dermira - Income Statement Analysis 2013-2022E

(Year Ended December 31)	2013A	2014E	2015E	2016E	2017E	2018E	2019E	2020E	2021E	20221
Total Revenue	-	-	-	-	-	34	113	226	335	431
Growth (% y/y)								100%	48%	29%
COGS	-	-	-	-	-	2	9	24	38	54
COGS (% of sales)				nm	nm	7%	8%	11%	11%	13%
Gross Profit	-	-	9	9	18	32	125	212	306	377
Gross Profit (% of sales)		nm	nm	nm	nm	93%	111%	94%	91%	87%
SG&A	4.4	8.1	12	14	32	73 <sup>*</sup>	91	91	134	151
SG&A (% of sales)		nm	nm	nm	nm	216%	81%	40%	40%	35%
R&D	18 💆	35	66	69	54	40	35	50	67	86
R&D (% of sales)		nm	nm	nm	nm	118%	31%	22%	20%	20%
Operating Income	(22.3)	(42.7)	(69)	(74)	(68)	(82)	(1)	71	105	140
Operating Margin (% of sales)						-241.6%	-0.7%	31.5%	31.5%	32.5%
Total Interest and Other Income/ (Expense)	(0.0)	(0.1)	-	-	-	-	-	-	-	-
Pre-tax Income	(22)	(43)	(69)	(74)	(68)	(82)	(1)	71	105	140
Change in Unrealized Gain / loss										
Taxes							0	0	0	0
Rate (% of pre-tax income)							0%	0%	0%	0%
Net Income	(22.4)	(42.8)	(69.0)	(74.0)	(67.5)	(81.7)	(8.0)	71.1	105.4	139.8
EPS	(\$2.31)	(\$2.78)	(\$2.80)	(\$3.01)	(\$2.28)	(\$2.76)	(\$0.03)	\$2.40	\$3.56	\$4.72
Average Shares Outstanding	10	15.4	24.6	24.6	29.6	29.6	29.6	29.6	29.6	29.6

Development Focus

Commercialization Focus

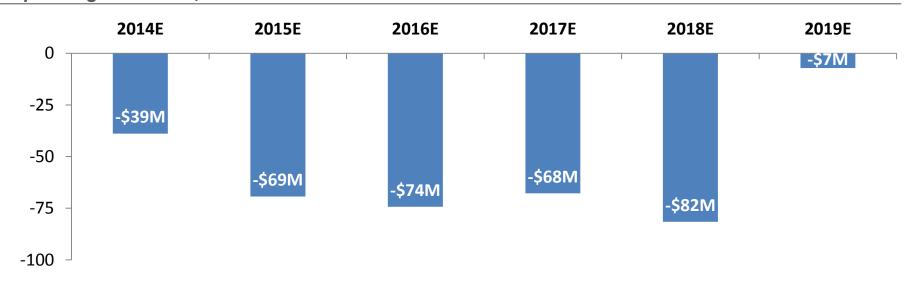
Profitability 2020+



### Cash Burn: We Expect One Additional Raise Prior to Profitability in 2020E

- We expect cash burn of ~\$70M per year through 2017E, with increased spend beginning to be offset by revenues in 2018E and reaching profitability in 2020E.
- We assume DERM will need to raise ~\$150M in additional financing in 2017E, assumed to be executed through offering of 5M additional shares.

#### DERM Operating Cash Flow, 2014E-2020E







### Valuation: We Arrive at a \$32 Price Target Based on Our DCF Analysis to 2026E

Dermira - Discounted Cash Flow Analysis 2014-2022E

Dormira DCE Valuation Assumptions	Dermira DCF Valuation Assumptions									
Del Illita DOF Valuation Assumptions										
Growth Rate	2.0%									
WACC used	12.0%									
Cash 2Q14	\$157									
Debt 2Q14	\$2.1									
% of Enterprise Value from Terminal Value	83%									

	Dermira DCF Valuation Analysis											
			Discount	t rate								
<u>e</u>		10.0%	11.0%	12.0%	13.0%	14.0%						
/alt	-1.0%	\$37	\$31	\$27	\$23	\$20						
<u> </u>	0.0%	\$39	\$33	\$28	\$24	\$21						
≟ِّ	1.0%	\$42	\$35	\$30	\$26	\$22						
Terminal Value	2.0%	\$46	\$38	\$32	\$27	\$23						
ř	3.0%	\$50	\$41	\$34	\$29	\$25						
	4.0%	\$57	\$46	\$37	\$31	\$26						

(\$ in Millions, Except EPS)  Year Ended December 31st,													
	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023	2024	2025	2026
Free Cash Flow (Net Income)	(\$43)	(\$69)	(\$74)	(\$68)	(\$82)	(\$1)	\$71	\$105	\$140	\$164	\$184	\$192	\$209
Discounted Free Cash Flow	(\$43)	(\$67)	(\$64)	(\$52)	(\$57)	(\$0)	\$39	\$52	\$61	\$65	\$65	\$60	\$58
Terminal Value	\$2,086												
Discounted Terminal Value	\$583												
Enterprise Value	\$700												
Less Debt	(\$2)												
Plus Cash	\$157												
Implied Cash From Options Exercise	\$5												
Equity Value	\$859												
Shares Outstanding	25												
Shares Outstanding Incl. Options	27												
Price/Share	\$31.96												

Source: Leerink Partners and Company Reports

#### **Dermira - Implied P/E Analysis**

2021 EPS	\$3.56
Implied P/E Multiple of DCF	18x
Discount rate	12%
Price target	\$32
2021 Sales	\$335
Implied P/S Multiple for DCF	5.2x
Discount rate	12%
Price target	\$32

## \$32 Price Target implies a P/E of 18x on 2021E EPS, assuming a 12% discount rate.

DERMIRA, INC. October 28, 2014



## **Valuation:** We Believe Dermira's Portfolio Warrants a Valuation in Line with Biotech Assuming Success, Particularly of DRM01

- As DERM develops a portfolio of unique dermatology products, we believe there are a number of comparable companies that demonstrate strong market and takeout values.
  - RVNC trades at a ~\$450M market cap driven by its Phase 2/3 development of non-injectable Botox in multiple indications
  - KYTH (OP) trades at a ~\$830M market cap driven by its FDA-filled submental fat injection, a high unmet need indication
  - Medicis's \$2.6B sale to VRX in 2012 occurred at 3.5-4x sales despite the impending launch of Solodyn generics.

	Price as of			Cale	ndar Year P/E			Price / Sales		
Stock	10/24/2014		2016E	2017E	2018E	2019E	2016E	2017E	2018E	2019E
Lg Cap Bio	otech									
Large Cap		Average	22.8x	20.9x	16.4x	13.2x	6.9x	6.0x	5.7x	5.2x
Biotech Inc	dex	Median	16.7x	14.6x	12.6x	12.2x	6.0x	5.4x	5.4x	5.2x
Mid Cap B	iotech									
Mid Cap		Average	27.8x	40.2x	17.0x	24.9x	6.7x	5.3x	4.8x	4.0x
Biotech Inc	dex	Median	22.1x	16.7x	13.0x	12.2x	6.6x	5.0x	3.9x	3.9x
Speculativ	re Biotech									
Speculativ	re	Average	459.6x	60.2x	20.5x	54.4x	72.9x	107.3x	10.4x	8.7x
Biotech Inc	dex	Median	193.8x	24.5x	13.3x	15.3x	19.2x	7.5x	4.2x	3.2x
Dermatolo	gy									
AGN	\$184.2		18.42	16.12	14.32	13.03	6.41	5.80	5.32	4.94
KYTH	\$36.5		na	35.68	11.69	7.69	6.01	3.58	2.40	1.75
RVNC	\$19.5		na	na	na	10.27	na	na	4.09	1.69
FOMX	\$5.5		na	na	15.60	6.07	11.17	4.84	1.12	0.69
Dermatolo	gy	Average	18.4x	25.9x	13.9x	9.3x	7.9x	4.7x	3.2x	2.3x
Index		Median	18.4x	25.9x	14.3x	9.0x	6.4x	4.8x	3.2x	1.7x

## Company Overview

## **DERMIRA**



### **Growth Investment Opportunity:** Development Stage Dermatology Company

- Strong management with a history of creating value for shareholders
  - Experienced leaders behind multiple successful dermatology companies
  - Development, regulatory, and commercial expertise
- Significant market opportunity addressing unmet dermatologic needs
  - Dermatology long overlooked by Pharma Industry
  - Industry Consolidation (VRX, GSK acq of Stiefel) creating opportunity given few active players supporting the specialty
  - Large, growing specialty market supported by strong patient and prescriber demand
  - Ripe for innovation with significant commercial opportunities
- Established regulatory pathway and low-cost development; addressing 11K dermatologists in US
- Promising pipeline
  - Three late-stage assets addressing psoriasis, hyperhidrosis, acne
  - Near-term catalysts as value creation opportunities



### **Experienced Leadership** Behind Multiple Successful Dermatology Companies

## Tom Wiggans Chairman & CEO

- Chairman & CEO, Connetics, Peplin
- · Chairman, Excaliard; director, Abgenix, Onyx
- 25 years in specialty pharma, 18 years in dermatology

## **Gene Bauer, MD** *CMO*

- · Co-Founder, Connetics; CMO, Peplin
- · Chairman, Dermatology, and Dean, Stanford Medical School
- Internationally recognized leader in dermatology

## **Andrew Guggenhime** COO and CFO

- · CFO, Calistoga, Facet, PDL, CardioDx, Neoforma
- · Banking, Merrill Lynch, Wells Fargo
- 24 years in finance and corporate development

# Luis Peña *EVP, Product Development*

- VP & Head, Global Prescription Product Development, Stiefel/GSK
- VP, Portfolio Planning & Management, Connetics
- 25 years in development (Genentech, Theravance, Nuvelo)

## Chris Griffith VP, Corp. Dev. & Strategy

- Corporate dev., strategy at Gilead, Genentech, Bay City Capital
- 13 years in business dev., strategy, investment management

Key management behind multiple successful dermatology companies (7 NDA approvals, \$200M annual sales, >\$1B market value)



### **Dermira Product Portfolio**

Program	Preclinical	Phase 1	Phase 2a	Phase 2b	Phase 3	Market
CIMZIA Injectable TNF	inhibitor (psoriasis	s <i>)</i>				
DRM04 Topical antichol	inergic (hyperhidr	rosis)				
DRM01 Topical sebum i	inhibitor (acne)					
DRM02 Topical PDE4 is (Infl. skin diseas						
DRM05 Topical photody therapy (acne)	rnamic					

**DERMIRA, INC.** 

October 28, 2014

**DRM01:** Topical Sebum Inhibitor

for Acne

## **DERMIRA**



### **DRM01 Summary: Product Overview & KOL Commentary**

#### **MARKET OPPORTUNITY & UNMET NEED**

- Two oral drugs, Accutane (isotretinoin) and spironolactone, have the best efficacy against the worst forms of acne, yet are severely limited by safety risks
- Need for novel mechanism of action (MOA) targeting key aspect of acne pathogenesis not addressed by current topicals

#### **SAFETY & TOLERABILITY**

- KOLs highlight the advantage of sebum inhibition with the potential of avoiding systemic side effects of oral Accutane.
- No treatment-related serious adverse events were reported, with slightly more treatment related events in the DRM01 arm (23% vs. 15%).

#### **EFFICACY DATA**

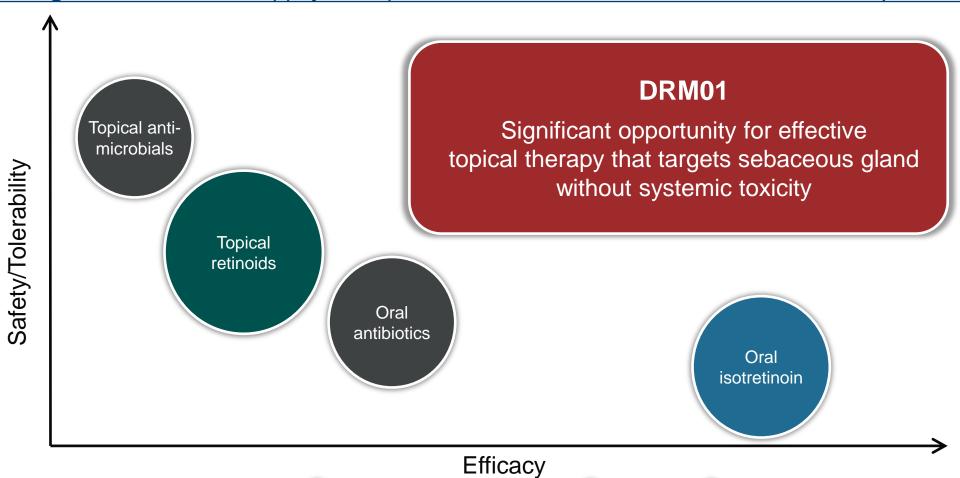
- KOLs highlight "strikingly good" Ph 2 data which suggests DRM01 monotherapy can potentially rival combination therapy with Epiduo. Epiduo is Galderma's combination of adapalene and benzoyl peroxide which has the most branded scripts on the market and took a much larger study to demonstrate significance.
- KOLs believe it is extremely likely that the drug will advance to Phase 3 based on DRM01's highly significant and clinically meaningful reductions on both lesion counts and Investigator's Global Assessment (IGA) in a 108-patient, placebo-controlled study. KOLs note that acne drugs rarely reach significance on any endpoint in Phase 2 studies.

#### **DEVELOPMENT & COMMERCIAL POTENTIAL**

- Well-defined and consistent endpoints. For the Ph 2b dose finding study, the co-primary endpoints are the absolute reduction in lesion counts and 2-point drop in IGA. These are the same as the Ph 2a study and will be the same going forward into Ph 3.
- KOLs highlight that cont'd success in trials would have meaningful impact for DRM01, even as monotherapy.
- KOLs emphasize the novel MOA and thus complementary nature ... which likely will allow specialists to mix and match for likely additive effect and pot'l for lifecycle extension
- Competitive agent from Novan may be a near-term headline risk. Despite its different mechanism of action, Novan's SB204 is backed by an experienced team, has solid early data from a Latin American study, and recently posted its Ph 2b on clinicaltrials.gov,



### Background: Attractive Oppt'y to Cope with Limitations of Decade-Old Acne Therapies



Therapy	Limitations
Oral Isotretinoin	Significant efficacy, but safety risks
Retinoids	Skin Irritation and moderate efficacy
Antimicrobials	Concerns of bacterial resistance, waning efficacy

Primary therapeutic target: Follicular keratinization P. acnes Sebaceous gland



### **Competition:** Examples of Acne Treatment Options

#### **Oral Isotretinoin**

Agent		Company
Accutane	isotretinoin	Multiple Branded Generics: Ranbaxy, Teva, Dr. Reddy's

**Antimicrobials** 

Agent		Company
Aczone	dapsone	Allergan

**Topical Retinoids** 

Agent		Company
Differin	adapelene	Galderma
Tazorac	tazorotene	Allergan
Fabior	tazorotene	Stiefel, GSK

**Topical Fixed-dose Combinations** 

Agent		Company
Epiduo	adapelene + BPO	Galderma
Duac	clindamycin + BPO	Stiefel, GSK

**Novel Topical Agents** 

Agent		Company	Phase
DRM01	Sebum inhibitor	Dermira	2b initiating 1H15
SB204	Nitrous-oxide releasing gel	Novan Therapeutics	2b initiated 2H14

Targets excess sebum production with dramatic efficacy but significant systemic toxicity

Target bacteria that drive acne production

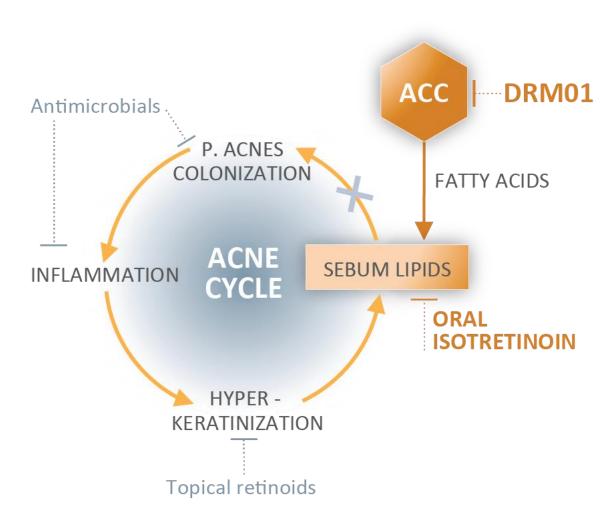
Target alteration of skin cells that contribute to clogged pores; skin irritation and moderate efficacy

Aim to increase compliance beyond single agent topicals

Novel mechanisms aimed at more direct sebum targeting and efficacious lesion reduction, without systemic side effects



### **DRM01 MOA:** Inhibiting Sebum Production to Break Acne Cycle



- Acetyl coenzyme-A carboxylase (ACC) drives first, rate-limiting step in fatty acid synthesis, required to build vast majority of sebum lipids
- ACC inhibition via topical DRM01 reduces sebum production in primary human sebocytes, animal models
- Opportunity for isotretinoin-like effects without systemic toxicity
- DRM01 targets key aspect of acne pathophysiology not addressed by available topical therapies

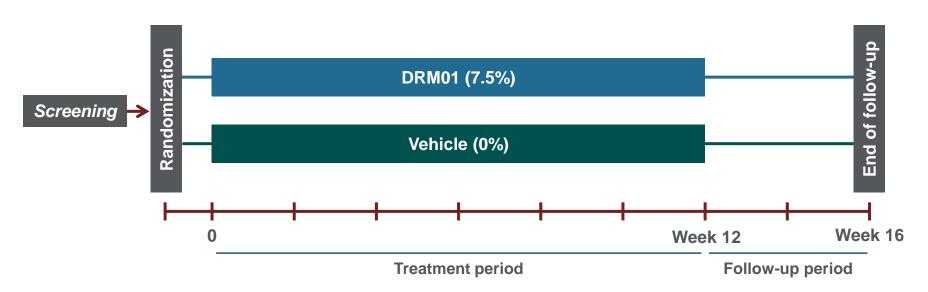
Specifically targeting ACC, key regulator of sebum production



### Phase 2a: 108-Patient Randomized, Double-Blind, Vehicle-Controlled Trial Completed

### STANDARD DESIGN BASED ON PUBLISHED FDA DRAFT GUIDANCE

Population	<ul> <li>108 moderate-to-severe acne adult patients</li> <li>≥20 inflammatory lesions</li> <li>≥20 non-inflammatory lesions</li> <li>Investigator's Global Assessment (IGA) score of ≥3</li> </ul>
Duration	DRM01 7.5% gel applied BID for 12 weeks
Primary Efficacy Endpoints	<ul> <li>FDA-recommended primary efficacy endpoints (week 12)</li> <li>Inflammatory lesion count: Absolute change from baseline</li> <li>Non-inflammatory lesion count: Absolute change from baseline</li> <li>IGA: Proportion of patients achieving ≥2-point reduction in IGA score</li> </ul>





## **Efficacy:** Improvement in Lesion Counts Comparable to Epiduo; Significant Impact on 2-FDA Recommended Primary Endpoints

### **Primary Endpoints: Absolute Changes in Lesion Counts at Week 12**

Avg % reduction in P-value

Avg %

P-value

reduction in

Inflammatory Lesion Count				
Vehicle	Vehicle DRM01 Differenc			
45.9%	63.9%	18.0%		
0.0006				

Inflammatory Lesion Count				
Vehicle	Epiduo	Difference		
30.2%	53.4%	23.2%		
< 0.001				

Non-inflammatory Lesion Count

Vehicle DRM01 Difference

28.8% 48.1% 19.3%

0.0025

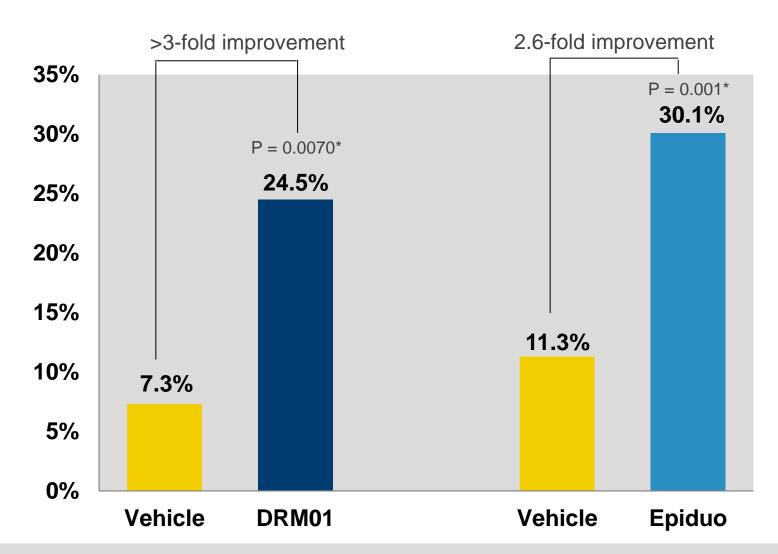
Non-inflammatory Lesion Count				
nc	Differe	Epiduo	Vehicle	
.99	24	48.1%	23.2%	
	•	< 0.001	_	

- DRM01 demonstrates superiority in a Phase 2a relative to vehicle following 12 weeks of treatment duration in investigating inflammatory and non-inflammatory lesion count, measured as absolute change from baseline in the number of acne lesions
- Efficacy was assessed at the end of the 12-week treatment period
- DRM01 appears comparable to approved Epiduo
- Two clinical endpoints are in accordance with FDA draft guidance regarding the development of acne products and supporting a marketing approval application.



## **Efficacy:** Improvement in IGA Response Comparable to Epiduo (3<sup>rd</sup> FDA-Recommended Co-Primary Endpoint)

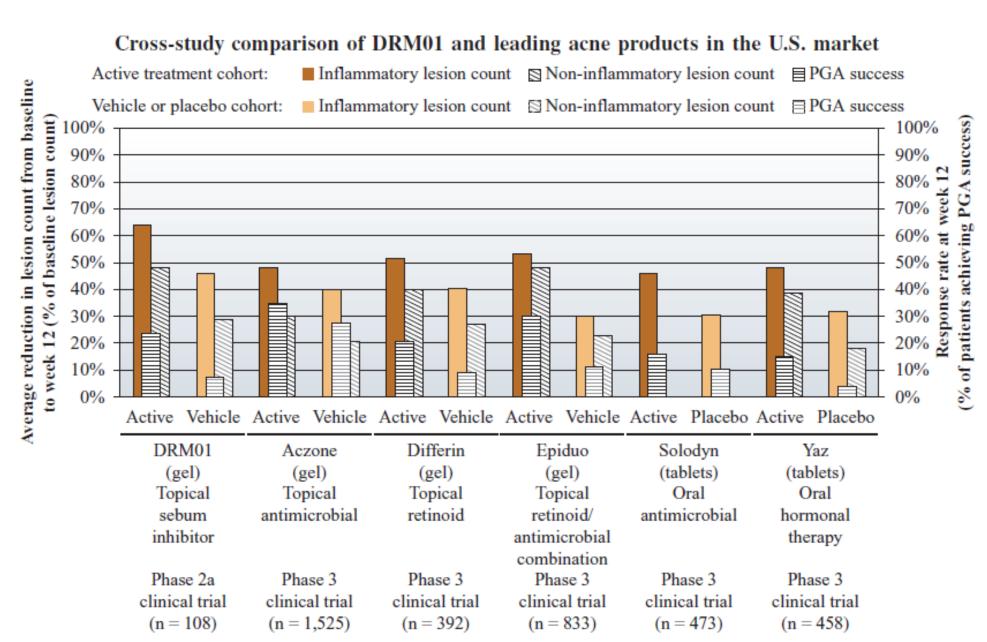
Primary Endpoint: Investigator's Global Assessment (IGA) Response Rate at Week 12



DRM01 patients were >3x more likely to respond than vehicle-only patients



### Efficacy: Cross Agent Comparison of DRM01 to Acne Agents





### **Development:** Initiating Ph 2b Dose-Finding Program in 1H15, Readout Expected IH16

	Ph 2a: Clinical POC	Ph 2b: Dose-finding	Ph 3 Registration
Objective	Safety and preliminary efficacy	Dose-selection	<ul><li>Confirmatory</li><li>Safety &amp; Efficacy</li></ul>
Рор	Adults with Acne Vulgaris N= 100	Adults with Acne Vulgaris N= 300	≥ 9 years Acne Vulgaris N= 600
Dosing	7.5% Topical 12 Weeks BID	Multiple Topical Doses 12 Weeks	Dose/ Frequency TBD 12 Weeks
Key Efficacy / Results	<ul><li>Acne lesion count</li><li>Acne IGA</li><li>Sebum excretion profile</li></ul>	<ul><li>Acne lesion count</li><li>Acne IGA</li><li>1H15 Start Ph 2b</li><li>1H16 data readout</li></ul>	<ul><li>Acne lesion count</li><li>Acne IGA</li><li>2018 data readout</li></ul>

• IGA = Investigator Global Assessment

Ph 2b Data

TH16

2018

2018

2018

Ph 3 Registrational Data

FDA Submission

2018

Commercial Launch



## Script-Based US Acne (DRM01) Market Model & Assumptions

	2019	2020	2021	2022	2023	2024	2025	2026
US Topical Acne Market								
Total Perscriptions (Rx)	13,246,137	14,042,750	14,820,994	15,585,255	16,261,386	17,026,479	17,742,102	18,489,332
Growth Rate	6%	6%	6%	5%	4%	5%	4%	4%
Retinoid (Isotretinoins / Tretinoin) Market	5,531,295	5,739,818	5,956,203	6,180,746	6,413,753	6,655,544	6,906,451	7,166,817
Growth Rate	3.8%	3.8%	3.8%	3.8%	3.8%	3.8%	3.8%	3.8%
% of Overall Rx	42%	41%	40%	40%	39%	39%	39%	39%
Antimicrobials	5,650,324	5,856,812	6,070,845	6,292,700	6,522,663	6,761,029	7,008,107	7,264,213
Growth Rate	3.7%	3.7%	3.7%	3.7%	3.7%	3.7%	3.7%	3.7%
% of Overall Rx	43%	42%	41%	40%	40%	40%	39%	39%
Fixed Dose Combinations	1,849,707	1,959,343	2,075,477	2,198,495	2,328,804	2,466,837	2,613,052	2,767,933
Growth Rate	5.9%	5.9%	5.9%	5.9%	5.9%	5.9%	5.9%	5.9%
% of Overall Rx	14%	14%	14%	14%	14%	14%	15%	15%
Novel Therapies	214,812	486,778	718,469	913,315	996,166	1,143,068	1,214,493	1,290,369
Growth Rate	·	127%	48%	27%	9%	15%	6%	6%
% of Overall Rx	2%	3%	5%	6%	6%	7%	7%	7%
(Dermira) DRM01 Topical	214,812	486,778	718,469	913,315	996,166	1,143,068	1,214,493	1,290,369
Price per Rx (\$)	\$471	\$471	\$485	\$500	\$515	\$530	\$546	\$562
Price Growth			3%	3%	3%	3%	3%	3%
DRM01 Gross to Net Adjusted (\$ MM)	\$76	\$172	\$261	\$342	\$384	\$454	\$497	\$544

Commercial Launch	2019E
Peak Sales Year	2023E – 2025E
Gross to Net Adjusted	25%
Pricing	In line with isotretinoin agent, Galderma Epiduo
Launch	Epiduo based launch trajectory with initial uptake dampened to potential launch with less sales resources

**DRM04:** Topical Anticholinergic for Hyperhidrosis (HH) Treatment

## **DERMIRA**



### **DRM04 Summary: Product Overview & KOL Commentary**

#### **MARKET OPPORTUNITY & UNMET NEED**

- Our KOL checks confirm a vast hyperhidrosis market where treatment options are limited to ineffective antiperspirants or burdensome Botox injections.
  - 9M Americans suffer from excessive sweating, 1M from severe hyperhidrosis (HH)
  - Significant psychosocial burden
  - Most noninvasive treatments provide little relief
- KOLs note significant need for noninvasive second-line treatment options to challenge the effective but burdensome use of every-6-month Botox injections. DRM04 – a convenient, easy to use glycopyrrolate wipe – is initially intended to inhibit axillary sweat production.

#### **EFFICACY DATA**

- In KOLs' opinions, Ph 2 demonstration of statistically significant reduction in sweat production and 40-50% improvement in HH score (HDSS) removes much of the technical risk for DRM04 program.
- Sweat production, though reported differently, seems to demonstrate Botox-like results. Botox trials show 80-85% of subjects demonstrating at least 50% reduction from baseline in axillary sweating at 4 weeks, while DRM04 achieving greater than 50% reduction in sweat production in various doses 1%, 2%, 3%, and 4% providing 53%, 61%, 76%, and 77% change from baseline, respectively.

#### **SAFETY & TOLERABILITY**

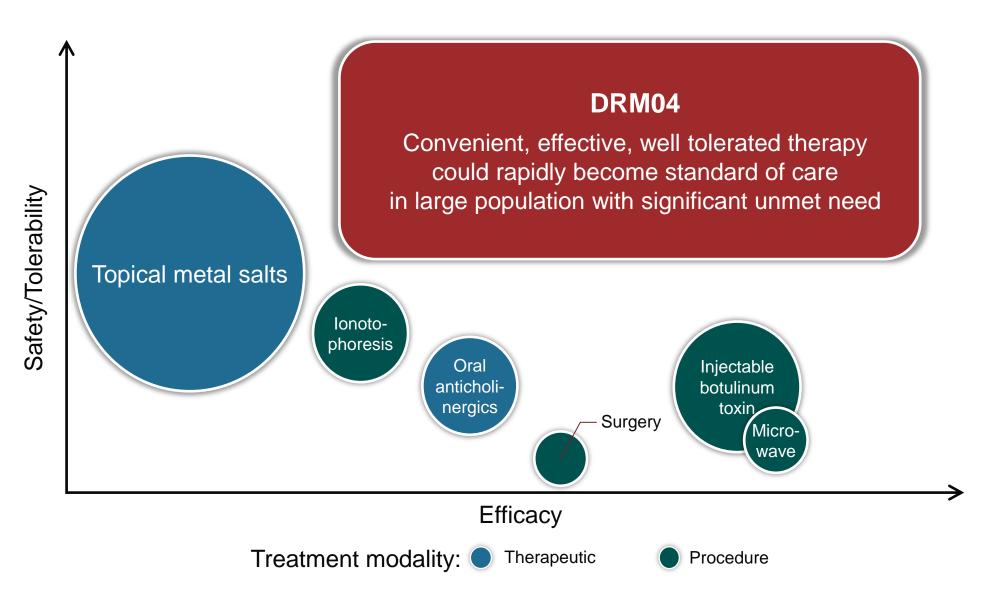
- The 2% dose, while highly active, appears to have a low incidence of dry mouth and blurred vision.
- KOLs do not believe low-grade dry mouth is worrisome at maximum tolerated dose (MTD). Oral administration glycopyrrolate shows therapeutic effect with tolerable degree of dry mouth and dry eye. KOLs highlight that in practice they are convinced the locally applied wipe will result in noticeably less side effect concerns.
- Ph 2 data give the boundaries and show a sweet spot of 2-3% dose range; DERM could theoretically even go to 2.5% for pivotals; data from HH01 together with the bridging study data will determine the like go-forward dose(s).

#### **DEVELOPMENT & COMMERCIAL POTENTIAL**

- Ph 3 endpoints TBD gravimetric test will definitely be used,
   ≥ 2 point reduction in HDSS also possible.
- KOLs believe that if successful and priced correctly, DRM04 could be the next step after antiperspirants followed by Botox or device use. Insurance coverage ought to follow given Botox's current coverage for HH.
- "RT-001 hasn't been as great as we might have expected,"
   according to specialists, who also expect a high price. Price
   sensitivity for topical Botox agents is expected to be geared
   toward aesthetic / cosmetic uses.



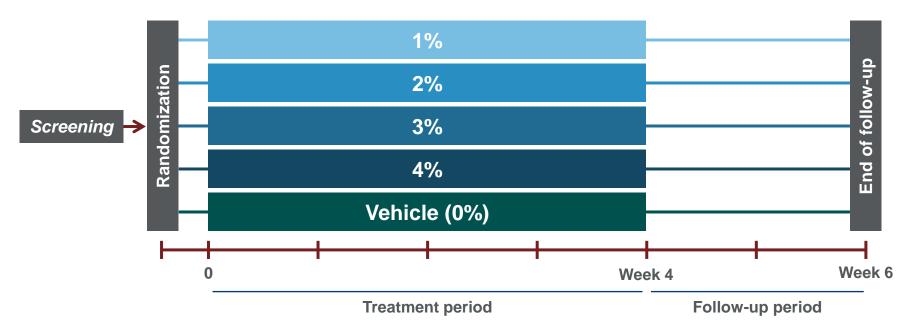
### Background: Current Therapies Largely Ineffective/Inconvenient/Poorly Tolerated





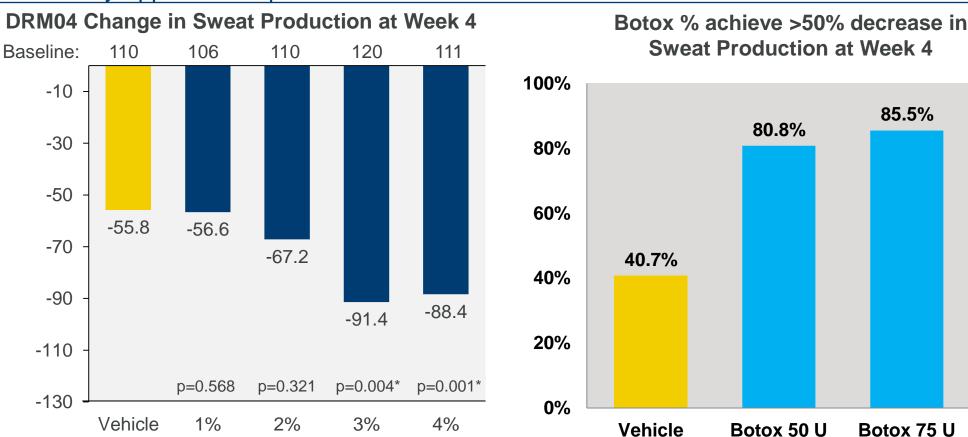
### Phase 2b: HH01 Dose-Ranging Completed for Reference Agent

- Well-characterized glycopyrrolate mechanism with clear dose-response curve
- Randomized double blinded vehicle controlled trial
  - 198 severe, primary axillary hyperhidrosis patients
  - Principal inclusion criteria: Adults with sweat production of ≥50 mg/5 min in each axilla (gravimetry), HDSS (Hyperhidrosis Disease Severity Score) score of 3-4
  - Topical formulation of reference agent applied via wipe QD for 4 weeks
  - 2 Key Efficacy Measures (Week 4)
    - Axillary Sweat Production: Absolute change from baseline (gravimetric sweat test)
    - PRO: Proportion of patients achieved ≥ 2-point reduction in HDSS score





## **Efficacy:** Statistically Significant Impact on Sweat Production (Gravimetry) Additionally Appears Comparable to Results Seen with Botox



- DRM04 demonstrated impact on sweat production as the average absolute change from baseline at the end of the 4-week treatment period
- Botox efficacy defined as percentage of subjects demonstrating at least 50% reduction from baseline in axillary sweating at 4 weeks
- DRM04 appears comparable in achieving greater than 50% reduction in sweat production in various doses 1%, 2%, 3%, and 4% providing 53% (55.6/106), 61% (67.2/110), 76% (91.4/120), and 77% (88.4/111), respectively

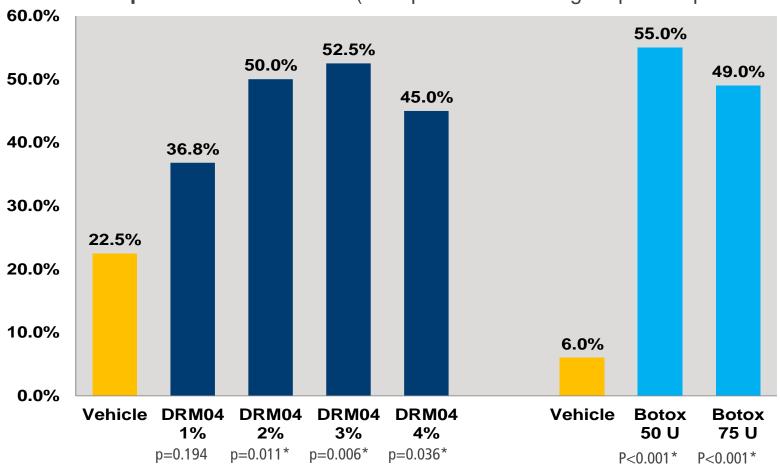
DERMIRA, INC.

October 28, 2014



## **Efficacy:** Statistical Significance, Dose-Dependence, and Comparability to Botox Validated on Patient Reported Outcome Scale

**HDSS Response Rate at Week 4** (% of patients achieving ≥2-point improvement)



## Positive impact on widely-used PRO (HDSS)



# **Development:** DRM04 Clinical Development Plan

	Ph 2a Clinical POC	Ph 2b: Do	se-finding	Ph 3 Registration
	Phase 2a Clinical POC	Ph 2b: HH01 Dose-finding	Ph 2b: HH02 Dose-finding	Phase 3 Registration
Objective	Established POC	Dose-selection	Support switch / PRO development	<ul><li>Confirmatory</li><li>Safety &amp; Efficacy</li></ul>
Рор	N= 36	N= 200	N=100	N= 600
Dosing	QD (4 Weeks)	QD (4 Weeks)	QD (4 Weeks)	QD (4 Weeks)
Key Efficacy / Results	<ul> <li>Attractive efficacy (HDSS, sweat production)</li> <li>Well tolerated</li> </ul>	<ul><li>HDSS score</li><li>Sweat production</li><li>Preliminary Pharmacokinetics</li></ul>	<ul><li>HDSS score</li><li>PRO score</li><li>Sweat production</li><li>Pharmacokinetics</li></ul>	<ul><li>PRO score</li><li>Sweat production</li><li>2H16 readout</li></ul>
HH02 Ph 2		FDA Subr	nission • POC = F	ratient Reported Outcome Proof-of-Concept
1H1	5	2017	7	

Ph 3 Registrational Source: Dermira Company Information and Leerink Partners

2H16

FDA approval

2018



## Patient-Based US Hyperhidrosis (DRM04) Market Model (p1)

	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023	2024	2025	2026
<b>US Axillary Hyperhidrosis</b>	s (HH) Marke	t												
Prevelance Rate (2.8%)	8,851,607	8,940,124	9,029,525	9,119,820	9,211,018	9,303,128	9,442,675	9,584,315	9,728,080	9,874,001	10,041,859	10,212,571	10,386,185	10,562,750
Growth Rate		1.0%	1.0%	1.0%	1.0%	1.0%	1.5%	1.5%	1.5%	1.5%	1.7%	1.7%	1.7%	1.7%
Penetration Rate														
Seek Treatment	3,540,643	3,576,049	3,611,810	3,647,928	3,776,517	3,814,283	3,871,497	4,121,256	4,183,074	4,245,821	4,418,418	4,493,531	4,569,921	4,753,237
www.sweathelp.org	40%	40%	40%	40%	41%	41%	41%	43%	43%	43%	44%	44%	44%	45%
Recommended Treatment	2,301,418	2,324,432	2,347,676	2,371,153	2,454,736	2,479,284	2,516,473	2,720,029	2,760,829	2,802,242	2,982,432	3,033,134	3,084,697	3,255,968
(% Receiving Rx)	65%	65%	65%	65%	65%	65%	65%	66%	66%	66%	68%	68%	68%	69%
Fill Prescriptions	1,726,063	1,743,324	1,760,757	1,778,365	1,841,052	1,859,463	1,887,355	2,067,222	2,098,230	2,129,704	2,311,385	2,350,679	2,390,640	2,555,935
	75%	75%	75%	75%	75%	75%	75%	76%	76%	76%	78%	78%	78%	79%

# Large market underpenetrated by branded pharmaceuticals

- Nearly nine million Americans (2.8 % of US population) with hyperhidrosis (HH)
- 40% (2 in 5) seek help for treatment
- Two-thirds receive prescription
- 75% of patients fill the script

### **DRM04 Target Profile**

- DRM04 represents the first topical wipe for hyperhidrosis with a well-characterized mechanism, positive Phase II data, and a well designed clinical program
- Topically targets local sweat gland activation
- Reduces sweat production and improves disease severity in hyperhidrosis patients
- Efficacy as comparable to systemic treatments
- Established pharmacology and well-tolerated 4week Ph 2a clinical data



# Patient-Based US Hyperhidrosis (DRM04) Market Model (p2)

										<u> </u>				
	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023	2024	2025	2026
(1st Line) HH Market Share	20.0													
Clinical Strength Antiperspirant Topical	70%	70%	70%	70%	69%	67%	62%	57%	53%	51%	50%	49%	48%	77%
Treated with Certain Dri OTC (AICI3)	1,208,244	1,220,327	1,232,530	1,244,855	1,261,121	1,236,543	1,170,160	1,178,316	1,101,571	1,075,500	1,144,136	1,140,079	1,147,507	1,968,070
Cost / Bottle (WAC \$4.30)	\$5.81	\$5.81	\$5.81	\$5.81	\$5.81	\$5.81	\$5.81	\$5.81	\$5.81	\$5.81	\$5.81	\$5.81	\$5.81	\$5.81
Treatment (Tx) Frequency Annualized	4	4	4	4	4	4	4	4	4	4	4	4	4	4
Antiperspirant (Topical) Sales (\$ MM)	\$28.1	\$28.3	\$28.6	\$28.9	\$29.3	\$28.7	\$27.2	\$27.4	\$25.6	\$25.0	\$26.6	\$26.5	\$26.6	\$45.7
Anticholinergic Orals	25%	25%	25%	25%	24%	23%	21%	18%	16%	14%	12%	11%	11%	10%
Treated with Glycopyrrolate Oral	431,516	435,831	440,189	444,591	441,853	418,379	386,908	372,100	335,717	287,510	277,366	258,575	262,970	255,593
Cost / Bottle / 100 pills (WAC \$88.49)	\$88.49	\$88.49	\$88.49	\$88.49	\$88.49	\$88.49	\$99.11	\$99.11	\$99.11	\$99.11	\$99.11	\$111.00	\$111.00	\$111.00
Tx Frequency Annualized	2	2	2	2	2	2	2	2	2	2	2	2	2	2
Anticholinergic Orals Sales (\$ MM)	\$76.4	\$77.1	\$77.9	\$78.7	\$78.2	\$74.0	\$76.7	\$73.8	\$66.5	\$57.0	\$55.0	\$57.4	\$58.4	\$56.7
(2nd Line) HH Market Share														
AGN Botox Market Share	5%	5%	5%	5%	5%	5%	5%	5%	5%	4%	4%	4%	3%	3%
Treated with Botox	86,303	87,166	88,038	88,918	92,053	92,973	94,368	103,361	94,420	85,188	80,898	82,274	71,719	76,678
Cost 100U (4 mL) per axilla	\$525	\$541	\$557	\$574	\$591	\$609	\$627	\$646	\$665	\$685	\$706	\$727	\$749	\$771
Tx Frequency Annualized	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5
Botox Injectable Sales (\$ MM)	\$68.0	\$70.7	\$73.6	\$76.5	\$81.6	\$84.9	\$88.7	\$100.1	\$94.2	\$87.5	\$85.6	\$89.7	\$80.5	\$88.7
	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023	2024	2025	2026
Needle-free Topicals to replace 2nd Li	ne Botox													
Dermira DRM04 topical glycopyrrolate (Ph	2b)					1%	3%	7%	11%	15%	16%	17%	17%	17%
Treated with DRM04	·					23,243	56,621	144,706	230,805	319,456	369,822	399,615	406,409	434,509
Cost						\$101	\$101	\$107	\$112	\$117	\$123	\$127	\$131	\$135
Tx Frequency Annualized						7	7	7	7	7	7	7	7	7
Gross to Net Adjusted (\$ MM)						\$12.4	\$30.2	\$80.9	\$135.5	\$196.9	\$239.4	\$266.4	\$279.1	\$307.3
Anterios ANT-1207 topical Botox (Ph 2b)						1%	3%	5%	7%	9%	11%	11%	12%	12%
Treated with ANT-1207						23,243	55,784	84,931	144,706	178,350	223,619	242,695	270,328	274,924
Cost						\$609	\$609	\$682	\$682	\$682	\$682	\$682	\$763	\$763
Tx Frequency Annualized						1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5
Gross to Net Adjusted (\$ MM)						\$15.9	\$38.2	\$65.1	\$111.0	\$136.8	\$171.5	\$186.1	\$232.2	\$236.1
Revance (RVNC) RT001 topical Botox							1%	2%	4%	6%	8%	9%	10%	10%
Treated with RT001							18,874	41,344	73,438	117,134	173,354	199,808	227,111	255,593
Cost Tx Frequency Annualized							\$627 1.5	\$627 1.5	\$627 1.5	\$627 1.5	\$627 <b>1</b> .5	\$702 1.5	\$702 1.5	\$702 1.5
Gross to Net Adjusted (\$ MM)							\$17.7	\$38.9	\$69.1	\$110.1	\$163.0	\$210.4	\$239.2	1.5 \$269.2
O1033 to Net Aujusteu (φ IVIIVI)							ψ11.1	φ30.9	φυσ. Ι	φ110.1	φ103.0	φ210.4	ΨΔΟΞ.Ζ	Ψ203.2
Total Sales (\$ MM)	\$172.4	\$176.2	\$180.1	\$184.1	\$189.1	\$215.9	\$278.7	\$386.1	\$501.9	\$613.3	\$741.0	\$836.5	\$916.0	\$1.003.8
Total Sales (\$ IVIIVI)	φ1/2.4	φ1/0.2	φ100.1	φ104. l	φ105.1	φ <b>2</b> 10.9	Ψ210.1	φ300. I	φυτ.9	φ013.3	φ/41.0	φουσ.υ	φ310.0	φ1,003.0

Source: Leerink Partners



## Patient-Based US Hyperhidrosis (DRM04) Market Model Assumptions

- Patient-based hyperhidrosis growth model that breaks down market share by 1<sup>st</sup> line, 2<sup>nd</sup> line, and alternative needle-free topical treatments to replace 2<sup>nd</sup> line Botox.
  - 1st Line industrial strength deodorant or anticholinergic orals
  - 2<sup>nd</sup> Line Botox providing excellent temporary relief, but insurance pushback given pricing
  - DRM04 will target 2<sup>nd</sup> line setting in replacing Botox as an injection-free topical alternative
  - Market share analysis depicts competitive landscape including Anterios ANT-1207 and Revance (RVNC) RT001, achieving commercialization by 2018E and 2019E, respectively.
- Key Financial Assumptions

Commercial Launch	2018E
Peak Sales Year	2022E – 2024E
Gross to Net Adjusted	25%
Pricing / Duration	In line with Botox 7-month duration

**Cimzia:** anti-TNFα for Psoriasis (PsO)

# **DERMIRA**

DERMIRA, INC.



### **Cimzia Summary: Product Overview & KOL Commentary**

#### **MARKET OPPORTUNITY & UNMET NEED**

- KOLs validate the favorable long-term prospects for TNFs to remain the first-line agent for the majority of psoriasis patients based on: (a) years of safety experience, (b) preferential effects in the third of psoriasis (PsO) patients with joint pain.
  - "Anti-TNF favored right out of gate" for patients with co-morbid joint pain/ psoriatic arthritis
- KOLs state they "absolutely need another TNF antagonist" given the 50%+ of patients who are non-responders and therapeutic limitations of Enbrel, Stelara, and Remicade.

#### **SAFETY & TOLERABILITY**

- Early discontinuation rate (3-4% vs. 5% for placebo) competitive with Humira's 7% (vs. 4% for placebo) discontinuation rate
- KOLs skeptical of safety advantage over Humira, until seen in larger studies. Construct of molecule doesn't have a potentially immunogenic hinge region that may affect Humira and Remicade. KOLs recognize that "this may suggest a decrease in anti-drug antibody against Cimzia, yet that's a scientific wild guess."
- Maintenance dosing may be key to commercial success.
   DERM is studying lower maintenance dosing of Cimzia post 12 & 16 weeks of induction dosing. This may be important for pricing.

#### **EFFICACY DATA**

- KOLs believe Cimzia could "leap frog" other anti-TNF agents used upon Humira failure, where they continue to look for an another anti-TNF option with "high performance" 70%+ skin clearance.
- Based on replication of Ph2 data, Cimzia ought to be preferred to:
  - Anti-TNF Enbrel which demonstrates <50% skin clearance
  - IL-12/23 Stelara given its lack of demonstrated relief for joint pain
  - Anti-TNF Remicade which is only used in last line setting due to need for infusion

#### **DEVELOPMENT & COMMERCIAL POTENTIAL**

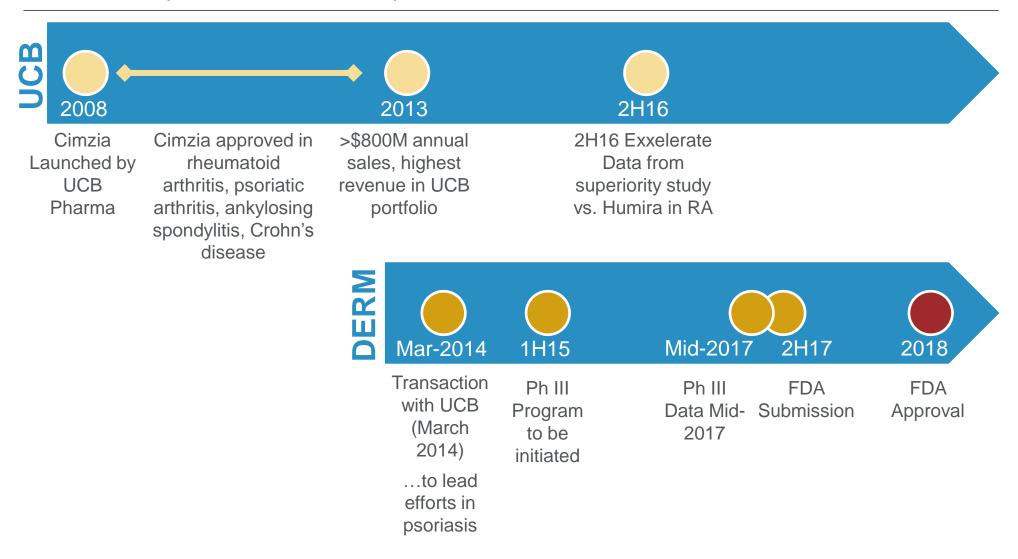
- Will still fall behind Humira in series of options, particularly once the biosimilar is introduced
- KOLs are acutely aware of threats from IL-17s and biosimilar Humira, yet continue to believe in commercial potential of Cimzia
- DERM will initiate its Phase 3 in 1H15. The program will include two placebo-controlled and one active comparator (vs. Enbrel) study which, together, we expect to: (a) satisfy US and EU regulatory requirements, (b) confirm skin clearance data and show superiority to Enbrel, and (c) support lower maintenance dosing from 12 & 16 through 52 weeks of treatment.

Source: Leerink Partners



# **Development:** Opportunity to Steer Valuable Indication for a Marketed TNF-Inhibitor While UCB's Focus on Its Success Continues

#### Cimzia Development Milestone Assumptions





### Background: Psoriasis Is a Complex, Debilitating Disease Requiring Long-Term Treatment

- Prevalent, chronic autoimmune skin disease
  - Hallmark is excessive epidermal proliferation (scaly plaques)
  - Plaque psoriasis is most common form
  - Increasing evidence suggests skin symptoms represent dermal manifestation of systemic inflammatory disorder
- Severity measured by a combination of factors
  - Includes consideration of lesion location, impact on quality of life, and body surface area (≥3% moderate to severe)
- Significant morbidity, co-morbidity
  - Physical, social function
  - Psoriatic arthritis occurs in 33-40% of psoriasis patients
  - Cardiovascular disease





# **Background:** Psoriasis Represents a Large, Underpenetrated Market with Biologic Treatment Gaining Momentum Among Dermatologists

# US Psoriasis Population

>7.5M people (~2.2%) have plaque psoriasis

>1.5M people (~20%)
have moderate to
severe disease

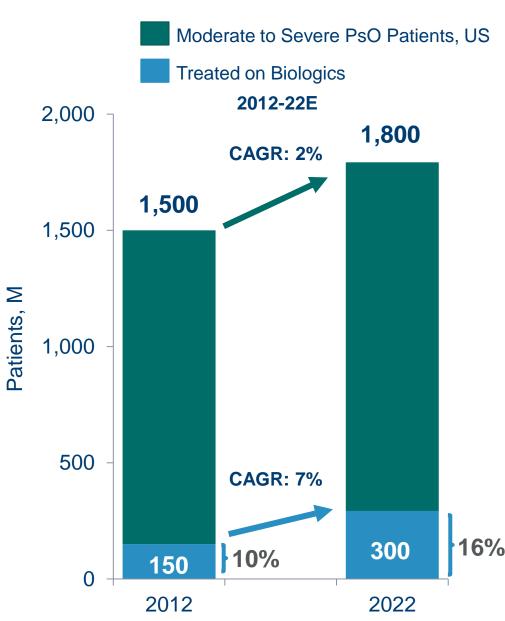
~150K (~10%) biologic penetration

- Large patient population
  - Substantial proportion develop systemic, inflammatory co-morbidities
- Market need persists
  - ~50% of patients dissatisfied with current treatment
  - ≤30% of severe patients not receiving treatment in accordance with guidelines
- Underpenetrated US market
  - Biologic penetration in dermatology remains low relative to other large biologic markets



### Background: Patients Treated on Biologics Are Expected to Double in the Next Ten Years

- Growth from underpenetrated US market
  - We forecast biologics penetration grows from historical use in ~10% of moderate to severe patients to >16% in 2022
- Dermatologists increasingly likely to prescribe biologics
  - IMS scripts for TNFs as well as overall biologics have grown at 12% and 15% CAGRs from 2008 to 2013
- Big players will drive growth with new products, large marketing budgets
  - Since 2009 introduction of Stelara (JNJ [OP]; IL-12/23), market growth has accelerated for all injectable biologics
- \$3.4B US market for injectable biologics forecasted to grow to >\$6B in 2022





# **Competition:** Evolving Psoriasis Market Landscape

### TNFα

Agent	Company	Status
Enbrel (etanercept)	AMGN	Approved
Humira (adalimumab)	ABBV	Approved
Remicade (infliximab)	JNJ	Approved
Cimzia (certolizumab)	Dermira (from UCB)	Ph III (to be initiated 1H15)
Biosimilar Humira	AMGN, NVS (Sandoz), Boehringer, Samsung	Ph III

### IL-23/12

Agent	Company	Status
Stelara (ustekinumab)	JNJ	Approved
Tildrakizumab	Sun Pharma (from MRK)	Ph III
Guselkumab	JNJ (Janssen)	Ph III

### **IL-17**

Agent	Company	Status
Secukinumab (IL17 cytokine)	NVS	Filed (PDUFA Jan-2015)
Brodalumab (IL17 receptor)	AMGN	Ph III
Ixekizumab (IL17 cytokine)	LLY	Ph III (Submission 1H15)

## **Orals**

Agent	Company	Status
Otezla (apremilast; PDE4)	CELG	Filed
Xeljanz (tofacitanib; JAK)	PFE	Ph III (complete)

Source: Leerink Partners



# **Phase 2:** Large, 176-Patient Ph 2 Trial Serves as a Solid Foundation for Soonto-Start Ph 3 Program

## Objective

 To evaluate the efficacy and safety of Cimzia in patients with moderate to severe plaque psoriasis

# Trial Overview

- 176 patients, randomized, double-blind, Phase 2 placebo-controlled
- 15 centers in France and Germany (Oct 2005 to Nov 2006)
- Study consisted of two periods:
  - Initial 12-week treatment period, primary endpoints: ≥75% improvement from baseline in PASI 75 and Physician Global Assessment (PGA) of clear-almost clear
  - Follow-up observation period without treatment 12-week duration for non-responders, and until relapse for responders (up to 24 weeks)
- A 12-week re-treatment extension study was offered to Cimzia responders who relapsed during the observation period; patients received the same treatment as they did in the first study (conducted from May 2006 to May 2007)



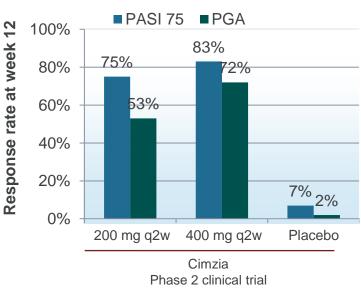
#### Phase 2: Skin Clearance Data

# DERM Objectives

Launch differentiated TNF inhibitor to derms with leading product profile

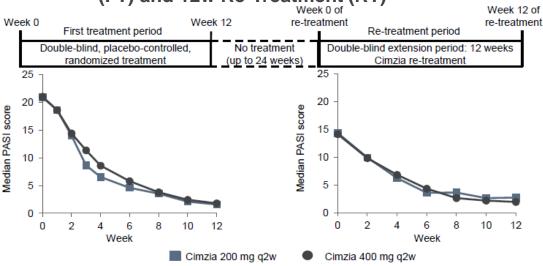
Efficacy comparable to Humira (mAb) with potential safety advantages of Enbrel (non-mAb)

#### PASI 75 12w RR at Two Doses



Phase 2 clinical trial Pegylated antibody fragment (n = 176, p < 0.001)





Note: PASI 75 = proportion of treated patients who achieved a 75% improvement in the clinical grading scale called the Psoriasis Area and Severity Index. PGA (Physician's Global Assessment) = proportion of patients who achieved clearing or near clearing of psoriasis as rated by the investigator.

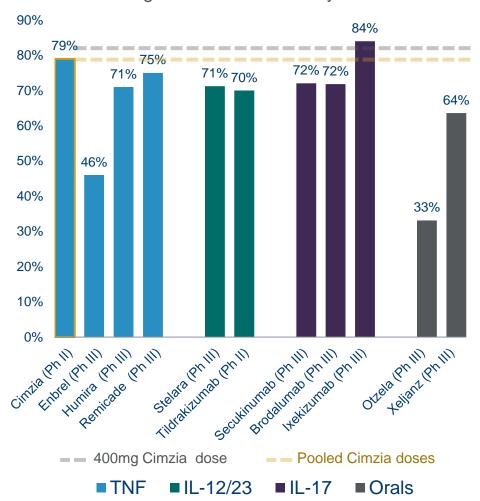
Note: Intention to Treat (ITT) population shown = all randomized patients (n=176) vs. Per protocol (PP) population = subset of ITT population comprising patients who had no major protocol deviations (n=150). Results from PP population were consistent with ITT population

# LEERINK

# **Efficacy:** Competitive Position vs. Other Marketed & Development Stage Psoriasis Therapies

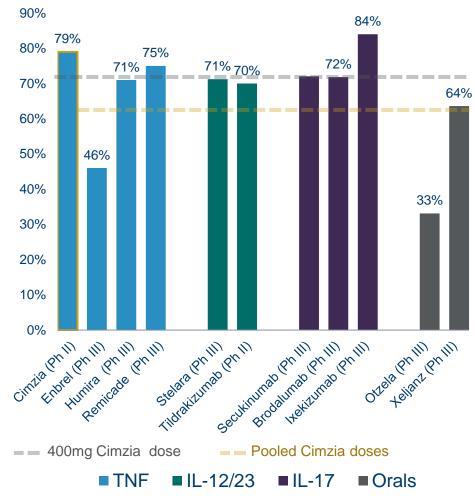
#### PASI 75 Response Rate at Week 12\*

- Tends to be favored by the EMA
- US Dermatologists almost exclusively talk about PASI



#### PGA Response Rate at Week 12\*

Tends to be Favored by FDA



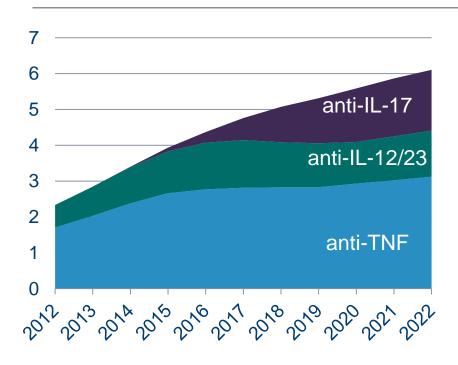
Note: Data from latest phase study with highest patient enrollment used; go-forward doses averaged, if two Source: ClinicalTrials.gov; Cimzia Company Information; Leerink Partners



### **KOL Commentary** on Psoriasis Tx Classes & Forecasted Evolution of US Market

Target	Clinical Benefits	Therapeutic Limitations	Commercial Implications
TNFα	<ul> <li>"High performance" skin clearance</li> <li>"Favored out of gate" in pts who also display signs of joint pain</li> </ul>	Expense (true for all injectables)	<ul> <li>"Maintain critical place in market"</li> <li>"Still first line because years of experience"</li> </ul>
IL- 12/23	"Good" skin clearance	<ul> <li>"Less established safety profile"</li> <li>Viewed as "less effective than IL-17s"</li> </ul>	Continued growth until introduction of IL-7 agents
IL-17	"Expect high performance skin clearance scores and clearance even at PASI-90 and -100 levels"	"Know from RA trials, that IL-17s are not the same as TNF antagonist in addressing joint pain"	<ul> <li>Rapid uptake expected with heavy promotional spend from number of competitors</li> </ul>

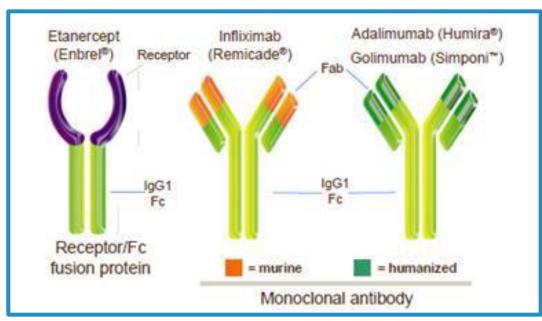
#### **US Injectable Psoriasis Market**, 2012-22E (\$B)



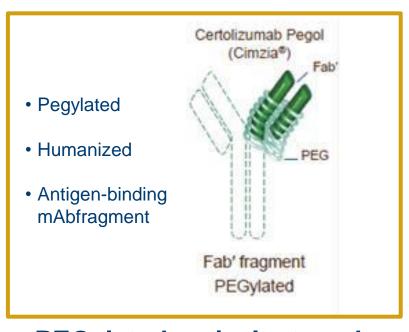
Source: ClinicalTrials.gov; Cimzia Company Information; Leerink Partners



### Safety: Cimzia's Mechanism: Differentiated from the anti-TNF Class



All 4 reagents are bivalent, have an active isotype Fc



# PEGylated, univalent, and does not have an Fc

# Site-specific pegylation, to improve stability in systemic circulation

- PEG (polyethylene glycol);
   hydrophilic, non-toxic, non-antigenic
- Increases Fab' half-life to ~14 days
- Enhanced penetration into inflamed tissue demonstrated in animal models

#### Fab' (no Fc region):

- May avoid potential Fc-mediated effects, i.e., complementdependent cytotoxicity or antibody-dependent cellmediated cytotoxicity
- Fc medicates active placental transfer of IgGs

DERMIRA, INC.

October 28, 2014



# **Safety:** Phase 2 Safety Suggests Cimzia May Be Able to Differentiate from Humira on Discontinuation Rate

	Cimzia						
	PBO (n=58)	CZP 200 mg Q2W (n=60)	CZP 400 mg Q2W (n=57)	All (N=175)			
Total AEs, n	133	156	125	414			
Any AE, n (%)	41 (71%)	43 (72%)	40 (70%)	124 (71%)			
Led to discontinuation, n (%)	3 (5%)	2 (3%)	2 (4%)b	7 (4%)b			
Serious AEs, n (%)	1 (2%)	2 (3%)	3 (5%)°	6 (3%)°			
Infections, n (%)	0	1 (2%)	2 (4%)	3 (2%)			

Humira	Enbrel
~7%	~4%

Note: CZP= Cimzia. The re-treatment period included patients who relapsed after a positive response with CZP during the observation period without treatment. No patients who received PBO met the criteria for relapse or were eligible for enrolment in the re-treatment period. bDoes not include one patient who discontinued due to pregnancy. cDoes not include two patients who reported a pregnancy as a serious AE. Treatment-emergent AEs were defined as having an onset date between first study drug administration and up to 12 weeks after last study drug administration. Safety analysis was performed on all patients who received at least one dose of CZP



# **Differentiation:** Combining the Attributes of Strong TNF Agents

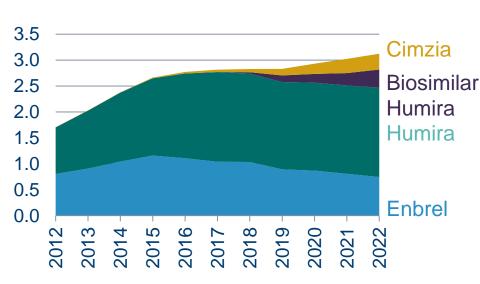
Agent	Efficacy	Safety	Dosing & Admin
Enbrel	+	++	+
	40-50% PASI 75 @ w12	Types and severity of infection were similar between Enbrel and the respective control group	2x weekly for 3 months, 1x weekly
Humira	++	+	++
	70-80% PASI 75 @ w12	Rx discontinuation 7% vs. 4% Pbo; Serious infections slightly more common than in Pbo	Loading dose week 1, Every other week starting week 2
Cimzia	++(+)	+(+)	++
	75-85% PASI 75 @ w12	Lower discontinuation than Pbo group; Infections slightly more common than in Pbo	Loading dose at week 1, 2 and 4, Every other week



### **KOL Commentary** on anti-TNFs & Forecasted Evolution of US anti-TNF Market

Agent	Clinical Benefits	Therapeutic Limitations	Commercial Implications
Enbrel	"Long safety track record"	"Humira edges out Enbrel in pts with PsA because of improved efficacy and dosing profile"	<ul> <li>"Humira favored"</li> <li>Market share (of TNFs) has dropped from 56% to 43% from 2010 to 2014</li> </ul>
Humira	<ul> <li>"High performance skin clearing drug"</li> <li>Helpful for psoriatic arthritis</li> </ul>	Tolerability somewhat less favorable than Enbrel (non- mAb)	<ul> <li>Dermatologists' top choice</li> <li>Market share (of TNFs) has risen from 44% to 57% from 2010 to 2014</li> </ul>
Biosimilar Humira	• Expense	<ul> <li>"Physician's trust"</li> <li>"If anything will reduce price by a third"</li> </ul>	Will be driven by payers and price sensitivity
Remicade	Good skin clearance	Outlier due need for infusion	<ul><li> "Rarely used by dermatologists"</li><li> "Only in last-line setting"</li></ul>
Cimzia	• "Ph 2 suggests pot'l for class-leading skin clearance"	Later-to- market	"Patients who do not respond on Humira"

#### US anti-TNF Market, 2012-22E



Source: Leerink Partners Estimates



# **Anti-TNF Class:** Competitive Profiles

### TNFα

Agent	Company	Status	Label	Dosing	Gross Price per Year (2010-14 YoY Price Increase)
Enbrel (etanercept)	AMGN	Approved	treatment of adult patients (18 years or older) with chronic moderate to severe plaque psoriasis (PsO) who are candidates for systemic therapy or phototherapy	50 mg twice weekly for 3 months, followed by 50 mg once weekly	\$34K (13%)
Humira (adalimumab)	ABBV	Approved	treatment of adult patients with moderate to severe chronic plaque psoriasis who are candidates for systemic therapy or phototherapy, and when other systemic therapies are medically less appropriate	80 mg initial dose, followed by 40 mg every other week starting one week after initial dose.	\$33K (13%)
Remicade (infliximab)	JNJ	Approved	treatment of adult patients with chronic severe (i.e., extensive and/or disabling) plaque psoriasis who are candidates for systemic therapy and when other systemic therapies are medically less appropriate	5 mg/kg at 0, 2 and 6 weeks, then every 8 weeks	\$23K (8%)
Cimzia (certolizumab)	Dermira (from UCB)	Ph III (to be initiated 1H15)	n/a	400 mg initially and at week 2 and 4, followed by 200 mg or 400 mg every other week; for maintenance dosing	\$36K (16%)
Biosimilar Humira	Multiple	Ph III	(see Humira)	(see Humira)	Expected to be ~1/3 lower

Source: PriceRx; Product Labels; Leerink Partners



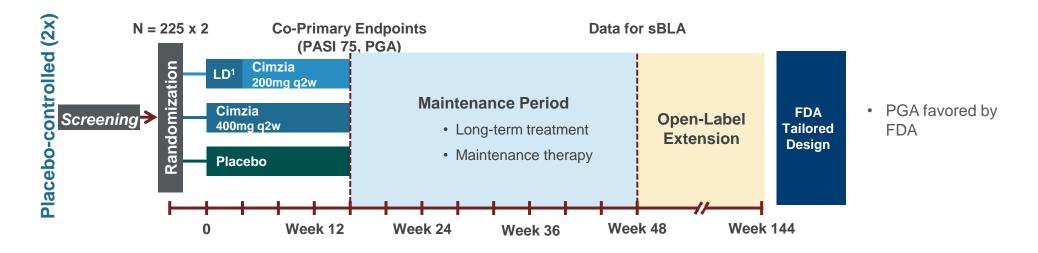
# **Anti-TNF Class:** Cross Trial Efficacy

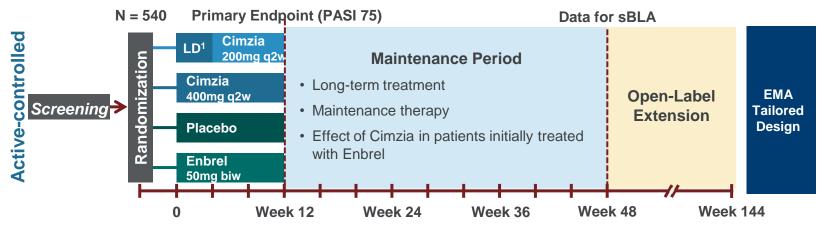
							DC A	For donation	Prior	Dulan	
Drug	Trial	Phase	Δrm	n	PASI 75	PASI 90	PGA PASI 100 (0 or 1)	(weeks)	systemic threapy	Prior biologic	Dosing frequency
TNF-alpha	TITOL	1 11430	AIIII	<u>.                                    </u>	1 731 73	1 731 30	1731100 (0011)	(WCCR3)	шсару	biologic	Dosing frequency
Enbrel	Study I	III	25 mg	169	14%		21%	5 12	)		1x wkly, SC
(etanercept; AMGN)			25 mg	167			32%		)		2x wkly, SC
(0.00			50 mg	168			47%		ทา-ทา%		2x wkly, SC
			Placebo	168			5%				2x wkly, SC
	Study II	III	25 mg	204	32%		37%	5 12	)		2x wkly, SC
	Stady II	•••	50 mg	203			54%				2x wkly, SC
			Placebo	204			3%				2x wkly, SC
Humira	Ps-I	III	40 mg	814	71%		62%	5 16	<u> </u>		every 2 wks
(adalimumab; ABBV)	)		Placebo	398	7%		4%	5 16	5		every 2 wks
	Ps-II	Ш	40 mg	99	78%		71%	5 16	5		every 2 wks
			Placebo	48	19%		10%	5 16	5		every 2 wks
Remicade	Study I	III	5 mg/kg	310	80%		80%	5 10	71%		wks 0, 2, 6, then every 8
(infliximab; JNJ)			Placebo	77	3%		4%	5 10	)		wks 0, 2, 6, then every 8
	Study II	Ш	3 mg/kg	313	70%		69%	5 10	)		wks 0, 2, 6, then every 8
			5 mg/kg	314	75%		75%	5 10	) 55%		wks 0, 2, 6, then every 8
			Placebo	208	2%		1%	5 10	)		wks 0, 2, 6, then every 8
	Study III	Ш	3 mg/kg	99	72%		72%	5 10	)		wks 0, 2, 6, then every 8
			5 mg/kg	99	88%		90%	10	100%		wks 0, 2, 6, then every 8
			Placebo	51	6%		10%	5 10	)		wks 0, 2, 6, then every 8
Cimzia		II	200 mg	59	75%	39%	53%	5 12	<u>)</u>		every 2 wks, up to wk 10
(certolizumab pegol	; DERM)		400 mg	58	83%	47%	72%	5 12	<u>)</u>		every 2 wks, up to wk 10
			Placebo	59	7%	2%	2%	. 12	2		every 2 wks, up to wk 10

Source: Data Labels and Ph II / III Data Publications; Leerink Partners



### Phase 3 Design: Reflective of FDA, EMA Feedback After End or Phase 2





- PASI 75 favored by the EMA
- EMA had no contention with Enbrel as comparator
  - 3(dose #1): 3(dose #2): 3(Enbrel): 1(placebo) randomization is sufficiently powered for P < 0.05 for each dose



# Phase 3 Design: Cimzia's Phase 3 Trial Design Compared With IL-17 Antibodies

Agent	Doses	Study Name	Comparator	Patients	Primary Outcome	Readout	NCT
			Placebo	FF0	PASI75 @ w16		FDA Tailored
Cimzia	200, 400 mg q2w		Placebo	- ~550	PGA @ w16	Mid-2017	Design
		Enbrel ~550 PASI75		PASI75 @ w12	-	EMA Tailored Design	
		AMAGINE-1	Placebo	661		Comp	NCT01708590
Brodalumab	140, 210 mg	AMAGINE-2	Ctoloro	1831	PASI @ w12 PGA @ w12	4Q14	NCT01708603
		AMAGINE-3	- Stelara	1881	-	4Q14	NCT01708629
	80 mg q4w, q12w	UNCOVER-1	Placebo	1416			
Ixekizumab	00	UNCOVER-2	Enbrel	1225	PASI75/100 @ w12	Topline Comp	NCT01597245
	80 mg q2w, q4w	UNCOVER-3	Enbrel	1225	PASI75/100 @ w12	_	NCT01646177
	150 mg	ERASURE	Placebo	739	PASI75 @ w12 PGA @ w12	Comp	NCT01365455
Secukinimab	150, 300 mg	SCULPTURE	Placebo	967	PASI75 @ w12	Comp	NCT01406938
	150, 300 mg	FIXTURE	Enbrel	1264	PASI @ w12	Comp	NCT01358578
	300 mg		Stelara	679	PASI90 @ 16w	Comp	NCT02074982



# **Triangulated Patient/ Script-Based Psoriasis (Cimzia) Market Model** (p1)

	Assumptions	2018	2019	2020	2021	2022	2023	2024	2025	2026
US Psoriasis (PsO) Market										
PsO patients (1000s) Growth Rate	2%	8,446 2%	8,615 2%	8,744 1.5%	8,876 1.5%	8,964 1%	9,054 1%	9,054 <i>0%</i>	9,054 <i>0%</i>	9,054 <i>0%</i>
Moderate to Severe	20%	1689	1723	1749	1775	1793	1811	1811	1811	1811
% Diagnosed	70%	1182	1206	1224	1243	1255	1268	1268	1268	1268
% Treated with Injectables Growth Rate	5%	227 19%	243 20%	259 21%	276 22%	293 23%	311 25%	326 26%	343 27%	360 28%
TNF Market										
Total PsO pts treated with anti-TNF		125	129	135	142	151	160	168	176	185
% Total PsO pts		55%	53%	52%	52%	52%	52%	52%	52%	52%
Total anti-TNF sales		2,828	2,831	2,931	3,024	3,124	3,258	3,366	3,475	3,610
IL-12/23 Market										
Total PsO pts rtreated with anti-IL-12/23		57	56	54	57	61	64	68	71	75
% Total PsO pts		25%	23%	21%	21%	21%	21%	21%	21%	21%
Stelara market share Stelara sales in PsO (compliance adj.)	75%	100% <b>1,256</b>	100% <b>1,225</b>	100% <b>1,161</b>	100% <b>1,225</b>	100% <b>1,286</b>	100% <b>1,350</b>	100% <b>1,403</b>	100% <b>1,459</b>	100% <b>1,516</b>
IL-17 Market										
Total PsO pts treated with anti-IL-17		46	59	70	77	81	86	91	95	100
% Total PsO pts		20%	24%	27%	28%	28%	28%	28%	28%	28%
IL-17 sales in PsO (compliance adj.)	75%	989	1,258	1,494	1,615	1,696	1,780	1,851	1,924	2,000

Source: Leerink Partners



# **Triangulated Patient/ Script-Based Psoriasis (Cimzia) Market Model** (p2)

	Assumptions	2018	2019	2020	2021	2022	2023	2024	2025	2026
TNF Market										
Total PsO pts treated with anti-TNF		125	129	135	142	151	160	168	176	185
% Total PsO pts		55%	53%	52%	52%	52%	52%	52%	52%	52%
Enbrel market share	*	36%	30%	28%	25%	22%	21%	20%	20%	20%
Enbrel sales in PsO (\$M) (compliance adj.)	75%	1,036	894	869	808	747	748	741	770	801
Humira market share	•	61%	59%	57%	55%	53%	52%	51%	50%	50%
Humira sales in PsO (compliance adj.) ABBV	75%	1,704	1,684	1,694	1,703	1,723	1,775	1,809	1,844	1,917
Cimzia market share	•	2%	4%	6%	8%	9%	9%	9%	8%	7%
Treated with Cimzia		2	5	8	11	13	14	14	13	13
Cost per year (gross to net adj.)	80%	33,085	32,754	32,426	32,102	31,781	31,463	31,149	30,837	30,529
Growth Rate		0%	-1%	-1%	-1%	-1%	-1%	-1%	-1%	-1%
Cimzia sales in PsO (compliance adj.)	75%	62	126	197	274	306	321	334	306	297
Cimzia sales to Dermatolotists	75%	46	95	148	206	229	241	250	230	223
Biosimilar Humira market share		2%	7%	9%	12%	17%	400/	240/	23%	23%
	750/						19%	21%		
Biosimilar Humira sales in PsO (compliance	e ac 75%	27	127	170	239	348	414	482	555	596
Total anti-TNF sales		2,828	2,831	2,931	3,024	3,124	3,258	3,366	3,475	3,610

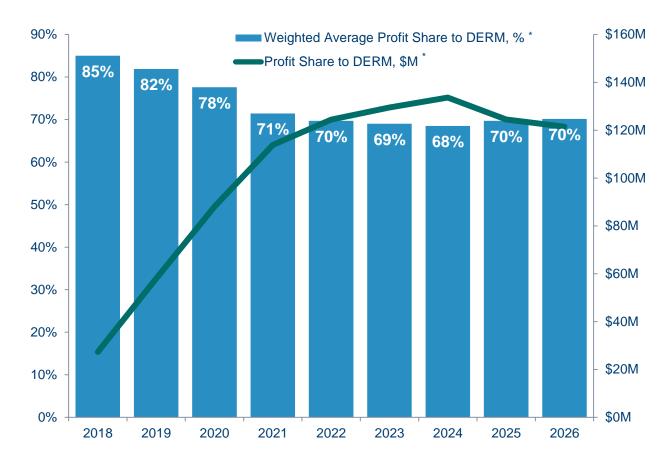
Commercial Launch	2018E
Peak Sales Year	2024E
Gross to Net Adjusted	20%
Pricing	Estimated in Line with other TNF inhibitors

Source: Leerink Partners



# **UCB Partnership:** Attractive Collaboration Structure Gives Dermira Disproportionate Share of Early Revenue

- Dermira receives share of gross margin from Cimzia sales attributed to dermatologists for all indications in US. Canada
- Share of gross margin tiered based upon increasing levels of annual net sales attributed to dermatologists in a given year
- Dermira retains higher share of gross margin initial sales dollars
- Though Dermira does not get credit for Cimzia PsO use if not prescribed by a dermatologist, once the PsO indication is established, the company will benefit from any dermatologist prescriptions whether for PsA or not
- Dermira is likely to have a "running start" in 2018 as current IMS scripts among derms show some adoption likely to occur prior to PsO indication





**Share of Gross Margin** 

Note: \*Specific tier cutoffs and share of gross margins reflect Leerink assumptions/ estimates Source: Leerink Partners and Dermira SEC Filings



# **UCB Partnership**: Strategically, UCB Involvement Allows Dermira to Leverage Presence in the Broader TNF Market

# Partnership Specifics

#### **Structure** International co-development partnership Following approval in psoriasis, Dermira promotes to dermatologists in US, Canada UCB retains all other commercial rights **Development** Development milestones offset a substantial portion of the costs of Ph 3 development program · Work side by side for market access, Infrastructure coverage · Factored into gross profit calculation yet expected to be low-mid single digit \$M **UCB** \$109.5M in cash and equity investment contribution • Investing \$7.5M in IPO, in addition to prior \$12.5M equity investment • Up to \$36M development milestone payments • Up to \$40M commercial + \$13.5M EU approval milestone payments

## Strategic Value

- UCB's Investment in Further Supporting Clinical Benefits in Joint Pain (RA superiority study vs. Humira)
- Pricing, Contracting, and Market Access Expertise
- Contracting Position, Given Cimzia
   Approval in 4+ Indications
- Equity Investment Ensures Further Incentive Alignment
- Nonetheless, Dermira Retains
   Promotional Control to Derms in
   Market Expect to Respond to Derm-Oriented Promotion

Dermira - Income Statement Analysis 2013-2022E

Product Revenue (POS adj.)	2Q14A	3Q14E - - - - - -	4Q14E - - - - - -	2014E	2015E	2016E	2017E	2018E 9 9 - 25 25	2019E  61 23 38  52 52	2020E  147 61 86  79 79	2021E  232 102 131  102 102	2022E  319 148 171  112 112	100% NM NM
DRM04       -       -         DRM01       -       -         Other DRM Pipeline       -       -         Royalty Revenue (POS adj.)       -       -         Cimzia Royalty (from UCB)       -       -         Other Revenue (POS adj.)       -       -         Total Revenue Incl 1x Milestones       -       -         Total Revenue       -       -			:	- - - -	- - - - -	- - - -	:	9 -	23 38 <b>52</b>	61 86 <b>79</b>	102 131 <b>102</b>	148 171 <b>112</b>	NM
DRM04       -       -         DRM01       -       -         Other DRM Pipeline       -       -         Royalty Revenue (POS adj.)       -       -         Cimzia Royalty (from UCB)       -       -         Other Revenue (POS adj.)       -       -         Total Revenue Incl 1x Milestones       -       -         Total Revenue       -       -			:		- - - -	- -	:	25	23 38 <b>52</b>	61 86 <b>79</b>	102 131 <b>102</b>	148 171 <b>112</b>	NM
DRM01         -         -           Other DRM Pipeline         -         -           Royalty Revenue (POS adj.)         -         -           Cimzia Royalty (from UCB)         -         -           Other Revenue (POS adj.)         -         -           Total Revenue Incl 1x Milestones         -         -           Total Revenue         -         -		:	:	:	- - - -	- - -	- -	25	38 <b>52</b>	86 <b>79</b>	131 <b>102</b>	171 <b>112</b>	NM
Royalty Revenue (POS adj.)	:	:	:	- - -	- - -	<u>.</u>	- -						NM
Cimzia Royalty (from UCB)	:	:	-	- -	- - 9	-	-						
Cimzia Royalty (from UCB)	:	-	-	-	9	-	-						
Total Revenue Incl 1x Milestones Total Revenue	- :	· :		-	9								
Total Revenue	:	- -	_		•	9	18	-	22	10	10	-	
Total Revenue		_		_	9	9	18	34	135	236	345	431	
			_	_			-	34	113	226	335	431	89%
Growth (% y/y)								04	110	1	0	0	0370
cogs				-	-	_	-	2	9	24	38	54	120%
COGS (% of sales)						nm	nm	0	0	0	0	0	12070
Gross Profit					9	9	18	32	125	212	306	377	86%
Gross Profit (% of sales)				nm	nm	nm	nm	1	1	1	1	1	0070
SG&A 4 2	2	2	3	8	12	14	32	73	91	91	134	151	20%
SG&A (% of sales)	2	2	3	nm	nm	nm	nm	2	1	0	0	0	2078
SG&A (% of OpEx)				0	0	0	0	1	1	1	1	1	
G&A 4 2	2	2	3	8	12	14	18	22	26	18	74	91	
G&A (% of sales)	2	2	3	o	nm	nm	nm	1	0	0	0	0	
Cimzia launch costs					11111	11111	4	14	11	9	U	U	
DRM04 launch costs							3	8	6	6			
DRM01 launch costs							3	3	4	4			
Sales Force							8	27	45	54	60	60	
Sales Force							0	21	45	54	60	60	
R&D 18 7	7	9	12	35	66	69	54	40	35	50	67	86	21%
R&D (% of sales)				nm	nm	nm	nm	1	0	0	0	0	
Operating Income (22)	(9)	(11)	(15)	(43)	(69)	(74)	(68)	(82)	(1)	71	105	140	NM
Operating Margin (% of sales)								(2)	(0)	0	0	0	
Total Interest and Other Income/ (Expense) (0) -	(0)	-	-	(0)	-	-	-	-	-	-	-	-	
Pre-tax Income (22) (9)	(9)	(11)	(15)	(43)	(69)	(74)	(68)	(82)	(1)	71	105	140	
Change in Unrealized Gain / loss													
Taxes									-	-	-	-	NM
Rate (% of pre-tax income)									-	-	-	-	
Net Income (22) (9)	(9)	(11)	(15)	(43)	(69)	(74)	(68)	(82)	(1)	71	105	140	
	(\$0.80)	(\$0.67)	(\$0.59)	(\$2.78)	(\$2.80)	(\$3.01)	(\$2.28)	(\$2.76)	(\$0.03)	\$2.40	\$3.56	\$4.72	
Average Shares Outstanding 10 9.7	11.0	16.3	24.6	15.4	24.6	24.6	29.6	29.6	29.6	29.6	29.6	29.6	

Source: Leerink Partners and Company Reports

Dermira - Income Statement Analysis 2013-2026E

(\$ in Millions, Except EPS)															CAGR
(Year Ended December 31)	2013A	2014E	2015E	2016E	2017E	2018E	2019E	2020E	2021E	2022E	2023E	2024E	2025E	2026E	'18E-22
Product Revenue (POS adj.)	-	-	-	-	-	9	61	147	232	319	372	427	458	503	
DRM04	-	-	-	-	-	9	23	61	102	148	180	200	209	231	100%
DRM01	-	-	-	-	-	-	38	86	131	171	192	227	249	272	NM
Other DRM Pipeline	-	-	-												NM
Royalty Revenue (POS adj.)	-			-	-	25	52	79	102	112	117	120	112	109	
Cimzia Royalty (from UCB)	-	-	-	-	-	25	52	79	102	112	117	120	112	109	
Other Revenue (POS adj.)	-	-	9	9	18	-	22	10	10	-	-	-	-	-	
Total Revenue Incl 1x Milestones	-		9	9	18	34	135	236	345	431	488	547	570	612	
Total Revenue	-	-	-	-	-	34	113	226	335	431	488	547	570	612	89%
Growth (% y/y)								1	0	0	0	0	0	0	
cogs	-					2	9	24	38	54	64	73	77	85	120%
COGS (% of sales)				nm	nm	0	0	0	0	0	0	0	0	0	
Gross Profit	-	-	9	9	18	32	125	212	306	377	424	475	493	527	86%
Gross Profit (% of sales)		nm	nm	nm	nm	1	1	1	1	1	1	1	1	1	
SG&A	4	8	12	14	32	73	91	91	134	151	161	170	171	171	20%
SG&A (% of sales)		nm	nm	nm	nm	2	1	0	0	0	0	o	0	0	
SG&A (% of OpEx)		0	0	0	0	1	1	1	1	1	1	1	1	1	
G&A	4	8	12	14	18	22	26	18	74	91	101	110	111	111	
G&A (% of sales)			nm	nm	nm	1	0	0	0	0	0	0	0	0	
Cimzia launch costs					4	14	11	9	-			_	-	_	
DRM04 launch costs					3	8	6	6							
DRM01 launch costs					•	3	4	4							
Sales Force					8	27	45	54	60	60	60	60	60	60	
R&D	18	35	66	69	54	40	35	50	67	86	98	109	114	122	21%
R&D (% of sales)	.0	nm	nm	nm	nm	1	0	0	0	0	0	0	0	0	2170
Operating Income	(22)	(43)	(69)	(74)	(68)	(82)	(1)	71	105	140	165	196	208	233	NM
Operating Margin (% of sales)	(22)	(40)	(03)	(14)	(00)	(2)	(0)	o	0	0	0	0	0	0	14101
Total Interest and Other Income/ (Expense)	(0)	(0)				-	-								
Pre-tax Income	(22)	(43)	(69)	(74)	(68)	(82)	(1)	71	105	140	165	196	208	233	
01		. ,	, ,	. ,	, ,	, ,	. ,								
Change in Unrealized Gain / loss													40	0.5	
Taxes Rate (% of pre-tax income)											1 0	11 <i>0</i>	16 <i>0</i>	25 0	NM
, ,					()		441								
Net Income	(22)	(43)	(69)	(74)	(68)	(82)	(1)	71	105	140	164	184	192	209	
EPS	(\$2.31)	(\$2.78)	(\$2.80)	(\$3.01)	(\$2.28)	(\$2.76)	(\$0.03)	\$2.40	\$3.56	\$4.72	\$5.55	\$6.21	\$6.48	\$7.04	
Average Shares Outstanding	10	15.4	24.6	24.6	29.6	29.6	29.6	29.6	29.6	29.6	29.6	29.6	29.6	29.6	

Source: Leerink Partners and Company Reports



# Disclosures Appendix Analyst Certification

I, Seamus Fernandez, certify that the views expressed in this report accurately reflect my views and that no part of my compensation was, is, or will be directly related to the specific recommendation or views contained in this report.



Distribution	as of 09/30/14 IB Se	erv./Past 12 Mos.		
Rating	Count	Percent	Count	Percent
BUY [OP]	138	69.30	51	37.00
HOLD [MP]	61	30.70	2	3.30
SELL [ŪP]	0	0.00	0	0.00

#### **Explanation of Ratings**

Outperform (Buy): We expect this stock to outperform its benchmark over the next 12 months.

<u>Market Perform (Hold/Neutral):</u> We expect this stock to perform in line with its benchmark over the next 12 months.

<u>Underperform (Sell):</u> We expect this stock to underperform its benchmark over the next 12 months. The degree of outperformance or underperformance required to warrant an Outperform or an Underperform rating should be commensurate with the risk profile of the company.

For the purposes of these definitions the relevant benchmark will be the S&P 600® Health Care Index for issuers with a market capitalization of less than \$2 billion and the S&P 500® Health Care Index for issuers with a market capitalization over \$2 billion.

#### **Important Disclosures**

This information (including, but not limited to, prices, quotes and statistics) has been obtained from sources that we believe reliable, but we do not represent that it is accurate or complete and it should not be relied upon as such. All information is subject to change without notice. This is provided for information purposes only and should not be regarded as an offer to sell or as a solicitation of an offer to buy any product to which this information relates. The Firm, its officers, directors, employees, proprietary accounts and affiliates may have a position, long or short, in the securities referred to in this report, and/or other related securities, and from time to time may increase or decrease the position or express a view that is contrary to that contained in this report. The Firm's salespeople, traders and other professionals may provide oral or written market commentary or trading strategies that are contrary to opinions expressed in this report. The Firm's proprietary accounts may make investment decisions that are inconsistent with the opinions expressed in this report. The past performance of securities does not guarantee or predict future performance. Transaction strategies described herein may not be suitable for all investors. Additional information is available upon request by contacting the Editorial Department at One Federal Street, 37th Floor, Boston, MA 02110.

Like all Firm employees, analysts receive compensation that is impacted by, among other factors, overall firm profitability, which includes revenues from, among other business units, Institutional Equities, and Investment Banking. Analysts, however, are not compensated for a specific investment banking services transaction.

MEDACorp is a network of healthcare professionals, attorneys, physicians, key opinion leaders and other specialists accessed by Leerink and it provides information used by its analysts in preparing research.



For price charts, statements of valuation and risk, as well as the specific disclosures for covered companies, client should refer to <a href="https://leerink2.bluematrix.com/bluematrix/Disclosure2">https://leerink2.bluematrix.com/bluematrix/Disclosure2</a> or send a request to Leerink Partners Editorial Department, One Federal Street, 37th Floor, Boston, MA 02110.

While IMS Health has been used as a source, the analysis contained herein has been arrived at independently by the firm and IMS is not responsible for the analysis or use of the data.

©2014 Leerink Partners LLC. All rights reserved. This document may not be reproduced or circulated without our written authority.

	Loorink Doutness L	I C Equity Bassar	
	Leerink Partners L	LC Equity Researc	cn
Director of Equity Research	John L. Sullivan, CFA	(617) 918-4875	john.sullivan@leerink.com
Associate Director of Research	Alice C. Avanian, CFA	(617) 918-4544	alice.avanian@leerink.com
7.0000.000	7.1100 017.tva.11a.11, 017.t	(017) 010 1011	andela variati e le crimine com
Healthcare Strategy	John L. Sullivan, CFA	(617) 918-4875	john.sullivan@leerink.com
	Alice C. Avanian, CFA	(617) 918-4544	alice.avanian@leerink.com
Biotechnology	Howard Liang, Ph.D.	(617) 918-4857	howard.liang@leerink.com
	Joseph P. Schwartz	(617) 918-4575	joseph.schwartz@leerink.com
	Michael Schmidt, Ph.D.	(617) 918-4588	michael.schmidt@leerink.com
	Gena Wang, Ph.D., CFA	(212) 277-6073	gena.wang@leerink.com
	Paul Matteis	(617) 918-4585	paul.matteis@leerink.com
	Jonathan Chang, Ph.D.	(617) 918-4015	jonathan.chang@leerink.com
	Richard Goss	(617) 918-4059	richard.goss@leerink.com
Life Science Tools	Dan Leonard	(212) 277-6116	dan.leonard@leerink.com
and Diagnostics	Justin Bowers, CFA	(212) 277-6066	justin.bowers@leerink.com
Pharmaceuticals/Major	Seamus Fernandez	(617) 918-4011	seamus.fernandez@leerink.com
	Ario Arabi	(617) 918-4568	ario.arabi@leerink.com
	Aneesh Kapur	(617) 918-4576	aneesh.kapur@leerink.com
Specialty Pharmaceuticals	Jason M. Gerberry, JD	(617) 918-4549	jason.gerberry@leerink.com
Medical Devices, Cardiology	Danielle Antalffy	(212) 277-6044	danielle.antalffy@leerink.com
3,	Puneet Souda	(212) 277-6091	puneet.souda@leerink.com
& Orthopedics	Richard Newitter	(212) 277-6088	richard.newitter@leerink.com
	Ravi Misra	(212) 277-6049	ravi.misra@leerink.com
Healthcare Services	Ana Gupte, Ph.D.	(212) 277-6040	ana.gupte@leerink.com
Healthcare Technology	David Larsen, CFA	(617) 918-4502	david.larsen@leerink.com
& Distribution	Christopher Abbott	(617) 918-4010	chris.abbott@leerink.com
Digital Health	Steve Wardell	(617) 918-4097	steven.wardell@leerink.com
Sr. Editor/Supervisory Analyst	Mary Ellen Eagan, CFA	(617) 918-4837	maryellen.eagan@leerink.com
Supervisory Analysts	Robert Egan		bob.egan@leerink.com
	Amy N. Sonne		amy.sonne@leerink.com
Editorial	Cristina Diaz-Dickson	(617) 918-4548	cristina.diaz-dickson@leerink.com
Research Assistant	Carmen Augustine	(212) 277-6012	carmen.augustine@leerink.com

**New York** 299 Park Avenue, 21<sup>st</sup> floor New York, NY 10171 (888) 778-1653 Boston One Federal Street, 37<sup>th</sup> Floor Boston, MA 02110 (800) 808-7525

San Francisco 201 Spear Street, 16<sup>th</sup> Floor San Francisco, CA 94105 (800) 778-1164