

Presentation of Acne Treatment (Improved New Drug)

2023. 05. 09.



ArcaEir Pharmaceutical Inc.

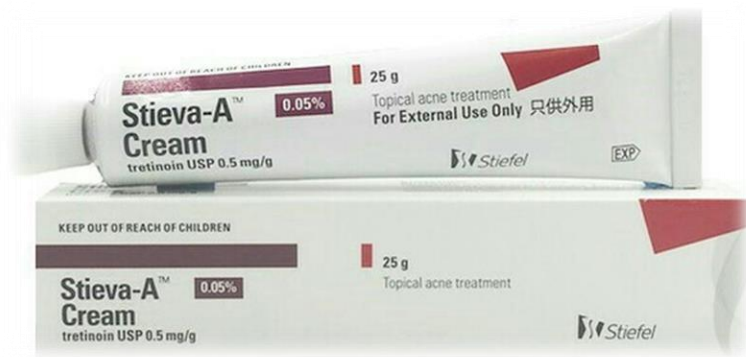


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Prescription (ETC)



Tretinoin

VS

Prescription (ETC) & Non-Prescription (OTC)



Tretinoin Potassium Salt



Acne Treatment Market

Regions	Revenue Share
North America	44.70%
Asia Pacific	17.40%
Europe	27.20%
Latin America	6%
MEA	4.70%

Acne Treatment Market Share, By Region, 2021 (%)

Fortune Business Insights

U.S. acne treatment Market

2021 : USD 4.27 billion

2022 : USD 4.50 billion **CAGR : 4.5%**

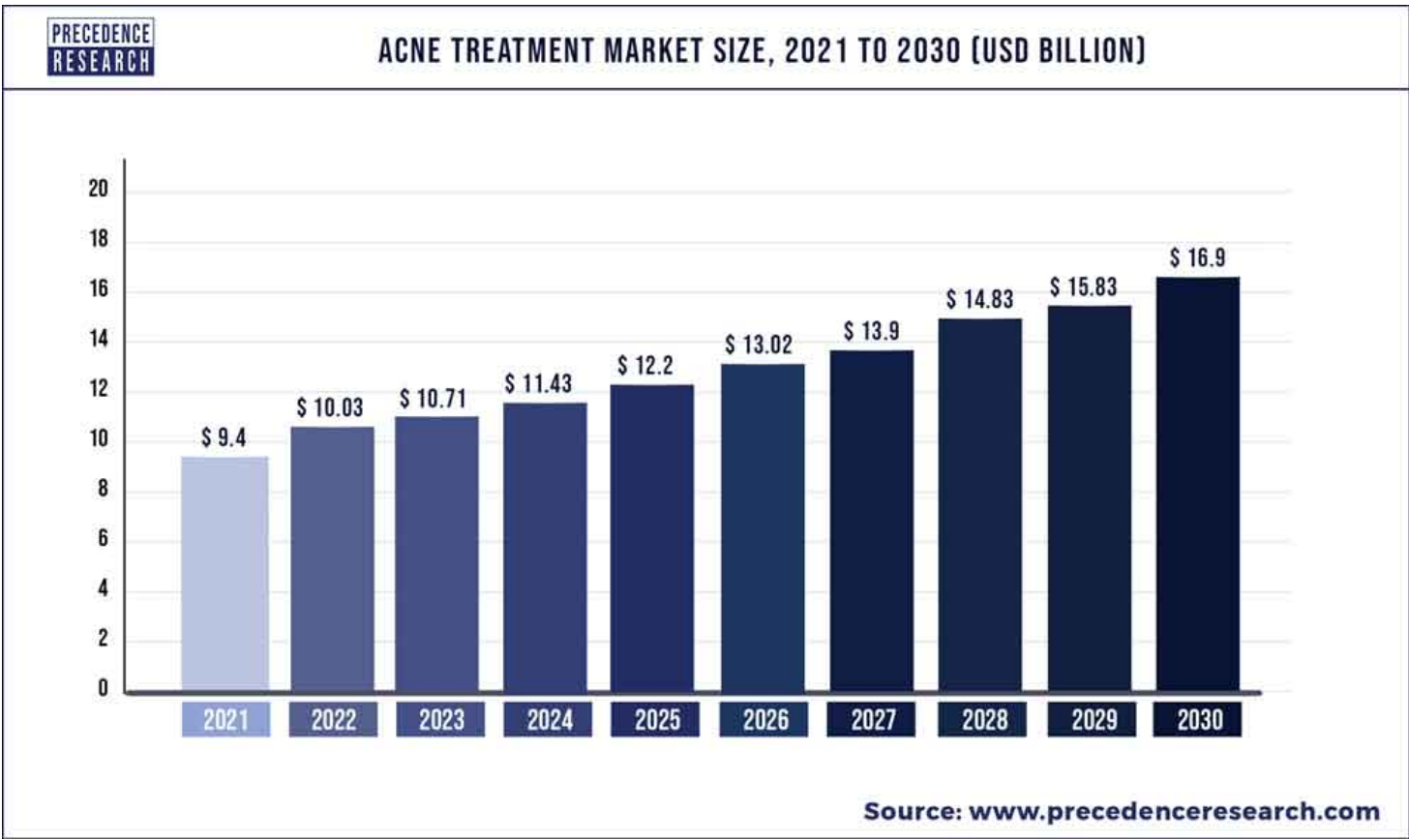
2029 : USD 6.12 billion

Global acne treatment OTC Market

2021 : USD 8.99 billion

2022 : USD 9.36 billion **CAGR : 4.8%**

2029 : USD 12.97 billion



Retinoids Acne Treatment Coverage

ETC

ETC & OTC

OTC



- Non-Prescription : Not to Use
- Prescription : Over 12
- Stieva-A® Cream :
Tretinoin 0.025 ~ 0.1%
- FDA approved : 12/1998
- Improvement effect : 6 weeks/ED



- **Non-Prescription : Over 12**
- **Prescription : Under 12**
- **TPS F-2 : Tretinoin Potassium Salt
0.025 ~ 0.1%**
- **FDA approved : 06/2025**
- **Improvement effect : 6 weeks/ED**



- Non-Prescription : Over 12
- Prescription : Under 12
- Differin® Gel : Adapalene 0.1%
- FDA approved : 07/2016
- Improvement effect : 12 weeks/ED



Acne medication side effects (Adverse Events : AEs)

❖ Cause : Residual skin surface components (RSSC)

		RSSC (mg/cm ²), mean ± SD		
Groups	n	Males	Females	All
White	135	0.09 ± 0.05	0.10 ± 0.07	0.10 ± 0.06
Asian	97	0.12 ± 0.07	0.13 ± 0.08	0.12 ± 0.07
African	34	0.18 ± 0.07	0.12 ± 0.07	0.13 ± 0.07

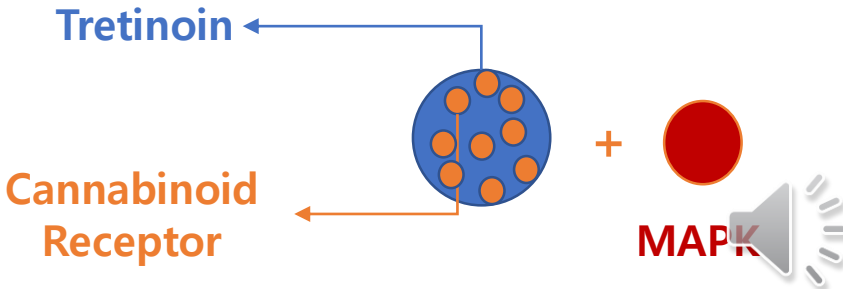
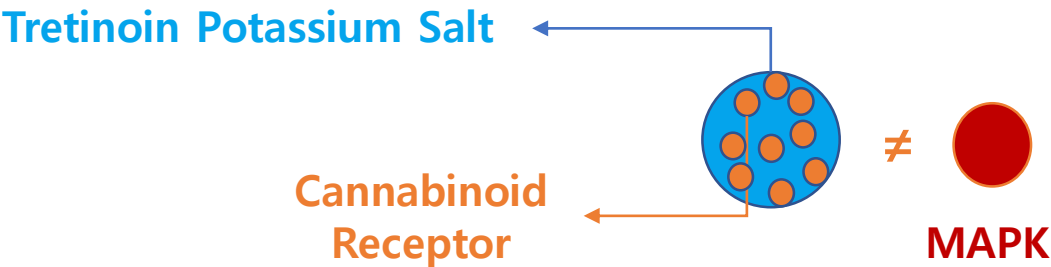
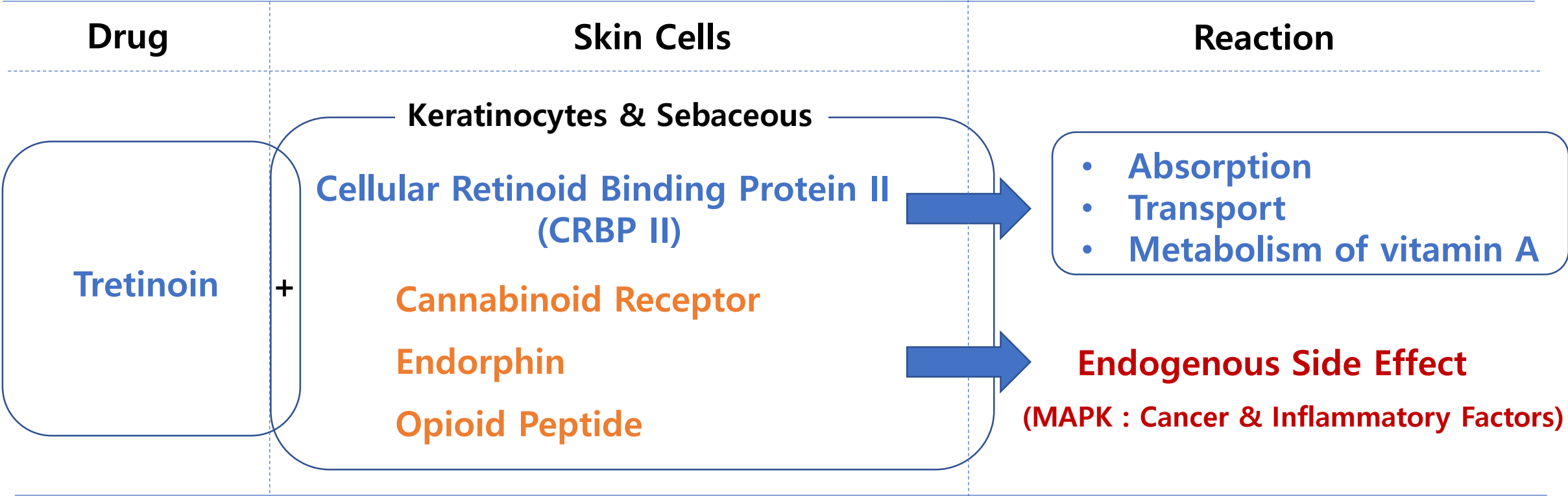
RSSC = White < Asian < African

Sour: Satyajit S. Shetage,Matthew J. Traynor,Marc B. Brown,Mahad Raji,Diepiriye Graham-Kalio,Robert P. Chilcott, Effect of ethnicity, gender and age on the amount and composition of residual skin surface components derived from sebum, sweat and epidermal lipids, Skin Research and Technology 2014;20:97–107, doi: 10.1111/srt.12091.




Reasons for Side Effects of Tretinoin Acne Treatment Products

❖ Tretinoin (atRA) Pathological findings of side effects




Development of tretinoin potassium salt formulation TPS-F2

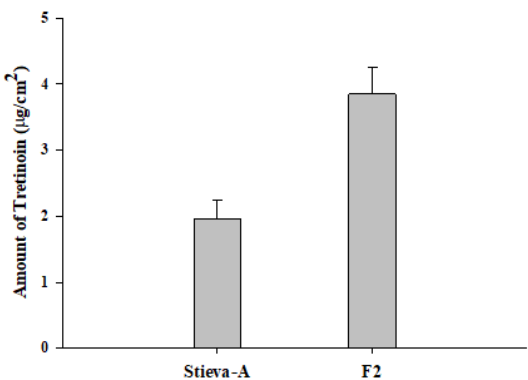
❖ TPS-F2 Cram(ArcaEir)

	API	Name	Wight (g)	Content (%)
	Main Ingredient	Tretinoin Potassium salt	0.0125	0.05
	Preservative	Benzoic acid (influenza virus inhibit)	0.025	0.1

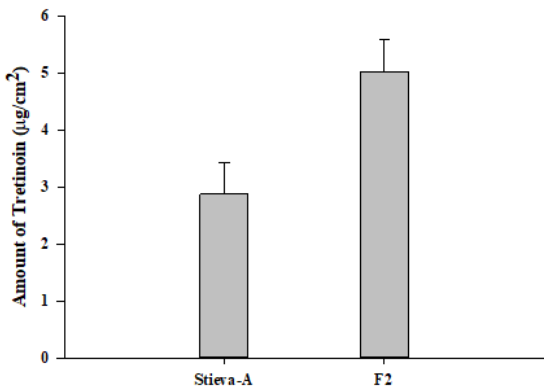
❖ Stieva-A® Cram(GSK)

	API	Name	Wight (g)	Content (%)
	Main Ingredient	Tretinoin	0.0125	0.05
	Preservative	Propylparaben Methylparaben	0.5	2
			2.0	0.8

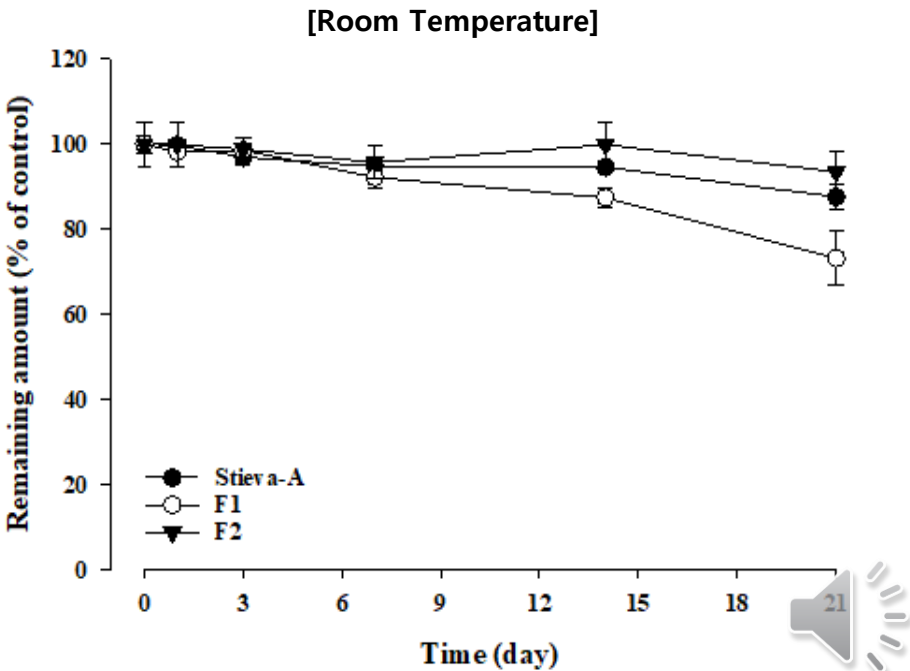
<Residuals in micropig skin>



<Residues in hairless mice>



<In Vitro Tretinoin Safety Assessment>



Type	Residual amount of tretinoin (µ g/cm²)
Stieva-A	1.77 ± 0.63
TPS-F1	3.41 ± 1.15

Type	Residual amount of tretinoin (µ g/cm²)
Stieva-A	2.87 ± 0.55
TPS-F2	5.02 ± 0.57

Competitiveness against ETC and OTC

❖ Compared to Prescription Drugs

TPS-F2	Vs.	Stieva-A®	Compared
Tretinoin Potassium Salt Water soluble		Tretinoin Fat soluble	Low stimulation
Primary skin irritation index (P.I.I.)			About ½
Skin absorption rate & residual level			About 3 times
Skin inflammation Protein Factor inhibit Skin inflammation Gene inhibit Keratin formation & Collagen destruction genes			30% Higher with QPCR, Western blotting, immunohistochemical staining etc.
Cutibacterium acnes treatment effect			More than 30%

❖ Compared to Non-Prescription Drugs

Tretinoin Potassium Salt 0.025% (TPS-F2)	Vs.	Adapalene 0.1% (Differin® Gel)	Compared
Primary skin irritation index (P.I.I.)			Same index
Bind to Cellular Retinoid Binding Protein II			Adapalene Binding



IP Status

❖ Korean patent

CERTIFICATE OF PATENT

Patent Number 10-2420820

Application Number 10-2022-0036031

Filing Date 2022.03.23.

Registration Date 2022.07.11.

Title of the Invention
Composition for inhibiting skin inflammation comprising Tretinoin Potassium Salt as an active ingredient.

Patentee
ArcaEir Inc.(160111-*****)
C-323, Daedeok Biz Center, 17 Techno4-ro, Yuseong-gu, Daejeon

Inventor
Inventors are filled out in a registration page.

This is to certify that, in accordance with the Patent Act, a patent for the invention has been registered at the Korean Intellectual Property Office.



특허청
Korean Intellectual
Property Office

2023.04.19.
COMMISSIONER,
KOREAN INTELLECTUAL PROPERTY OFFICE
이인실



Check your current
registration with QR code



❖ PCT

발급번호 : 5-5-2022-055476182



출원사실증명원
CERTIFICATE OF APPLICATION



출원인 Applicant	성명 Name	(주)아크에어 ARCAEIR CO. LTD.	주민번호 Residence No	
	주소	대한민국 34013 대전광역시 유성구 테크노4로17,대덕비즈니스센터C동323호	전화번호	042-487-2981
	성명 Name	권도형 GWON, Do Hyeong	주민번호 Residence No	
	주소	대한민국 34013 대전광역시 유성구 테크노4로17,대덕비즈니스센터C동323호	전화번호	
	성명 Name	박영식 PAK, Young Sik	주민번호 Residence No	
	주소	대한민국 34013 대전광역시 유성구 테크노4로17,대덕비즈니스센터C동323호	전화번호	
	성명 Name	한보람 HAN, Boram	주민번호 Residence No	
	주소	대한민국 34013 대전광역시 유성구 테크노4로17,대덕비즈니스센터C동323호	전화번호	
	성명 Name	신병철 SHIN, Byoung Cheol	주민번호 Residence No	
	주소	대한민국 34013 대전광역시 유성구 테크노4로17,대덕비즈니스센터C동323호	전화번호	
발명자 Inventor	성명 Name	이지은 LEE, Ji Eun	주민번호 Residence No	
	주소	대한민국 34013 대전광역시 유성구 테크노4로17,대덕비즈니스센터C동323호	전화번호	
	성명 Name	박은수 PARK, Eun Soo	주민번호 Residence No	
	주소	대한민국 34013 대전광역시 유성구 테크노4로17,대덕비즈니스센터C동323호	전화번호	
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성명 Name	권도형 GWON, Do Hyeong	주민번호 Residence No	
주소	대한민국 34013 대전광역시 유성구 테크노4로17,대덕비즈니스센터C동323호	전화번호	
대리인 Agent	성명 최석진	대리인 번호	9-2011-000352-2
주소	대한민국 35214 대전광역시 서구 대덕대로325, 1501호		
출원번호 Application Number	PCT/KR2022/009745	출원일자 Filing Date	2022년 07월 06일 JUL 06, 2022
발명(고안)의 명칭, 디자인을 표현할 물품, 상품(서비스업)류 구분	TRETINOIN POTASSIUM SALT를 유효성분으로 포함하는 피부염증 억제용 조성물		
Title of Invention, Product(s) Embodied in Design, or Classification of Mark			
용도	확인용	IPC 분류	
최종처리상태		최종처리일	
위 사실을 증명함. This is to certify that the above applicant has filed as stated in this certificate at the Korea Intellectual Property Office			
2022년 11월 01일 특허청 COMMISSIONER			

◆본 증명서는 인터넷으로 발급되었으며, 특허청 홈페이지(www.kipo.go.kr)의 '특허권·증명서 발급' 메뉴를 통해 발급번호 또는 문서제언의 바코드로 내용의 위·변조 여부를 확인해 주십시오. 단, 발급번호를 통한 확인은 90일까지 가능합니다.

Tretinoin Potassium salt –F2 IMD data submission scope in Korea

Regulations on pharmaceutical manufacturing and quality control [Ministry of Food and Drug Safety in Korea Notice No. 2021-87, November 4, 2021, partially revised]








Incrementally Modified Drugs : Drugs that slightly modify the structure, formulation, or use of existing drugs

1	2				3		4			5			6		7	8
	A		B		B		F			A	B	C	A	B		
	1) ~ 7)	8)	1 ~ 2)	3) ~ 7)	1)	2)	1)	2)	3)							
○	○	X	△	○	○	X	△	△	△	△	△	△	○	X	○	○

- Data on the origin or discovery and development of No. 1 : Completed
- **Items A and B of No. 2 : Development of DS & DP production and quality control technology in progress**
- **Item 3 B : DS & DP stability data development in progress**
- Item 4, 5 toxicity and pharmacological action cell and animal test evaluation data: completed
- Item No. 6 (Clinical plan) : completed
- Item No. 7 (Data on the status of use in foreign countries, etc) : Completed
- Item No. 8 (Comparative review with domestic similar products and data on the characteristics of the drug) : completed

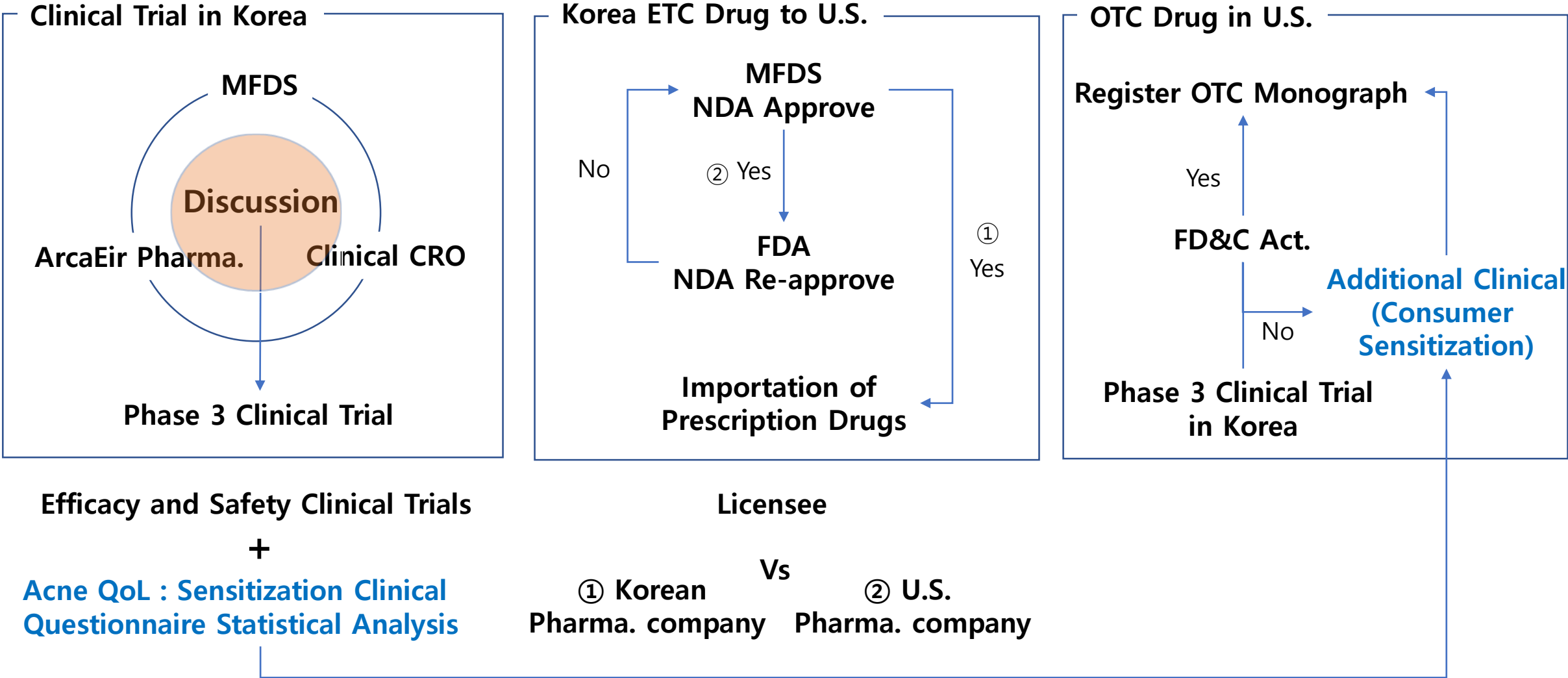


Market Development Strategy

License Share 40%(licenser) 60%(licensee)	ETC in Korea				OTC in U.S.		
							
Term	1H / 2023	2 nd / 2023	1H / 2024	2 nd / 2024	1H / 2025	2 nd / 2025	1H / 2026
Cost	USD100,000						
		USD300,000					
			USD4,000,000 (in Korea)	USD100,000 (ETC)		USD1,000,000 (in U.S.)	
Revenue					USD12 Million rNPV: 30 Million		USD40 Million rNPV: 100 Million



Risks and Barriers



※ Main activity : Participating to the pharmaceutical for contact Big Pharma

Early stage drug development company

C.E.O.

Byong-Cheol Shin

USA

Suite 100, 600 Jefferson Street, Rockville, MD 20852, USA

Korea

#205, Building D, 17, Techno 4-ro, Yuseong-gu, Daejeon (Gwanpyeong-dong, DaedeokBiz Center)

Established

2013. 06. 28

Patents

16 patent registrations (including 1 US registration), 2 PCT applications

Staffs

8 people

Certifications

Organ On-chip Monitoring System KC Certification

R&D Team

Byong-Cheol Shin

- Education
 - Graduated from Emory University Medical School
 - US UGA Ph.D. Economics
- Major Career
 - 3 years at dispatched to the US CDC
 - 10 years at Ministry of Food, Agriculture, Forestry and Fisheries in Korea

Young-Sik Park

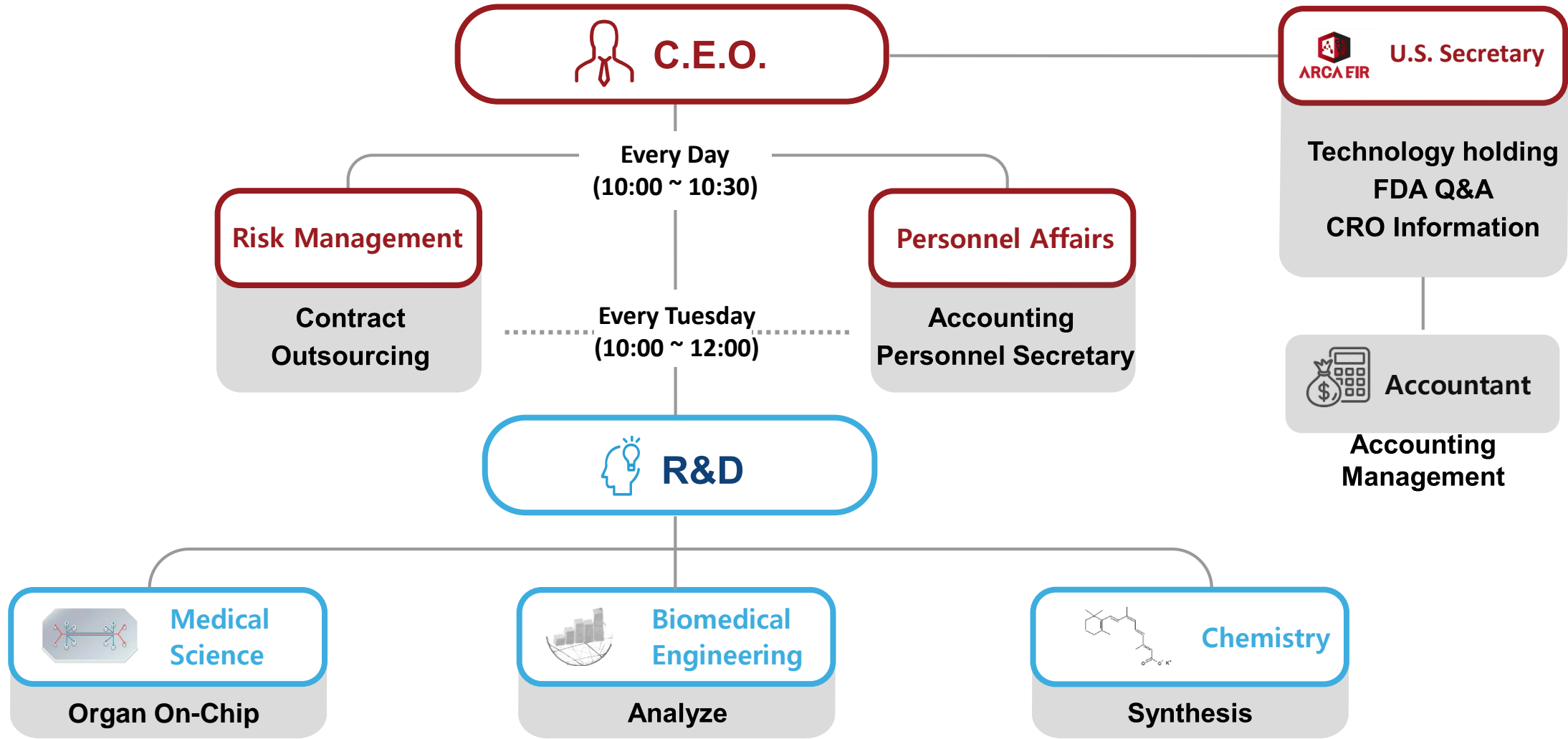
- Education
 - Ph.D., Chungnam National University (Biomedical Engineering)
- Major Career
 - 2 years at Chungnam National University Analysis Center
 - 3 years at Korea Basic Science Institute
 - 6 years at ArcaEir Pharmaceutical Inc.

Do-Hyung Kwon

- Education
 - Master's degree at Chungnam National University (Medicine/Science)
- Major Career
 - 2 years at Ajou University Hospital
 - 5 years at ArcaEir Pharmaceutical Inc.



Organization : Team / Company Status



Thank you

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