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APIMEDS Pharmaceuticals US, Inc.

JANUARY 2022

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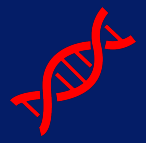
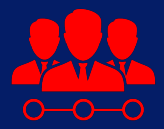
APIMEDS PHARMACEUTICALS US (APUS): AT A GLANCE

We are a clinical stage biotechnology company focused on the development and commercialization of Apitox in the United States for the treatment of quality of life symptoms and pain associated with Multiple Sclerosis

- **Headquarters:** Hopewell, NJ
- **Wholly Owned by:** Apimeds Inc. (Korea), its parent company (Inscobee Inc.) and Officers and Directors
- **US Subsidiary Established:** May 2020



Technology: Our lead candidate is an injectable, lyophilized, sterile Active Pharmaceutical Ingredient (API) derived from the venom of *Apis mellifera*, or honey bee. Numerous fractions of venom have therapeutic effects on many autoimmune diseases based on its biochemical properties.



Clinical Pipeline: Approved for use by the Korean FDA in 2003 for the treatment of pain associated with osteoarthritis under the brand, Apitoxin. Apimeds Pharmaceuticals has an approved US FDA Investigational New Drug (IND) and protocol for a Phase III trial to demonstrate improvements in Quality of Life (QoL) and pain in Multiple Sclerosis (MS). Clinical experience provides insight and confidence to the potential efficacy trial other indications.

Status: APUS has agreements for manufacturing of drug product and execution of the Phase III clinical. APUS has secured agreements with a global Contract Manufacturing Organization (CMO) based in the USA and a global Contract Research Organization (CRO) for the execution of the clinical trials.

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MANAGEMENT & BOARD

CHRIS **KIM**
(Founder, Chairman & CMO)

Professor and Medical Practitioner
Pain Medicine & Biotherapy Specialist
Author, Bee Venom Therapy
Experienced MS Therapy with Bee Venom over 20 years in the US

SCOTT **HOLLANDER**
(CEO & Director)

30 years of experience in pharmaceuticals and medical devices. Leadership roles with Mallinckrodt, Bracco and Otsuka

MICHAEL ROONEY, PHD
(Chief Development Officer)

25 years of drug development experience. Clinical Scientist & Lead Medical/Regulatory Writer with Linical Americas. Senior Medical Writer with Pfizer & Pharmacia

ROBERT **BROOKS,** PHD
(Chief Operating Officer)

40+ years in the pharmaceutical industry with positions at the FDA, Walter Reed and Tamara Industries. Warren Foundation Grant Senior Fellow, Center for Biologic Evaluations and Research FDA

JAKAP **KOO** - DIRECTOR
(CEO & President, Apimeds Korea/Inscobee)

35 years as C-level executive in financial institutions and IT companies. Management and operational experiences in banking, asset management, VC, PE and biotech companies. Stern School of Business, NYU

HYUKJAE **LEE** - DIRECTOR
(CFO, Apimeds Korea/Inscobee)

Roles at BIEMT, Samil PricewaterhouseCoopers, Samsung Electronics, and Morgan Stanley. Univ. of California, Berkeley

IN SOO **YOU** - DIRECTOR
(Chairman, Apimeds Korea)

30 years executive, fund manager LG Securities. 20 years as a strategic investor. Wharton, Univ. of Pennsylvania

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APITOX DEVELOPMENT PIPELINE

APUS – DEVELOPMENT PIPELINE

Disease	Pre-Clinical	Clinical Trial			Status
		Phase 1	Phase 2	Phase 3	
Multiple Sclerosis	→	→	→		IND# 122804 Approved Protocol

APUS HAS THE OPTION TO DEVELOP APIMEDS (KOREA) R&D PIPELINE IN THE USA

Disease	Pre-Clinical	Clinical Trial			Approval
		Phase 1	Phase 2	Phase 3	
Rheumatoid Arthritis	→				
Pain (Other)	→				
Lupus	→				
Psoriasis	→				
Nano Technology Melittin Breast Cancer*	→				

* In-vitro efficacy testing and formulation research.

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MULTIPLE SCLEROSIS BASICS

- Multiple sclerosis (MS) is an autoimmune disease that primarily impacts women (73%) between the ages of 20 and 50[1]
- MS is an autoimmune disease in which your own immune cells attack your central nervous system (CNS)[2]
- MS causes immune mediated damage to the myelin sheaths that protect neurons, causing pain, fatigue, and a range of other neurological symptoms[3]
- Disease modifying agents such as Beta Interferons have improved the outlook for MS patients, especially those with the relapsing / remitting (RRMS) form of the disease[4]
- However, the vast majority of patients, continue to have symptoms[5]
- No drugs are approved for pain specific to MS
- Acorda's Ampyra and its generic are the only supportive care pharmaceuticals approved for QoL symptoms in MS

Symptoms, Comorbidities, and Effects on MS That Can Diminish Quality of Life in MS Patients[3]

Common	Rare
Gait and mobility impairments	Speech disorders
Fatigue	Difficulty swallowing
Spasticity	Hearing loss
Muscle weakness	Headache
Pain	Itching
Impaired balance and coordination	Tremors
Cognitive dysfunction	Breathing difficulties
Bladder and bowel dysfunction	Seizures
Paresthesias	
Loss of sensation/numbness	
Sexual dysfunction	
Vertigo, dizziness	
Vision impairments (eg, optic neuritis)	
Depression	
Anxiety	
Reduced employment or unemployment	

1. Wallin, Mitchell T. "The prevalence of MS in the United States: A population-based estimate using health claims data." Neurology. February 2019. Neurology
2. https://www.mayoclinic.org/diseases-conditions/multiple-sclerosis/symptoms-causes/syc-20350269
3. Am J Manag Care. 2011 May;17 Suppl 5 Improving:S139-45.Improving quality of life in multiple sclerosis: an unmet need. Howard L Zwibel Jennifer Smrtka
4. Alroughani et al. Neurol Ther. 2019 Jun; 8(1): 13–23. Published online 2019 Mar 15. doi: 10.1007/s40120-019-0129-0
5. Zwibel HL. Contribution of impaired mobility and general symptoms to the burden of multiple sclerosis. *Adv Ther*. 2009;26(12):1043-1057

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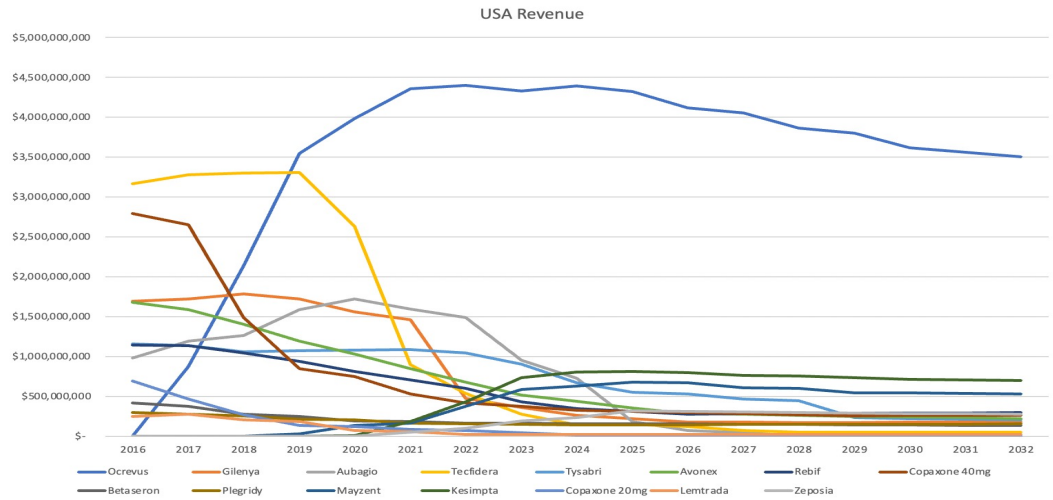
MULTIPLE SCLEROSIS MARKET OPPORTUNITY

- Approximately 1 million people in the US have MS, with prevalence increasing[1]
- The 2021 market opportunity for pharmaceuticals treating the progression of MS is approx. $20.56 B with seven products with sales in excess of $1.0B annually[2]
- Disease modifying agents improve outcomes for patients with (RRMS) Relapsing / Remitting MS, the most common form[3]
- Manifestations effecting QoL, such as fatigue, weakness, unstable gait, spasm and bladder control, are not addressed by current therapies, with the exception of gait and balance improvement for which Ampyra is approved[4]

Historical and Projected Revenues for Disease Modifying Pharmaceuticals for MS

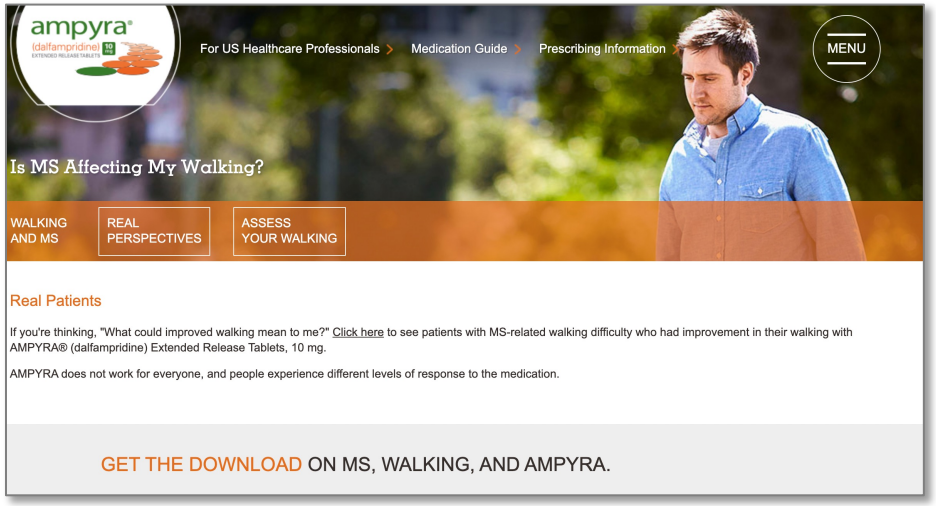


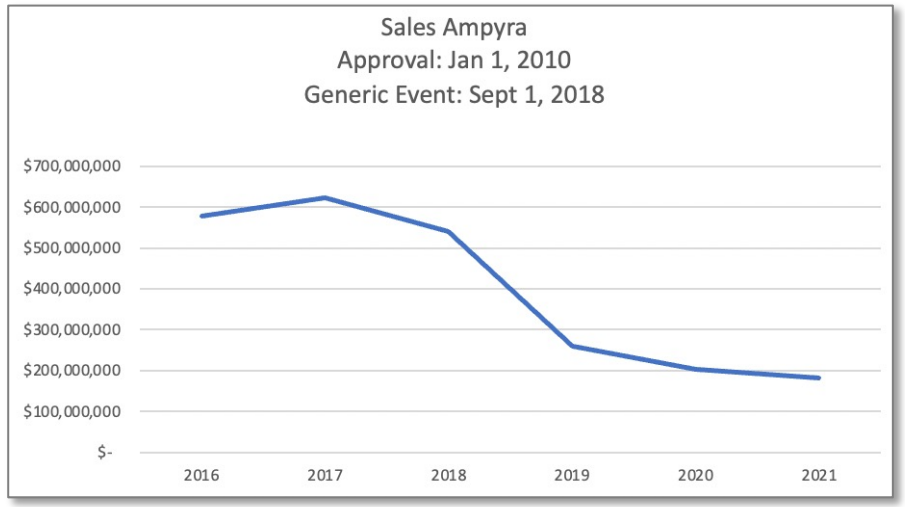
Source: Inthought Research (September 15, 2021)

1. Wallin, Mitchell T. "The prevalence of MS in the United States: A population-based estimate using health claims data." Neurology. February 2019. Neurology
2. Source: Inthought Research (September 15, 2021)
3. National MS Society, https://www.nationalmssociety.org/Treating-MS/Medications
4. Ampyra® Package Insert 11/21

COMMERCIAL SUCCESS OF BRANDED AMPYRA®

- Amprya is the only approved pharmaceutical addressing QoL issues in MS patients
- Approved for a **single** indication
  - *AMPYRA® (dalfampridine) is a potassium channel blocker indicated to improve walking in adult patients with multiple sclerosis (MS). This was demonstrated by an increase in walking speed*





Sources: Ampyra® is property of Acorda Therapeutics ; Inthought Research (September 15, 2021)

APITOX AND UNMET NEED FOR SYMPTOMS ASSOCIATED WITH MS

Quality of Life Improvement A Clear Unmet Need

- Current pharmaceuticals, such as interferon based agents, treat the progression of the disease and the reduction of the occurrence of exacerbations (Relapse)
- One agent, Ampyra, addresses only ONE symptom associated with MS QoL, gait and balance improvement
- The National MS Society, based on information from the MS community, highlighted four symptoms of particular interest to MS patients: fatigue, mobility and upper extremity impairment, pain, and cognitive impairment[1]
- APITOX(IN) demonstrated improvement in mobility and pain in a Phase III Osteoarthritis trial
- Our APITOX clinical Phase III trial will study multiple QoL improvements in MS patients
- During the Phase III MS trial, patients will continue existing therapies while taking APITOX

Source: Mult Scler. 2021 Jun; 27(7): 989–1001. Published 2021 Mar 15. KM Zackoski et al.

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APITOX(IN) - DEMONSTRATED SAFETY AND EFFICACY IN PHASE III OSTEOARTHRITIS (OA) TRIAL

- Phase III clinical trial randomized 538 patients
- Patients treated with Apitox(in) demonstrated significant improvement versus control in WOMAC pain score (p=0.0057) that resulted in highly significant improvements in their self-assessed OA condition: Patient Global Assessment (PGA); p=0.0001
- The VAS pain score improved significantly versus control while walking (-4.8 vs. -2.9; p=0.001)
- The physician global assessment (PhGA) and patient global assessment of OA condition showed more favorable improvement (”very good/good”) with HBV versus Control (82.1% versus 54.9%; p=0.0015).
- In conclusion, the Phase III trial demonstrated that HBV biotherapy had superior and sustained improvement over control in reducing knee OA pain and functional impairment

THE JOURNAL OF ALTERNATIVE AND COMPLEMENTARY MEDICINE
Volume 00, Number 00, 2019, pp. 1–11

DOI: 10.1089/acm.2019.0121

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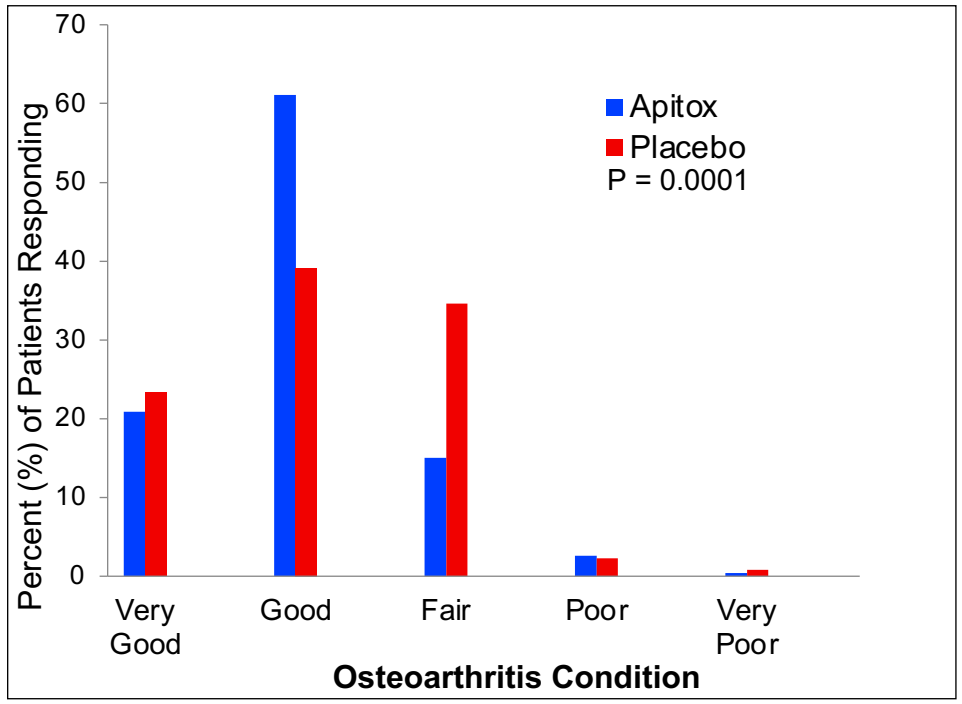

Patient Global Assessment (PGA); p=0.0001

WOMAC: Western Ontario and McMaster Universities Osteoarthritis Index; HBV: Honey Bee Venom ; VAS: Visual Analog Scale PGA: Patient Global Assessment
Source: Efficacy and Safety of Honey Bee Venom *(Apis mellifera)* Dermal Injections to Treat Osteoarthritis Knee Pain and Physical Disability: A Randomized, Active-Controlled Trial
Vicki J. Conrad, MD , Lydie L. Hazan, MD, Agustin J. Latorre, MD, Anna Jakubowska, MD, and Christopher M.H. Kim, MD

POTENTIAL BENEFITS OF APITOX IN MULTIPLE SCLEROSIS PATIENTS - IMPROVEMENT IN QOL SYMPTOMS COMMON IN MS PATIENTS

Pain

Pain sensations like burning, stabbing, sharp and squeezing sensations. In **MS** you can experience acute neuropathic **pain** and chronic neuropathic **pain**.

Extreme Fatigue

MS fatigue is different from regular **tiredness**. Described as **feeling** like you're **weighed down** and every movement is difficult or clumsy.

Weakness

MS patients also experience muscle **weakness** along with spasticity. Spasticity in **MS** usually affects the legs more than the arms, and it can affect standing, walking, and transferring.

Unstable Gait/Balance

Difficulty in walking - also known as **problems with gait** - is among the **most common** mobility limitations in MS.

Bladder Control

Bladder dysfunction happens when **MS lesions block or delay** transmission of nerve signals in areas of the central nervous system (CNS) that **control** the **bladder** and urinary sphincters.

Involuntary Spasm

It is one of the more common symptoms of **MS**. **Spasticity** may be as mild as the feeling of tightness of muscles or may be so severe as to produce painful, uncontrollable **spasms of extremities**, usually of the legs.

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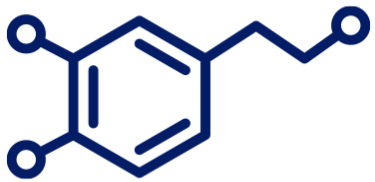
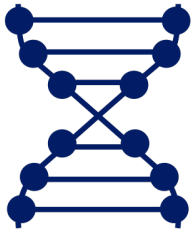
APITOX – BASIC PHARMACOLOGY

Bee venom's analgesic and anti-inflammatory effects as well as its safety has been documented in well controlled, statistically significant clinical studies and used globally for centuries



7 Active Amines

- Histamine
- Dopamine
- Norepinephrine
- Glucose and Fructose
- 6 Phospholipids
- r-aminobutyric acid
- b-aminoisobutyric acid

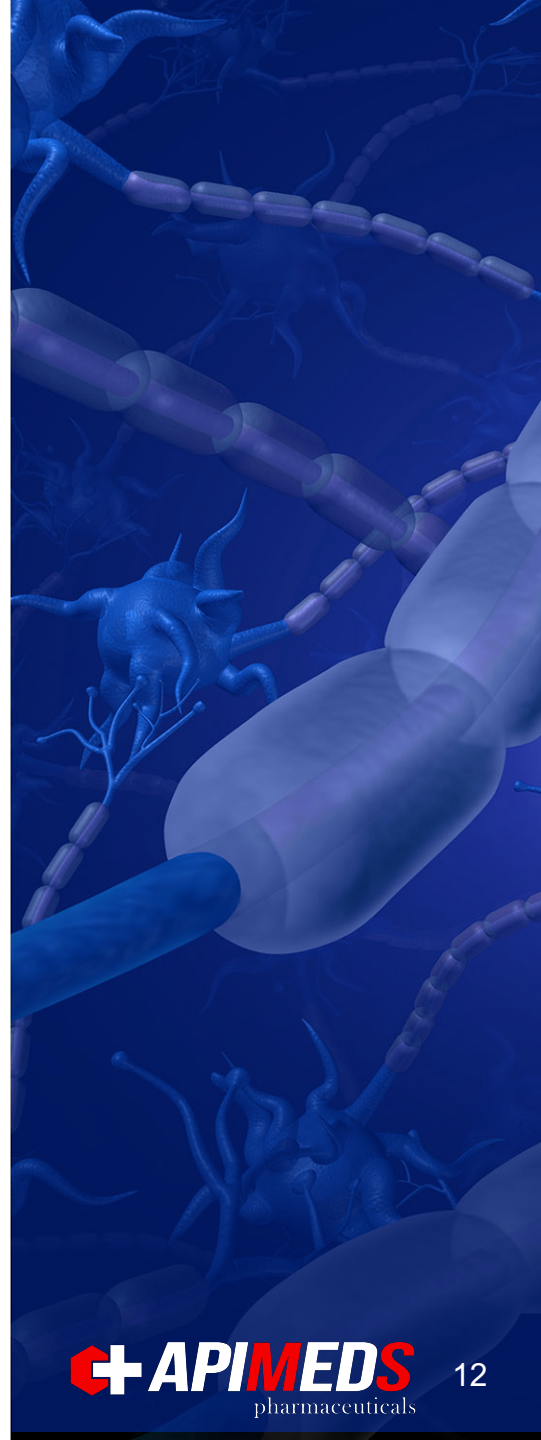


5 Active Enzymes

- Hyaluronidase
- Phospholipase
- -D-Glucosidase
- Acid phosphomonoesterase
- Lysophospholipase

10 Active Peptides

- Melittin
- Apamin
- MCD Peptide
- Adolapin
- Protease inhibitor
- Secarpin
- Tertiapin
- Melittin F
- Procamine A,B
- Minimine

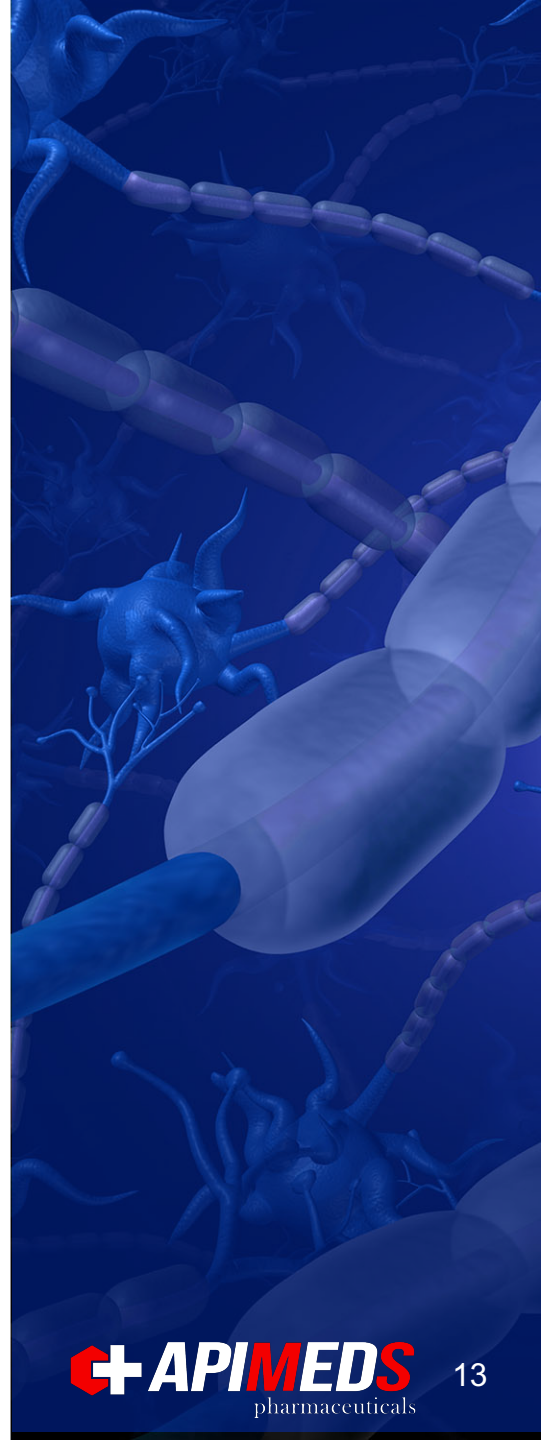


APITOXIN / APITOX – EXTENSIVE CLINICAL DEVELOPMENT HISTORY

Demonstrated efficacy and positive long-term safety profile

	Phase 1	Phase II	Phase I	Phase III	NDA (KFDA)	Phase II	Phase IV*	Phase II	FDA/Phase III Osteoarthritis
Company/ Investigator	Brando Pharma/ Chris Kim, MD	Brando Pharma/Guiu Pharma	Hauser et al Altern Compl Ther.	Guiu Pharma Apimeds Korea	Guiu Pharma Apimeds Korea	Wesselius et al Neurology MS Society Sponsored Study	Guiu Pharma Apimeds Korea	Apimeds Korea	Apimeds Korea
Indication	Osteoarthritis Mobility/Pain	Osteoarthritis Mobility/Pain	Multiple Sclerosis	Osteoarthritis Mobility/Pain	Osteoarthritis Mobility/Pain	Multiple Sclerosis	Osteoarthritis Mobility/Pain	Osteoarthritis Mobility/Pain	Osteoarthritis Mobility/Pain
Year	1994	1996	2001	2002	2003	2005	2003-2009	2011	2016
Subjects	20	161	51	407	N/A	26	3,194	40	330
Design	Toxicity and Safety	Efficacy and Safety	Safety and Efficacy	Efficacy and Safety	Regulatory Submission	Safety and Efficacy	Post Marketing Safety	Efficacy and Safety	Efficacy and Safety
Results	No Neg Safety Signals	Improvement in mobility and pain reduction	Improvement in MS fatigue, endurance, balance, bladder control, coordination No Serious Adverse Events	Improvement in OA mobility and reduction in pain	Approved	Mean Improvement in MS Functional Composite symptoms No Serious Adverse Events	No Serious Adverse Events No negative safety signals	No Serious Adverse Event Improvement of OA Symptoms	Improvement in OA mobility and reduction in pain
Statistical and Clinical Significance	No Negative Safety Signals	Significant reduction in pain and disability (p = 0.0177)	MS Outcome Improved: 35 patients No Improvement 16 Patients	Significant reduction in pain and disability (p = 0.0019	N/A	MS Functional Composite Baseline -0.85 ± 1.41 Venom -1.12 ± 1.95	No Serious Adverse Events	Significant pain reduction (p = 0.0355) Apitox vs Control	Significant pain reduction (p = 0.0057) with Apitox dose vs Placebo

*Apimeds, Inc. (Korea) KFDA Post Approval Safety Surveillance Study 2003-2009
Submitted to US FDA. Update Korean Safety Report Annually with FDA.



IMPROVEMENT IN RELATED OBSERVABLE SYMPTOMS SCALE IN MS PATIENTS TREATED WITH BEE VENOM

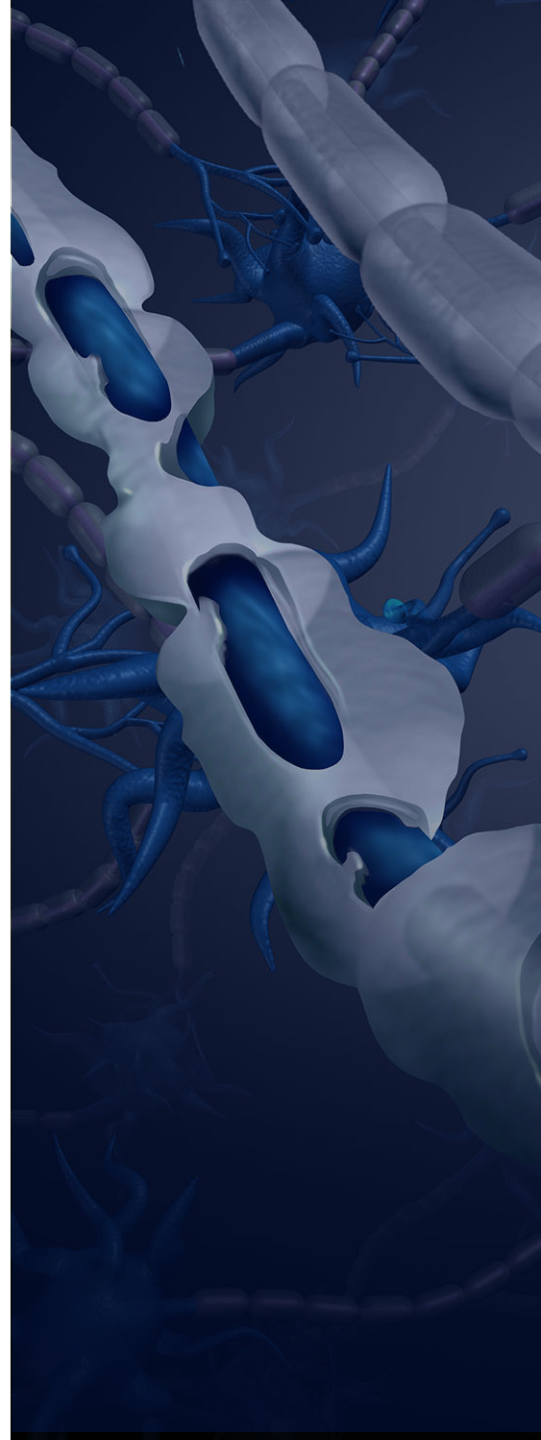
- Descriptive analysis of the ROSS clinical outcomes showed that more than 68% of MS patients showed some kind of positive improvement in disability (dramatic, good or minimal) and 58% demonstrated a marked improvement (dramatic or good)

Table A. Summary of Patient Disability Improvement to Bee Venom Treatment Using the Related Observable Symptoms Scale (ROSS)

	N	% of Participants	Follow-up Survey (% improvement)	Related Observable Symptoms Scale (points improvement)
Dramatic	15	29.4%	>30%, or	>12 points
Good	15	29.4%	10–29%, or	7–12 points
Minimal	5	9.8%	<10%, or	<7 points
None	15	29.4%	<2%, or	< 2 points
Negative	1	2.0%	Any total negative response	Any total negative response

After 1 year of bee-venom injections, 68.6 percent of participants showed improvement. N = number of participants.

Ref: Hauser RA, Daguio M, Wester D, Hauser M, Kirchman A, Skinkis C. Bee venom therapy for treating multiple sclerosis: A Clinical Trial. Altern Complement Ther. Feb 2001; 7:37-45.



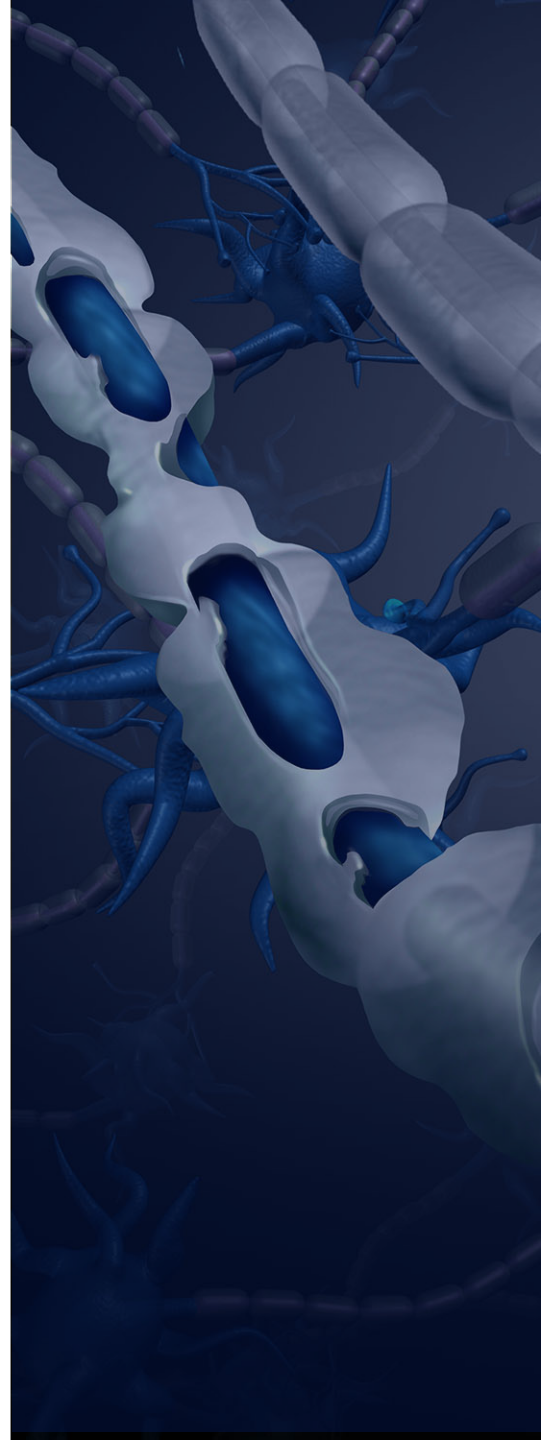
MULTIPLE SCLEROSIS FUNCTIONAL COMPOSITE (MSFC) SCORE IMPROVEMENT[1]

- As expected, Table B shows little change in Expanded Disability Status Scale (EDSS) score while the MSFC score shows an overall clinically notable improvement, influenced predominantly by improvements (negative scores) in leg and arm function (i.e. decreased z-score): almost 32% from baseline to bee sting treatment (-0.85 to -1.12) and about 44% from no treatment to bee sting treatment (-0.78 to -1.12)
- While this pilot study indicates effectiveness of bee venom treatment in MS, the size of the pilot study dictates the need for a larger well-controlled Phase III trial which we plan to conduct

Table B. Summary of Improvement in Patient Disability and Fatigue Following Bee Sting Therapy Utilizing the EDSS and MSFC

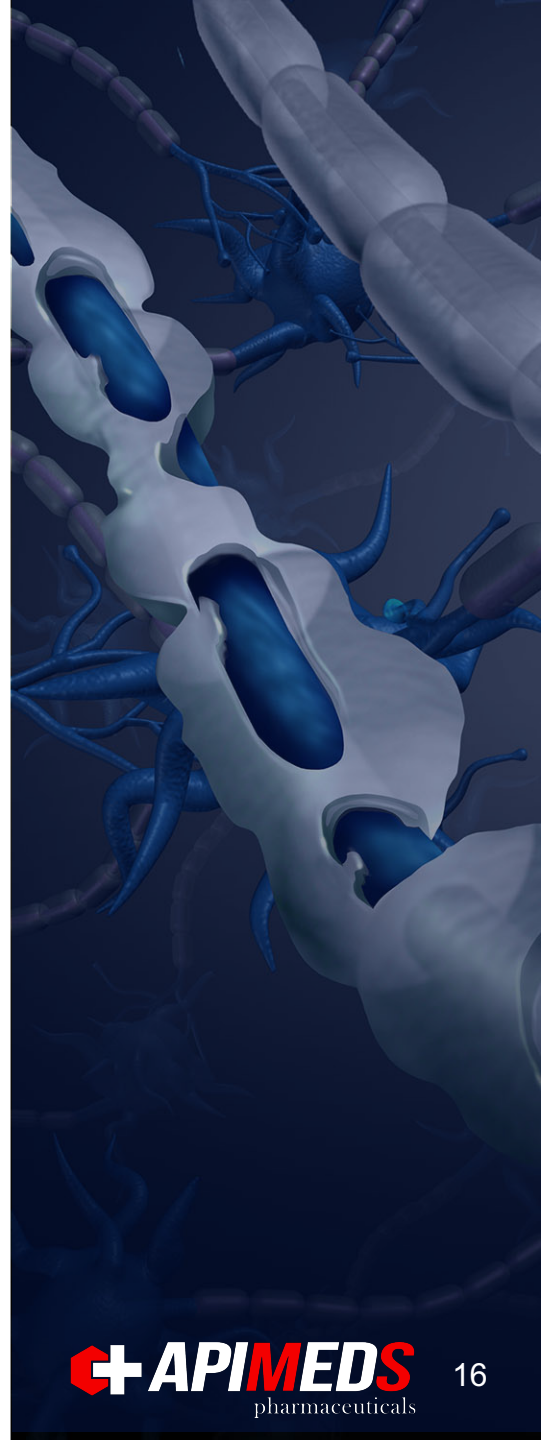
Finding	Bee sting therapy first, then off treatment n=12	No treatment first, then bee sting therapy n=13	Overall n=25
Expanded Disability Status Scale			
Baseline	4.9 ± 1.6	5.7 ± 1.6	5.2 ± 1.7
Bee sting period	4.8 ± 1.8	6.0 ± 1.0	5.4 ± 1.5
No treatment period	4.7 ± 1.8	5.7 ± 1.6	5.3 ± 1.6
Multiple Sclerosis Functional Composite			
Baseline	-1.12 ± 1.9	- 0.58 ± 0.69	-0.85 ± 1.41
Bee sting period	-1.16 ± 2.3	- 1.62 ± 1.61	-1.12 ± 1.95
No treatment period	- 0.89 ± 1.9	- 0.69 ± 1.33	-0.78 ± 1.56

1. Wesselius et.al. A randomized crossover study of bee sting therapy for multiple sclerosis. Neurology. 2005 Dec 13;65(11):1764-8.
Changes are mean ±



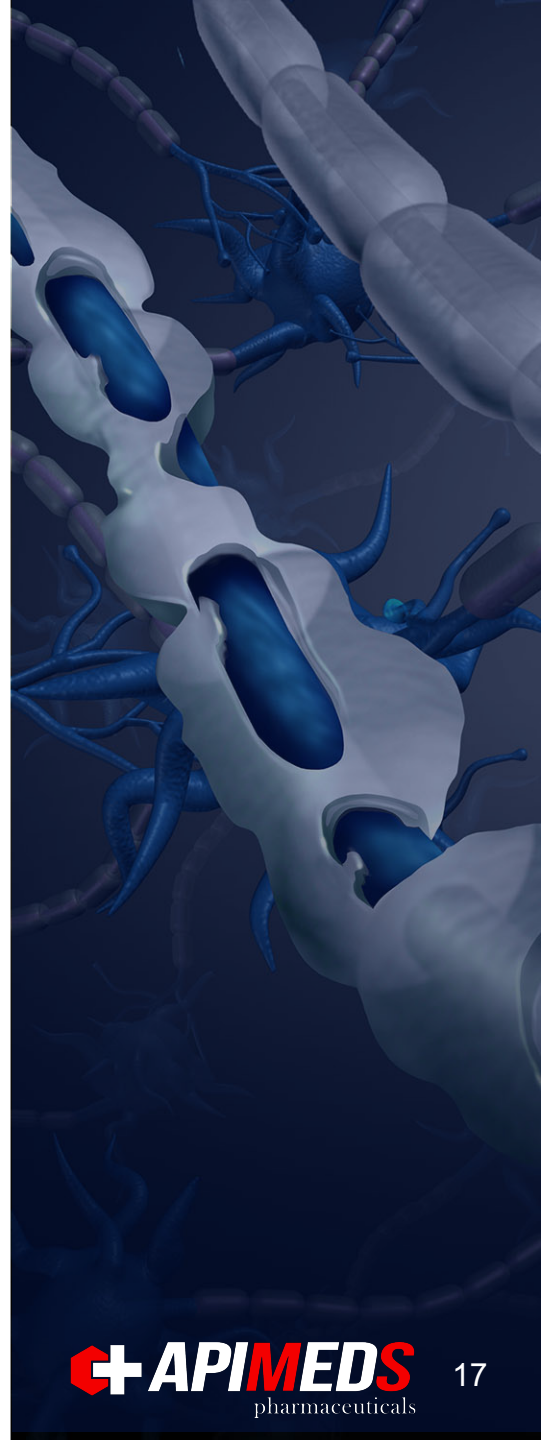
PROPOSED APITOX MS PHASE III TRIAL DESIGN - IND# 122804

- **Protocol Design accepted by FDA's CBER Neurology in 2018**
- **Number of Patients / Arms in each trial (Two trials are required for approval)**
  - 428 patients randomized 1:1
  - Add-on therapy vs placebo
- **Primary Endpoints:**
  - Efficacy: Changes in Expanded Disability Status Scale (EDSS) and Multiple Sclerosis Functional Composite (MSFC) through week 16
  - Safety: Serious adverse events (SAE), adverse events (AE) and tolerability
- **Secondary Endpoints:**
  - Quality of life (MS QoL-54)
  - Functional System Scores (FSS)
  - Progression of Disability Utilizing the change in EDSS and MSFC
  - Pain intensity Numerical Rating Scale (PI-NRS)
  - Patient Global Impression of Pain (PGA)
  - Physicians Global Assessment (PhGA)



ESTABLISHED MANUFACTURING – CLINICAL AND COMMERCIAL

cGMP supplier of Venom (API)	Global Testing and Quality Assurance Company	Global Manufacturer – Drug Product- Clinical and Commercial	Global Contract Research Organization	Global Logistics Provider
Supply of Active Pharmaceutical Ingredient – honey bee venom	**Third Party Quality and Identification of API**	**Drug product manufacturing** ▪ API put into solution ▪ Compounded ▪ Vial fill ▪ Lyophilization ▪ Sterilization ▪ Labeling (commercial)	**Clinical Trials** ▪ All aspects of trial management and execution.	**Labeling (clinical) Distribution to clinical sites Tracking**
Budget Established Agreement in House	Budget Established Agreement in House	Budget Established Agreement in House	Budget Established Agreement in House	Budget Established Agreement in House
Signed	Signed	Pending Signature	Pending Signature	Signed
Venom Harvested	Cell Line Work Underway			Current utilizing storage services



INTELLECTUAL PROPERTY AND PROTECTION

10-year exclusive agreement with only known cGMP supplier of raw bee venom

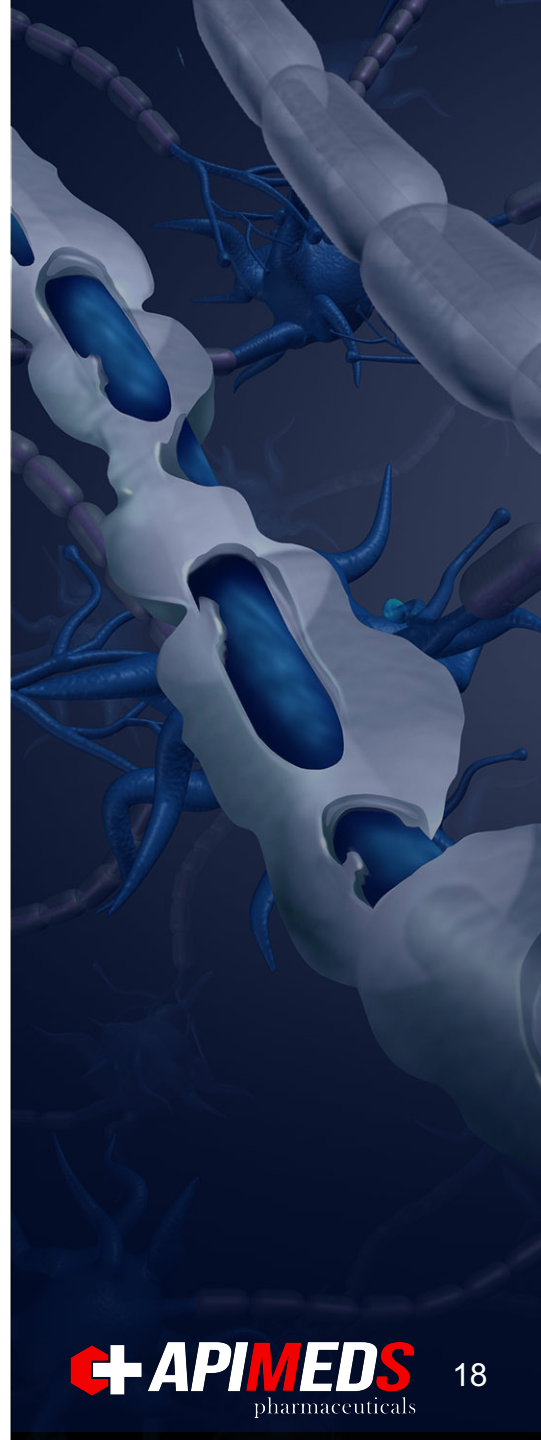
12 proprietary analytical methods for drug identification and potency

Proprietary methods associated with manufacturing raw venom into lyophilized form

Existing 5-year stability data

12-year BLA exclusivity upon approval[1]

1. The Affordable Care Act (PPACA) provides 12 years of exclusivity for approved Biologics License Applications (BLAs). Biologics can also receive orphan drug and pediatric exclusivities.



Thank You

APIMEDS pharmaceuticals

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