



+ **APIMEDS**
pharmaceuticals

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DECEMBER 2020

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APIMEDS PHARMACEUTICALS US (APUS): AT A GLANCE

We are a late stage biotechnology company focused on the development and commercialization of Apitox in the United States

- **Headquarters:** Pennington, NJ
- **Wholly Owned by:** ApiMeds Korea and its parent company (Inscobee Inc).
- **US Subsidiary Established:** May 2020
- **Total Invested Capital in Apitox Globally:** \$41 Million



Technology: Our lead candidate is an injectable, lyophilized, sterile Active Pharmaceutical Ingredient derived from the venom of *Apis mellifera*. The 13 fractions of venom has 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 Osteo Arthritis. Apimeds Pharmaceuticals has an approved US FDA Investigational New Drug (IND) and protocol for a Phase 3 study to demonstrate improvements in Quality of Life and pain in multiple sclerosis. Clinical experience provides insight and confidence to the efficacy of other indications.



Status: APUS has secured agreements for manufacturing, both investigational and commercial quantities, an experienced CRO for the execution of the Multiple Sclerosis clinical study, reimbursement and all other aspects to develop the compound or partner.

MULTIPLE SCLEROSIS BASICS

- MS is an autoimmune disease that primarily impacts women between the ages of 20 and 50
- Multiple sclerosis (MS) is an autoimmune disease in which your own immune cells attack your central nervous system (CNS)
- MS causes immune mediated damage to the myelin sheaths that protect neurons, causing pain, fatigue, and a range of other neurological symptoms
- 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
- However, MOST patients continue to have symptoms
- No drugs are approved for pain associated with MS.
- Acorda's Ampyra and its generics are the only supportive care MS drugs, approved for MS walking difficulties.

MS Symptoms Addressed by APITOX

- Pain
- Extreme Fatigue
- Extreme Weakness
- Unstable Gait / Balance
- Losing Bladder control
- Involuntary Spasms

GAP IN TREATMENT FOR MS PATIENTS



Quality of Life Improvement

- ✓ Current pharmaceuticals such as interferon based agents treat the progression of the disease and the reduction of the occurrence of exacerbations.
- ✓ One agent, Ampyra addresses only the symptom of gait and balance improvement.
- ✓ PROVEN – APITOX demonstrated symptom improvement in Phase 3 Osteo Arthritis trial
- ✓ APITOX clinical trial will demonstrate improvement in symptom relief and Quality of life improvement in MS Patients.
- ✓ Patient can continue with existing therapies while taking APITOX.

BENEFITS OF APITOX IN MULTIPLE SCLEROSIS PATIENTS IMPROVEMENT IN QUALITY OF LIFE

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**. Describe as **feeling like** you're weighed down and **like** 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 even offset muscle **weakness** and aid in standing, walking, and transferring.



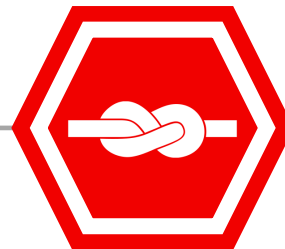
Unstable Gait/Balance

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



Bladder Control

Bladder dysfunction, which occurs in at least 80 percent of people with **MS**, 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.

MULTIPLE SCLEROSIS MARKET OPPORTUNITY

- Approximately 1 million people in the U.S. have MS, with prevalence increasing.
- MS drugs generated over \$12 billion in 2019 revenue in the U.S., and another \$6 billion internationally.
- Disease modifying agents improve outcomes for patients with relapsing / remitting disease, the most common form. Progressive MS is poorly controlled with existing medicines.
- Manifestations effecting quality life such as fatigue, weakness, unstable gait, spasm and bladder control are not addressed by current therapies.

Select MS Drugs

Drug	Company	Mechanism / Use	U.S. Sales
Ampyra	Acorda	K+ channel blocker, enhances MS walking	\$535M at peak in 2017
Avonex	Biogen	Interferon antibody, disease modifying	\$1.2B in 2019
Tecfidera	Biogen	Neuroprotective; disease modifying	\$1.7B in 2019
Tysabri	Biogen	Integrin inhibitor, disease modifying	\$1.0B in 2019
Gilenya	Novartis	S1P Inhibitor, disease modifying	\$1.7B in 2019

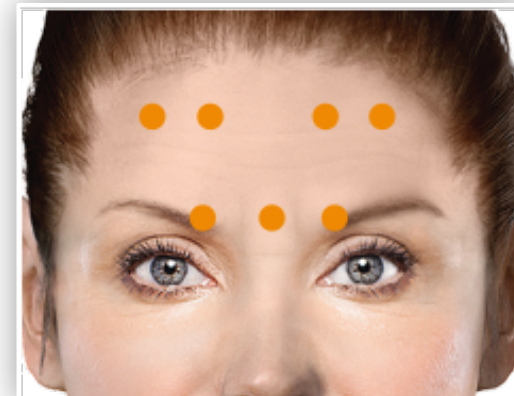
MARKET ACCEPTANCE OF TOXINS



- Naturally occurring toxin: *Apis mellifera* (honey bee) venom
- Treats an array of symptoms (pain, inflammation, etc.)
- Multiple injection sites (low volume, small needle, 15 minute procedure)
- Generic versions difficult to show equivalency



- Naturally occurring toxin (botulinum toxin)
- Treats an array of symptoms (wrinkles, migraines, etc.)
- Multiple injection sites (example below for migraine)
- 2019 U.S. Revenue of \$2.7 billion, including \$1.7 billion for therapeutic use and \$1.0 billion for cosmetics
- Generic versions difficult to show equivalency – Botox sales remain strong in spite of multiple approved botulinum toxin formulations

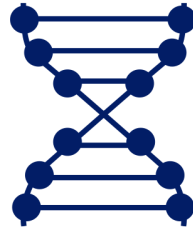


APITOX - PHARMACOLOGY



7 Active Amines

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



5 Active Enzymes

- Hyaluronidase
- Phospholipase
- -D-Glucoidase
- Acid phosphominiesterase
- Lysophospholipase



10 Active Peptides

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

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.

PROVEN SAFETY AND EFFICACY IN PHASE 3 OSTEOARTHRITIS TRIAL

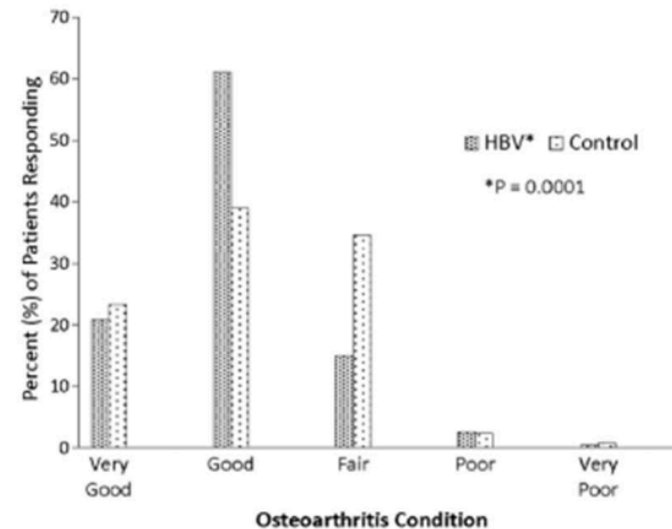
THE JOURNAL OF ALTERNATIVE AND COMPLEMENTARY MEDICINE
Volume 00, Number 00, 2019, pp. 1-11
© Mary Ann Liebert, Inc.
DOI: 10.1089/acm.2019.0121

JACM

Efficiency and Safety of Honey Bee Venom (*Apis mellifera*) Dermal Injections to Treat Osteoarthritis Knee Pain and Physical Disability: A Randomized Controlled Trial

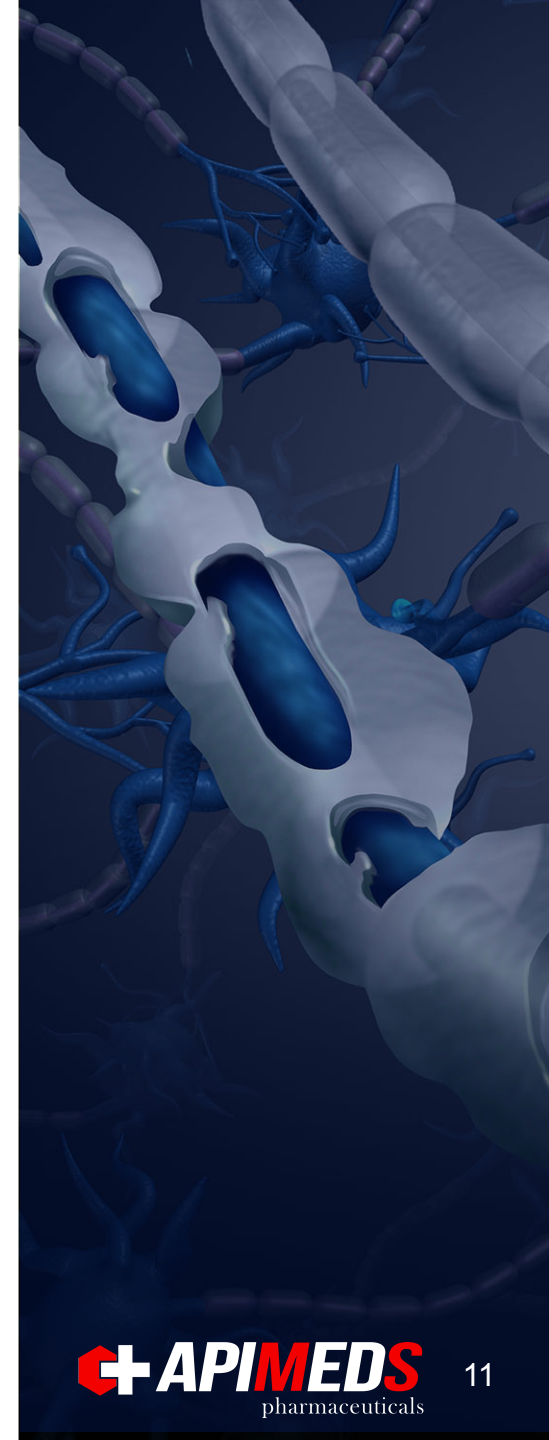
Vicki J. Conrad, MD,¹ Lydie L. Hazan, MD,² Agustin J. Latorre, MD,³ Anna Jakubowska, MD,⁴ and Christopher M.H. Kim, MD⁵

- Demonstrated significant improvement over control in WOMAC pain score after 12 weeks $p=0.0010$
- VAS was significantly improved $p=0.0001$
- PGA and PhGA shows patients responded favorably $p=0.0015$
- Significant improvements Osteoarthritis knee pain and physical function



APITOX MS PHASE 3 CLINICAL STUDY OVERVIEW

- **Number of Patients**
 - 428 patients randomized 1:1
 - add-on therapy vs placebo
- **Protocol Design** accepted by FDA's CBER Neurology in 2018
- **Primary Endpoints:**
 - Efficacy: Changes in EDSS and MSFC through week 16
 - Safety: SAE, 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)



APITOX IN MULTIPLE SCLEROSIS

Strength

- Long successful clinical experience
- Excellent safety and efficacy profile
- Addresses significant unmet need in MS.
- Proven execution of P3 clinical study
- 12 year exclusivity with BLA

Weaknesses

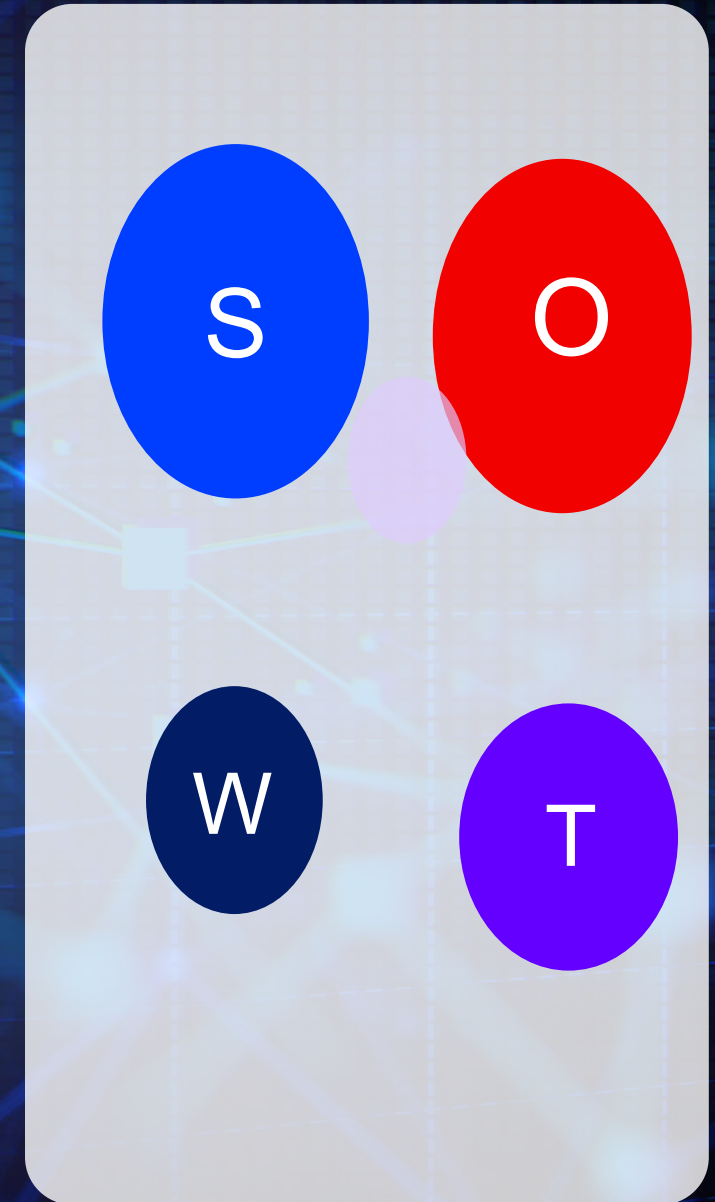
- Multiple injection sites: similar to Botox™
- Patients concerned about allergy to bees

Opportunities

- Potential in multiple indications: osteoarthritis, lupus, multiple rare autoimmune diseases, fibromyalgia, etc.
- Enhanced drug delivery device

Threats

- With sales potential over \$1.0B, threat exists for other competitive formulations to arise.



INTELLECTUAL PROPERTY AND PROTECTION

PATENT Status & Protection

No.	Title	Country	Certificate No.	Appl. Date	Reg. Date
1	Bee Venom Treatment Without the Sting	Korea	# 0405128	01.02.01	03.10.30
2		Japan	# 3989188	01.04.27	07.07.27
3	Bee Venom Treatment Without the Sting	USA	09/615,437	00.07.13	
3			10/690,772	03.12.22	divisional
3*	A Standardized Preparation of Bee Venom		12/152,216 ①	08.08.07	13.05.14
			②	2013	14.04.08

Potential to extend through **2028**

U.S. Patent

1. US 8,440,234 B2 (May 14, 2013)
2. US 8,691,283 B2 (April 8, 2014)

BLA Exclusivity

Biologics are also entitled to FDA-regulated exclusivities. 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.

A biologic product exclusivity expiry date indicates the date that is 12 years from the date of first licensure as described in 351(k)(7)

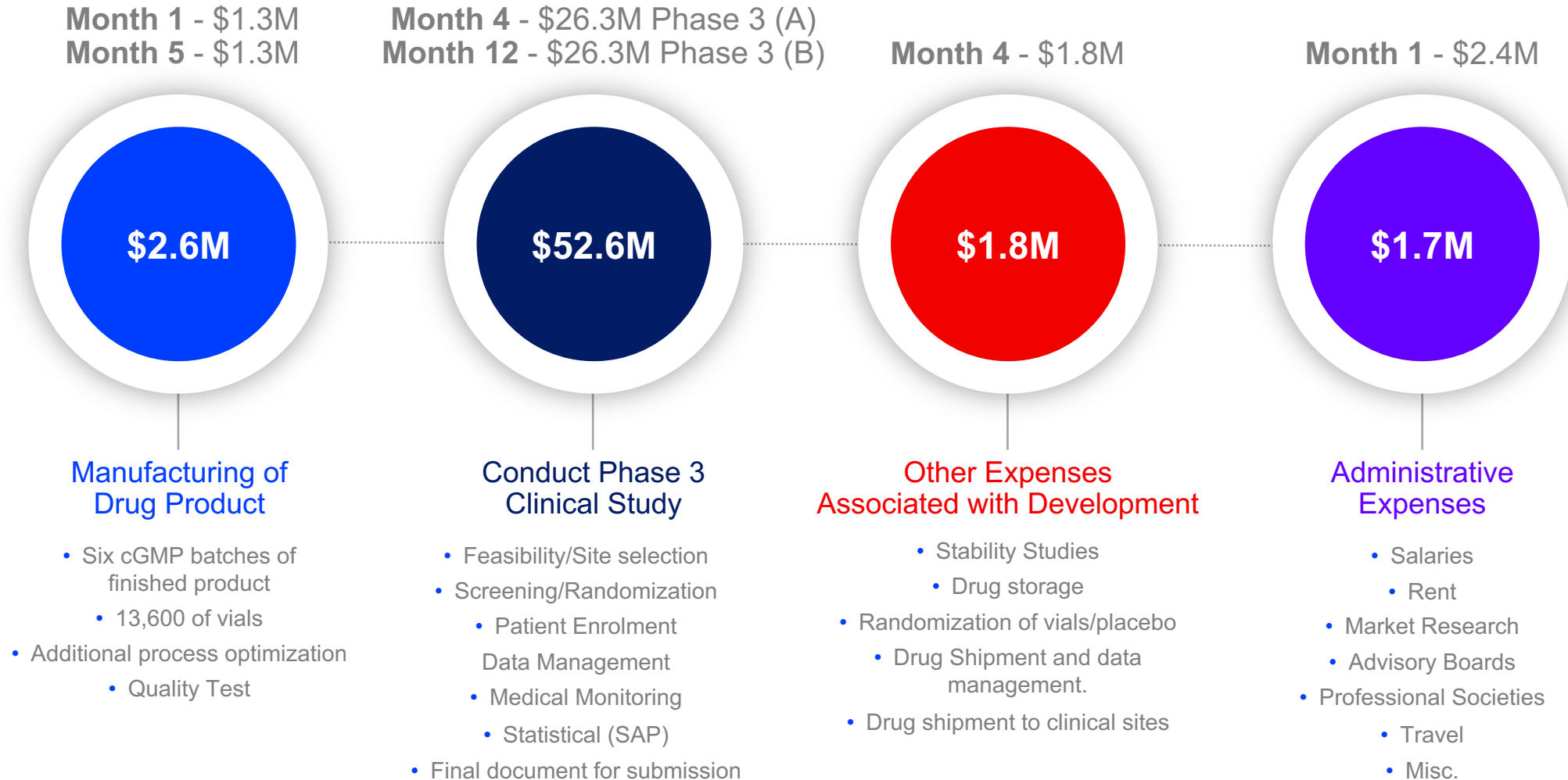
REIMBURSEMENT STRATEGY

- CPT Review of Apitox Administration by Multiple Intradermal Injections.
- Medical Coverage Policy Analysis
- Medicare Local Coverage Analysis and Implications
- Analyze available medical policies for 5 large state Medicaid agencies (based on population and geographic variation) and major commercial payers (where publicly available)
- Payer Policy Internal Expert Interviews
- Conduct payer interviews with relevant Medicare, Medicaid and commercial policy advisors. For the interviews, APUS will provide a product profile (blinded) for ADVI's use. ADVI will use the profile to develop an interview outline to present to the interviewee.
- The payer interviews are intended to test theories and assumptions based on the research and our expectations of the market and the product assumptions.
- HCPCS Coding and Payment Assessment
- HCPCS and OPPS application timelines (and potential evolution leading to launch)
 - Coding/access implications prior to code assignment (e.g., NOC/miscellaneous codes), review the merits/risks of Q-code
- Review of reimbursement implications:
 - Methodologies (ASP, WAC, AWP), role of sequestration, 340B, patient financial burden

APITOX DEVELOPMENT SUMMARY AND PIPELINE

Apitox		Pre-Clinical	Phase 1	Phase 2	Phase 3	Market
OA-Pain and Inflammation		Marketed in Korea				
OA-Pain and Inflammation		Phase 3 Complete				
Multiple Sclerosis		Phase 3 Ready				
Lupus, Fibromyalgia, Rare autoimmune conditions		Phase 2 Ready				

USE OF PROCEEDS FOR CURRENT CAPITAL CAMPAIGN



Month 1 - \$1.3M
Month 5 - \$1.3M

Month 4 - \$26.3M Phase 3 (A)
Month 12 - \$26.3M Phase 3 (B)

Month 4 - \$1.8M

Month 1 - \$2.4M

\$2.6M

\$52.6M

\$1.8M

\$1.7M

Manufacturing of Drug Product

- Six cGMP batches of finished product
 - 13,600 of vials
- Additional process optimization
 - Quality Test

Conduct Phase 3 Clinical Study

- Feasibility/Site selection
- Screening/Randomization
 - Patient Enrolment
- Data Management
- Medical Monitoring
 - Statistical (SAP)
- Final document for submission

Other Expenses Associated with Development

- Stability Studies
 - Drug storage
- Randomization of vials/placebo
 - Drug Shipment and data management.
- Drug shipment to clinical sites

Administrative Expenses

- Salaries
- Rent
- Market Research
- Advisory Boards
- Professional Societies
 - Travel
 - Misc.



CHRIS KIM
(Founder, Chief Medical Officer)

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



SCOTT HOLLANDER
(Chief Executive Officer)

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



ROBERT BROOKS, PHD
(Chief Operating Officer)

Author of osteoarthritis IND013754 &
multiple sclerosis IND122804. 40+ years in
the pharmaceutical industry with positions at
the FDA, Walter Reed and Tamra Industries.



JAKAP KOO
(CEO & President, ApiMeds Korea/Inscobee)

35 years mostly as C-level executives in
various financial institutions and IT
companies. Management and operational
experiences covers banking, asset
management, venture capital, private
equity and biotechnology companies.
Stern School of Business, NYU.



HYUKJAE LEE
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Roles at BIEMT Co Samil
Pricewaterhouse Coopers, Samsung
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University of Calif Berkeley



IN SOO YOU
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30 years executive, fund manager LG
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Thank You



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