



**Apimeds Pharmaceuticals**  
*Treating today to improve tomorrow*

**NYSE American (proposed) : APUS**

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# Forward-Looking Statements

This presentation contains "forward-looking statements" that are subject to substantial risks and uncertainties.

All statements, other than statements of historical fact, contained in this presentation are forward-looking statements. Forward-looking statements contained in this presentation may be identified by the use of words such as "anticipate," "believe," "contemplate," "could," "estimate," "expect," "intend," "seek," "may," "might," "plan," "potential," "predict," "project," "target," "aim," "should," "will," "would," or the negative of these words or other similar expressions, although not all forward-looking statements contain these words. Forward-looking statements are based on Apimeds Pharmaceuticals US, Inc. current expectations and are subject to inherent uncertainties, risks and assumptions that are difficult to predict. Further, certain forward-looking statements are based on assumptions as to future events that may not prove to be accurate.

These and other risks and uncertainties are described more fully in the sections titled "Risk Factors and "Management's Discussion and Analysis of Financial Condition and Results of Operations" in the Company's Registration Statement on Form S-1 (No. 333-282324) and the amendments thereto with the Securities and Exchange Commission (the "SEC"). Forward-looking statements contained in this announcement are made as of this date, and Apimeds Pharmaceuticals US, Inc. undertakes no duty to update such information except as required under applicable law.

Past performance is not indicative of future results. There is no guarantee that any specific outcome will be achieved. Investments may be speculative and there is a total loss of your investment.

We have filed a registration statement (including a prospectus) on Form S-1 (File No. 333-282324) with the SEC for the offering to which this communication relates. Before you invest, you should read the prospectus in that registration statement and other documents we have filed with the SEC for more complete information about Apimeds Pharmaceuticals US, Inc. and this offering. You may get these documents for free by visiting EDGAR on the SEC Web site at [www.sec.gov](http://www.sec.gov). Alternatively, the issuer or any underwriter participating in the offering will arrange to send you the prospectus if you request it by contacting D. Boral Capital LLC, 590 Madison Ave 39th Floor, New York, NY 10022, by email at [info@dboralcapital.com](mailto:info@dboralcapital.com), or by telephone at +1 (212) 970-5150.



# Offering summary for APUS on NYSE American

ISSUER	APIMEDS PHARMACEUTICALS INC, US
Offering Size	4.5 mm Shares
Over-Allotment	15% Over Allotment
Price Range	\$4.00 - \$5.00
Exchange/Ticker	NYSE American I APUS
Use of Proceeds	Corporate and Clinical Development
Lock-Up	180 Days
Sole Bookrunner	D Boral Capital LLC
Co-Managers	N/A



# Apimeds Pharmaceuticals US, Inc.

## Ready to Maximize the Apitox\* Opportunity



### US company established in May 2020

- Based in Matawan, NJ
- Subsidiary of Inscobee Inc
- Form S-1 filed with the SEC on September 25, 2024



### Primary asset is Apitox, licensed from Apimeds Korea

- Initially being developed as a potential treatment for pain and inflammation in patients with knee osteoarthritis



### Apitox has a demonstrated track record of real-world usage and experience, with facilities in South Korea administering Apitox commercially since 2003

- ~330 patients were treated in a previously conducted Phase 3 knee osteoarthritis trial, which demonstrated clinical efficacy and safety of Apitox in a US population
- A follow-up FDA meeting in 2018 confirmed the need for a second confirmatory Phase 3 trial



### Clinical activity is projected to be completed in approximately 24 months, within the funding runway from the capital raise

- Phase 3b study in osteoarthritis of the knee
- Two corporate-sponsored investigator studies in inflammatory indications



### Strong management team and Board of Directors in place

#### Erik Emerson, CEO

*Prior executive positions at Gilead, XOMA, Symplmed, Adhera, Mezzion Pharma, and Odyssey NeuroPharma*

#### Christopher Kim, MD, Chief Medical Officer

*A leading investigator in the field of bee therapy and co-author of the book Biotherapy: History, Principles and Practice, a practical guide to diagnosing and treating diseases using living organisms*

#### Mark Corrao, CFO

*A seasoned CFO with decades of experience serving as a CFO at public companies. His background includes over 40 years in accounting, finance, and public company regulations*

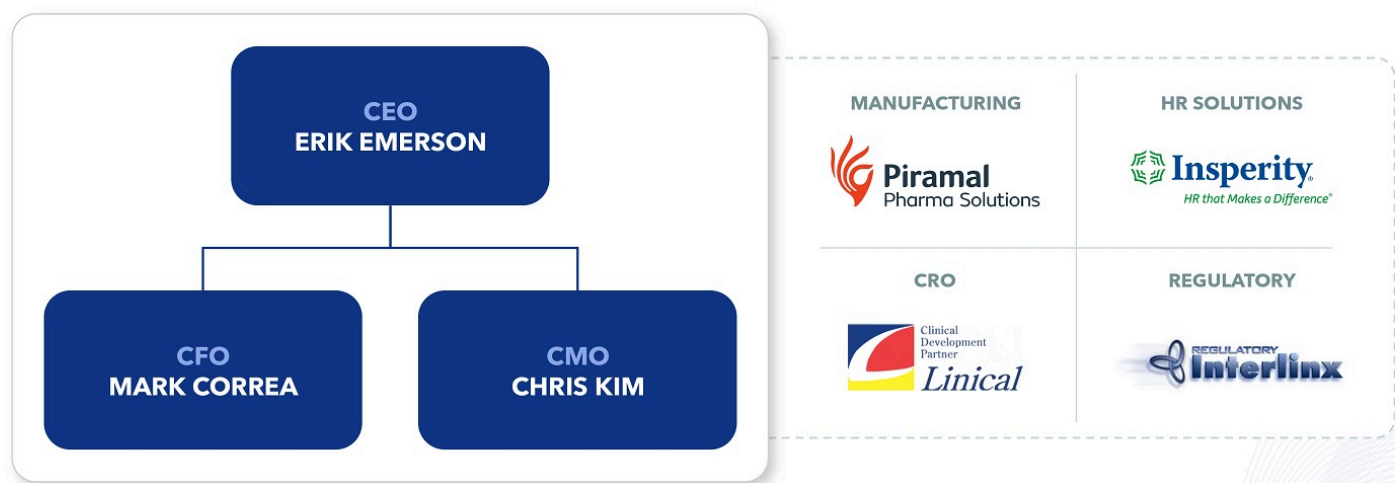
\*Tradename pending FDA review and approval

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# Company Leadership and Operational Partners



# Drive Immediate Executional Imperatives

- 1 **Initiate** a Phase 3 confirmatory trial in Knee Osteoarthritis
- 2 **Launch** a corporate-sponsored study in Multiple Sclerosis
- 3 **Identify** and pursue a 3rd development indication, initiating a corporate-sponsored study





# Apitox

## Positioned for Success in the US Market

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### Differentiation from traditional therapies

- Apitox provides an alternative to NSAIDs, corticosteroids, and biologics, **offering a new option for patients** who have experienced **limited efficacy or adverse effects**
- Positioning **Apitox as an essential option** for managing complex, chronic conditions

2

### Potential efficacy across multiple indications

- Honey-bee venom has **demonstrated therapeutic potential** in multiple inflammatory-related conditions, such as Knee OA and Multiple Sclerosis

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### Untapped market potential

- Apitox **novel mechanism of action** may fill gaps in the treatment of inflammation and immune modulation
- With **limited competition in this space**, and extensive history of success for toxin related therapies, Apitox is well positioned for success





# **Differentiation from traditional therapies**





# Apitox

Demonstrated efficacy with >20 years of safety



A purified formulation of honeybee venom that has **potent anti-inflammatory and analgesic properties**



A Phase 3 trial has demonstrated that patients experienced clinically significant **pain relief and improved physical functioning**



Standard-of-care treatments such as **NSAIDs and opioids come with risks of systemic toxicity, dependency, and abuse**; by contrast, Apitox offers a natural, non-addictive solution for managing joint pain



Apitox may provide patients with a path to pain relief without the heavy burden of abuse potential, ushering in a **new era of safer, non-addictive pain management**



Apitox is under consideration for its **potential to modulate immune responses** in other conditions, **extending the lifecycle and value of Apitox**



# Knee Osteoarthritis Pain

## A Strategic First Indication for Apitox

### Defining knee osteoarthritis

- Osteoarthritis is a degenerative joint disease, which, when affecting the knee, is a leading cause of pain and disability in the US

### Commercial proof-of-concept and proven track record established by Apimeds Korea

- Approved by the Korean Ministry of Food and Drug Safety in 2003 for the treatment of pain and inflammation associated with osteoarthritis
- Over 810,000 doses administered to patients at over 1200 facilities, with no serious adverse events reported

### Osteoarthritis market size and growth

- An estimated 32 million US adults suffer from osteoarthritis
- The US osteoarthritis therapeutics market was valued at \$8.28 billion in 2022 and is projected to grow to \$20.24 billion by 2032

### US knee osteoarthritis strategy

- Initial clinical study on safety in the US completed in 2017
- Planned 8-week Phase 3 trial for patients with more severe, presurgical knee osteoarthritis
- BLA for pain and inflammation associated with knee osteoarthritis will be filed upon successful completion of Phase 3 studies



# Guidelines Suggest Various Treatments for Knee OA, But All Fall Short—Creating a Clear Need for Better Solutions

Recommended pharmacologic therapies for the management of knee osteoarthritis, based on the 2019 guideline from the American College of Rheumatology (ACR) and the Arthritis Foundation (AF)

	DRUG CLASS	CONSIDERATION(S)
Strongly recommended	Oral NSAIDs	Risk of systemic side effects and drug interactions
	Topical NSAIDs	Not consistently recommended across anatomical sites
	Intraarticular glucocorticoids	Unclear long-term efficacy; may contribute to cartilage loss
Conditionally recommended	Topical capsaicin	Inconsistent efficacy (small effect sizes and wide confidence intervals)
	Acetaminophen	Poor efficacy; risk of hepatotoxicity
	Duloxetine	Issues regarding tolerability and side effects
	Tramadol	Modest efficacy; risk of addiction and side effects

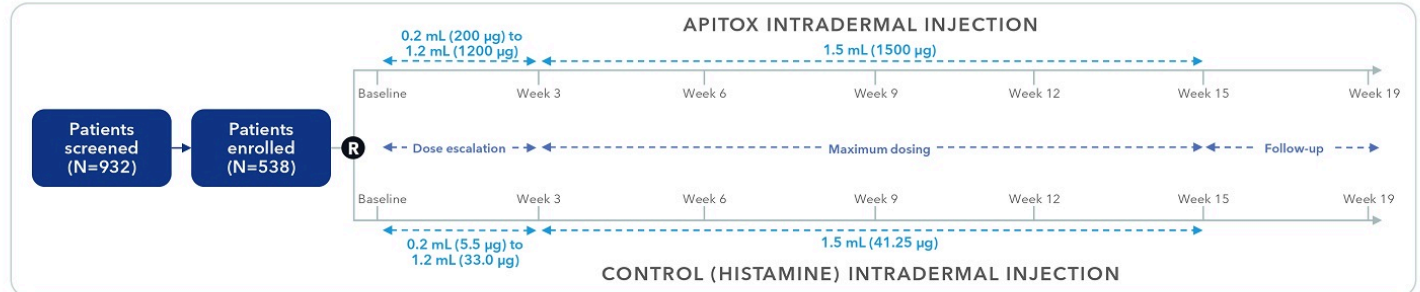


The limitations of existing pharmacologic treatments for knee osteoarthritis underscore the clinical need for new anti-inflammatory analgesic agents, such as Apitox



# Apitox Was Rigorously Evaluated in a Phase 3 Trial

A Phase 3, multi-center, randomized, double-blind, parallel-group clinical trial evaluating Apitox in subjects with knee osteoarthritis



## Key inclusion criteria

- Kellgren-Lawrence radiograph grade 1-3
- Score  $\geq 2$  on question no. 1 of WOMAC
- Use of chronic pain medication  $\geq 4$  days/week in the 28 days before screening

## Key exclusion criteria

- Hypersensitivity to bee venom
- Positive skin test to bee venom
- Intraarticular hyaluronic acid, corticosteroids, or Synvisc
- Use of  $\beta$ -blockers, chronic oral antihistamines, or cytochrome P450 inhibitors
- Concurrent inflammation or injury to target knee

## Primary endpoint

- Absolute change in WOMAC pain subscale score from baseline to Week 15

## Secondary endpoint

- Absolute change in WOMAC physical function subscale score from baseline to Week 15

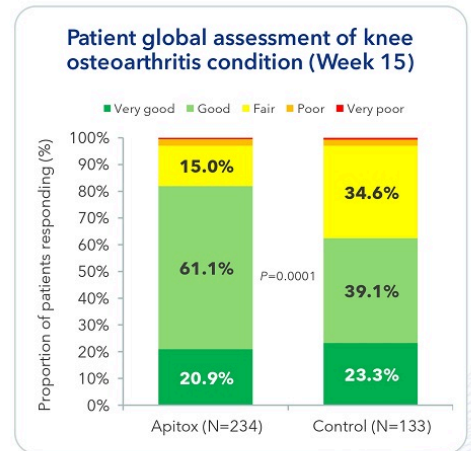
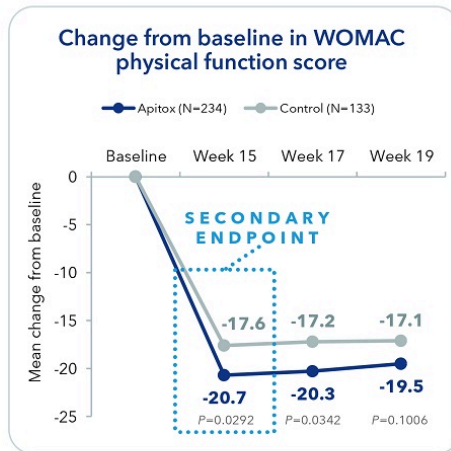
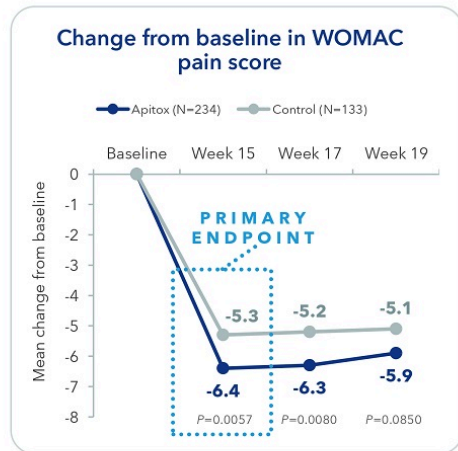
WOMAC=Western Ontario and McMaster Universities Osteoarthritis Index  
Conrad VJ, et al. *J Altern Complement Med.* 2019;25(8):845-855.

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# Apitox Was Significantly More Efficacious Than Control Treatment at Week 15 and Through Week 19



Efficacy outcomes achieved by Apitox at Week 15 were comparable to those achieved with Synvisc-One, an FDA-approved hyaluronan viscosupplement intraarticular injection

WOMAC=Western Ontario and McMaster Universities Osteoarthritis Index  
Conrad VJ, et al. *J Altern Complement Med*. 2019;25(8):845-855.

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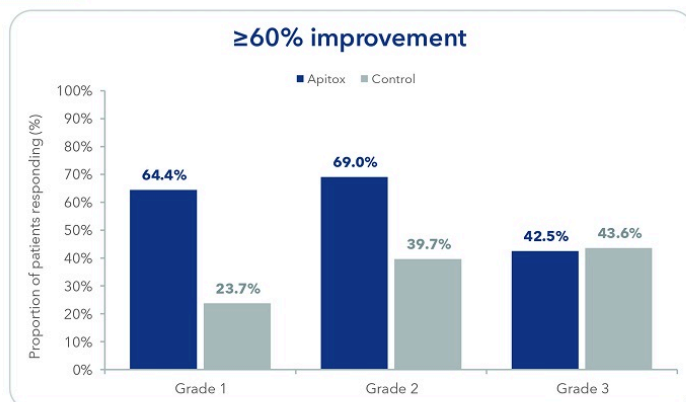
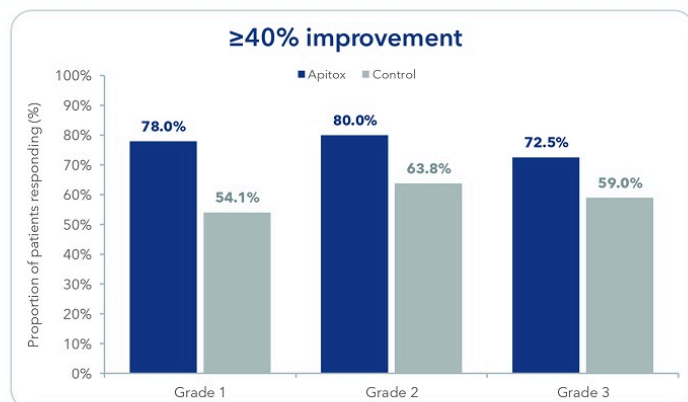
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# Apitox Demonstrated Efficacy Across All Grades of Knee Osteoarthritis Severity

Rate of WOMAC physical function score response (Week 15)



All grades of knee osteoarthritis showed greater rates of clinical response in the Apitox arm at Week 15, including higher-severity patients who are the most likely candidates for knee replacement surgery

WOMAC=Western Ontario and McMaster Universities Osteoarthritis Index  
Apimeds Pharmaceuticals. Data on file.

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# FDA Feedback Confirmed Need for a Second Study to Support Initial Trial

FDA meeting held on January 18, 2018



## Notable comments regarding the additional trial

- "Replicated evidence from two adequate and well-controlled studies will be required for your BLA."
- "After extensive discussion, the Sponsor was told that they may submit the full results of Study 01-013 to the IND."
- "The Division also recommended that the results from Study 01-013 be used to design future studies, and these studies should minimize dropouts and missing data."



## No safety issues raised

- Will utilize post marketing surveillance from South Korea as a component of the safety database



## Review jurisdiction confirmed

- Will be classified as a biologic with the Division of Anesthesia, Analgesia, and Addiction Products (DAAAP)

BLA=Biologics License Application; IND=Investigational New Drug (IND) application

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# Countdown to Success

## Phase 3b Knee OA Trial Timeline

### General Assumptions



#### Protocol

01-13



#### Site distribution

US: 10 sites



#### Number of patients

230 screened | 120 enrolled | 120 completed



#### Enrollment rate

2.0 patients/site/month based on sponsor RFP

TLFs=tables, listings, and figures; eTMF=electronic trial master file



#### Project Timeline

<b>Feasibility:</b> 1 month	<b>Treatment:</b> 4 months
<b>Startup:</b> 3 months	<b>Follow-up:</b> 1 month
<b>Enrollment:</b> 6 months	<b>Closeout:</b> 3 months

**TOTAL STUDY DURATION:** 18 MONTHS



Expected execution from first site initiated to transfer of eTMF file is 15-18 months





## Potential efficacy across multiple indications



# Unmet Need in Multiple Sclerosis (MS) Pain Management Presents a Key Opportunity for Apitox



## **MS is an autoimmune disease in which the immune system attacks the central nervous system (CNS)<sup>1</sup>**

- Primarily affects women between the ages of 20 and 50<sup>2</sup>
- Causes immune-mediated damage to the myelin sheaths that protect neurons, leading to pain, fatigue, and other neurological symptoms<sup>1</sup>



## **Disease-modifying agents, such as beta-interferons, have improved the outlook for MS patients, particularly those with relapsing/remitting MS (RRMS)<sup>1</sup>**

- However, most patients continue to experience symptoms<sup>1</sup>



## **No drugs are currently approved for MS-related pain**

- Acorda's Ampyra and its generics are the only supportive care drugs approved for MS-related walking difficulties<sup>3,4</sup>

1. McGinley M, et al. *JAMA*. 2021;325(8):765-779. 2. Milo R, Kahana E. *Autoimmun Rev*. 2010;9(5):A387-A394.  
3. Dunn J, Blight A. *Curr Med Res Opin*. 2011;27(7):1415-1423. 4. Ampyra prescribing information.



# Benefits in Treating MS Patients with Pain Complications



## Anti-inflammatory effects

- Apitox has **potent anti-inflammatory properties**<sup>1,2</sup>, which may help reduce the inflammation associated with MS, **potentially slowing disease progression**



## Immune modulation

- MS is an autoimmune condition where the immune system attacks the nervous system<sup>3</sup>; Apitox **may help modulate immune responses**, reducing the severity of attacks<sup>1,2</sup>



## Neuroprotection

- Some studies suggest that Apitox has **neuroprotective effects**, helping to preserve nerve function and reduce tissue damage<sup>2</sup>



## Pain relief

- MS often causes chronic pain<sup>3</sup>, and Apitox's **analgesic properties may provide relief**, improving patient quality of life<sup>2</sup>



## Natural alternative

- As a naturally derived compound, Apitox offers a **unique mechanism of action** compared to conventional synthetic treatments for MS<sup>2</sup>

1. Wehbe R, et al. *Molecules*. 2019;24(16):2997. 2. Conrad VJ, et al. *J Altern Complement Med*. 2019;25(8):845-855.  
3. McGinley M, et al. *JAMA*. 2021;325(8):765-779.



# Initial Proposed Single-Site MS Study

Protocol design accepted by FDA's CBER Neurology, revised in 2022

## Trial design

- The trial design will incorporate feedback from the FDA's CBER Neurology revision to the Phase 3 protocol submitted in 2022
- Will be conducted as a smaller, single-site study to validate the hypothesis in a controlled clinical environment

### PRIMARY ENDPOINTS

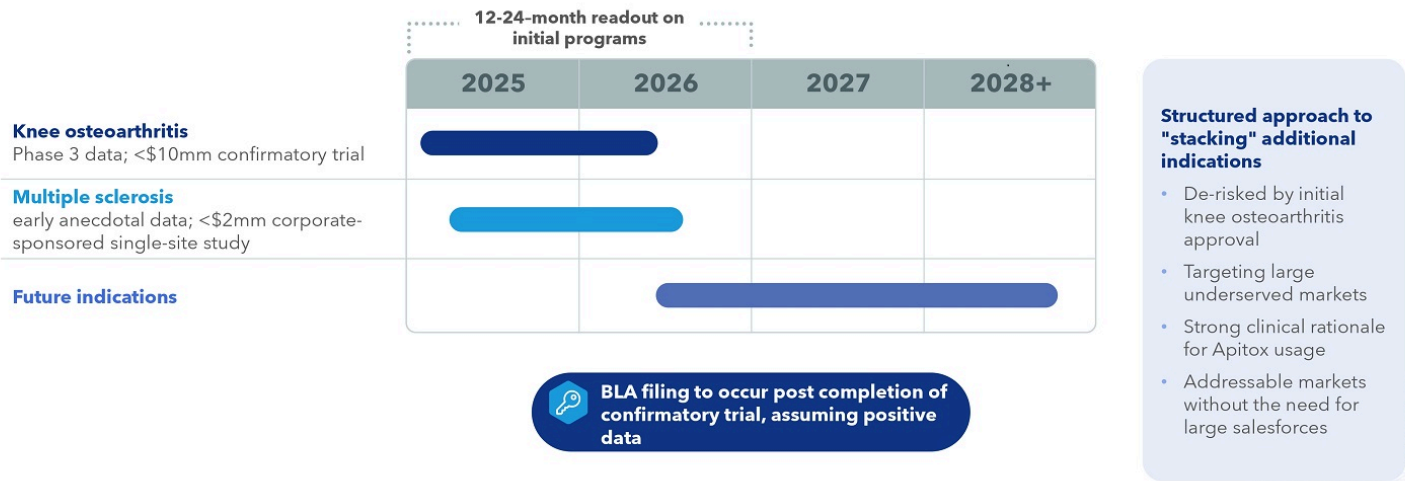
<b>Efficacy</b> Changes in Expanded Disability Status Scale (EDSS) and Multiple Sclerosis Functional Composite (MSFC) through Week 16
<b>Safety</b> Serious adverse events, adverse events, and tolerability

### SECONDARY ENDPOINTS

Quality of life (MSQoL-54)	Pain Intensity Numerical Rating Scale (PI-NRS)
Functional System Scores (FSS)	Patient Global Assessment (PGA)
Progression of disability, utilizing the change in EDSS and MSFC	Physician Global Assessment (PhGA)



# Multiple Near-term, Value-creating Milestones, Unlocking Significant Growth Opportunities for Investors



BLA=Biologics License Application

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## Untapped market potential





# Harnessing Nature's Power

## Breakthrough Therapies from Venom-Derived Compounds



### Capoten

Derived from the  
Jamaican pit viper

 Bristol Myers Squibb



### Integrilin

Derived from  
Southeastern pygmy  
rattlesnake venom

 MERCK



### Prialt

Derived from the  
venom of *Conus  
magus*, also known as  
the "magician's  
cone snail"

 TerSera<sup>®</sup>  
therapeutics



### Byetta/Bydureon

Derived from a  
hormone found  
naturally in the saliva  
of the Gila monster

 Lilly



### Botox


Derived from  
*Clostridium botulinum*,  
the bacterium that  
causes botulism

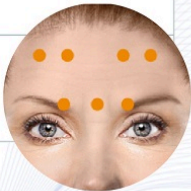
 Allergan



# Similarities Exist between Botox and Apitox

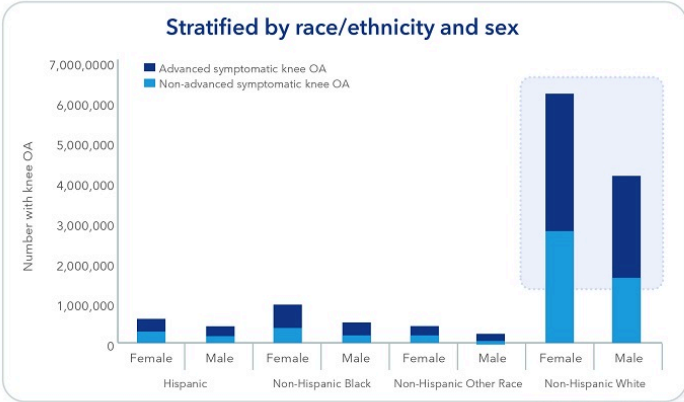
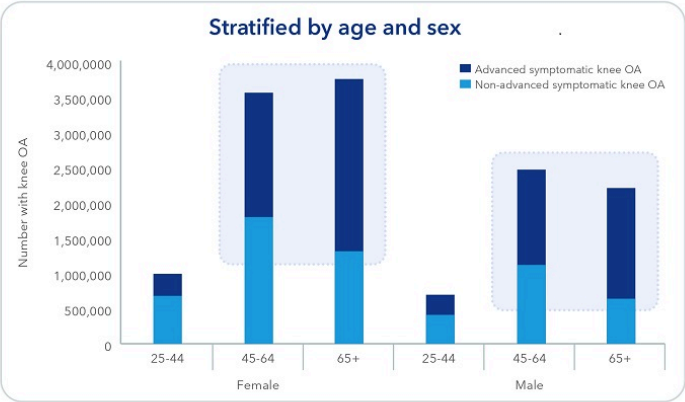
Apitox
Naturally occurring toxin: <i>Apis mellifera</i> (honeybee) venom
Treats an array of symptoms (pain, inflammation, etc.)
Multiple injection sites (low volume, small needle, 15-minute procedure)
Generic versions difficult to show equivalency


Naturally occurring toxin (botulinum toxin)
Treats an array of symptoms (wrinkles, migraines, etc.)
Multiple injection sites (example shown for migraine)
Generic versions difficult to show equivalency; Botox sales remain strong despite multiple approved botulinum toxin formulations



# Knee OA Affects Millions, Making Personalized, Effective Treatments More Crucial than Ever

Number of persons with knee osteoarthritis (OA) in the United States, by age, sex, and race/ethnicity (2007-2008)



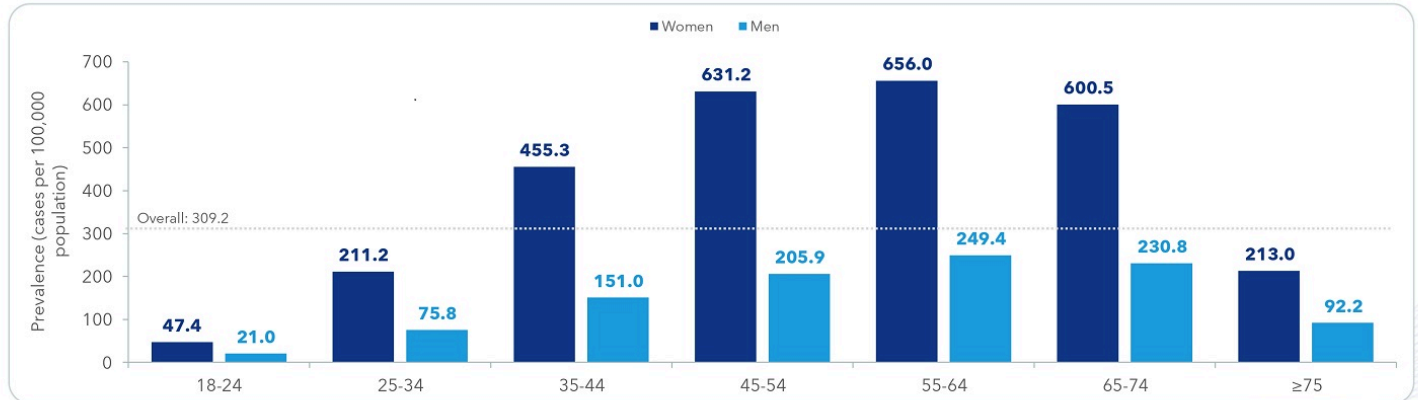
 ~7% of the total US population  $\geq 25$  years of age has symptomatic knee osteoarthritis, with significant variation across demographic groups

Deshpande BR, et al. *Arthritis Care Res (Hoboken)*. 2016;68(12):1743-1750.



# MS Affects Over a Million Patients in the US, Underscoring the Market Potential of this Population

Estimated number of persons with multiple sclerosis (MS) in the United States, stratified by age and sex (2010)



~0.3% of the adult population of the US has MS, with the disease burden disproportionately borne by middle-aged women



# Apitox's Novel Biologic Status Ensures 12 years of Market Exclusivity, Driving Long-term Growth



Under Section 351(k)(7)(c), biologic entities newly approved through the Centers for Biologics Evaluation and Research (CBER) receive **12 years of market exclusivity** from the date of approval

- No products may seek approval using Apitox as a reference for 12 years post-approval



We anticipate Apitox will **operate independently of bee venom competition** for the treatment of associated diseases **for ≥12 years post-approval**, if appropriate exclusivity granted

## Guidance for Industry

Reference Product Exclusivity for  
Biological Products Filed Under  
Section 351(a) of the PHS Act



# Investing in the Company Behind Apitox

## A Proven Path to Market Leadership and Growth



### Untapped market with significant growth potential

- Global market for inflammatory and autoimmune treatments is **growing rapidly**
- Apitox **offers a differentiated solution** with significant potential to capture market share



### Proven efficacy with unique mechanism of action

- Apitox's unique mechanism of action, **differentiates it from conventional therapies**
- **Natural composition appeals to both patients and HCPs**, offering a competitive edge



### Innovative product with expanding indications

- Apitox has shown to be a potential **therapeutic option** for the treatment of Knee OA and Multiple Sclerosis
- The broad therapeutic potential **opens new revenue streams**



### Experienced leadership and strategic vision

- Company's leadership team brings years of **expertise in the biopharmaceutical industry**, with a proven track record of bringing innovative therapies to market





# Transformative Impact

## FDA Approval Unlocks the Potential of the Apitox Pain Franchise

Apitox



Knee  
osteoarthritis



Multiple  
sclerosis



Other anti-inflammatory opportunities

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