



Apimed's Pharmaceuticals

Treating today to improve tomorrow

NYSE American: APUS
apimed'sus.com

July 2025

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 Apimed's 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. Forward-looking statements contained in this announcement are made as of this date, and Apimed's Pharmaceuticals US, Inc. undertakes no duty to update such information except as required under applicable law.

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Apimed's Pharmaceuticals US, Inc.

Maximizing Apitox* for Inflammation and Pain Management



US company established in May 2020

- Subsidiary of Inscobee Inc.
- May 2025 IPO raised \$13.5 million



Confirmatory trial projected to be completed in ~24 months

- Phase 3b study in OA of the knee
- Current cash is sufficient to fund Apimed's through the completion of the trial



Primary asset is Apitox, licensed from Apimed's Korea

- Purified, pharmaceutical-grade honeybee venom-based toxin administered intradermally
- Apitox has been sold and used in South Korea since 2003



Additional Apitox opportunity in multiple sclerosis (MS) pain

- Unmet need with no approved therapies
- Apimed's holds rights to FDA-cleared IND for a Phase 3 study
- Clinical plan is a single-site study with 25-35 patients
- Study designed to confirm the reduction of pain associated with MS exacerbations



Initial clinical focus is knee osteoarthritis (OA)

- ~330 patients were treated in a US Phase 3 knee OA trial, which demonstrated clinical efficacy and safety
- A follow-up meeting with FDA in 2018 confirmed the need for a second Phase 3 trial



Company Leadership and Key Partners



Erik Emerson – CEO

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



Christopher MH Kim, MD – CMO

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



Erick J. Frim – CFO

More than 40 years of experience as an accountant, financial executive and consultant including public company experience



Brian Peters – SVP, ai² Division

Senior commercial executive with more than 30 years of experience in global branding, business development and product launches



Susan Kramer – SVP, Clinical Development

Senior clinical executive with more than 30 years of experience in biopharmaceutical research and development



Near-term Executional Imperatives

- 1 **Initiate** the Phase 3 confirmatory trial in **knee osteoarthritis**
- 2 **Launch** a corporate-sponsored study in **multiple sclerosis**
- 3 **Identify** and pursue a third development indication, initiating a corporate-sponsored study



Apitox

Positioned for Success

1

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

- Honeybee venom has **demonstrated therapeutic potential** in multiple inflammatory-related conditions, such as **knee osteoarthritis** and **multiple sclerosis**

3

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 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

First Indication for Apitox in the US

Defining knee osteoarthritis

- Osteoarthritis is a degenerative joint disease
- When afflicting the knee, it is a leading cause of pain and disability

Osteoarthritis market size and growth

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

Commercial proof-of-concept established by Apimed's Korea

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

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 of 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)

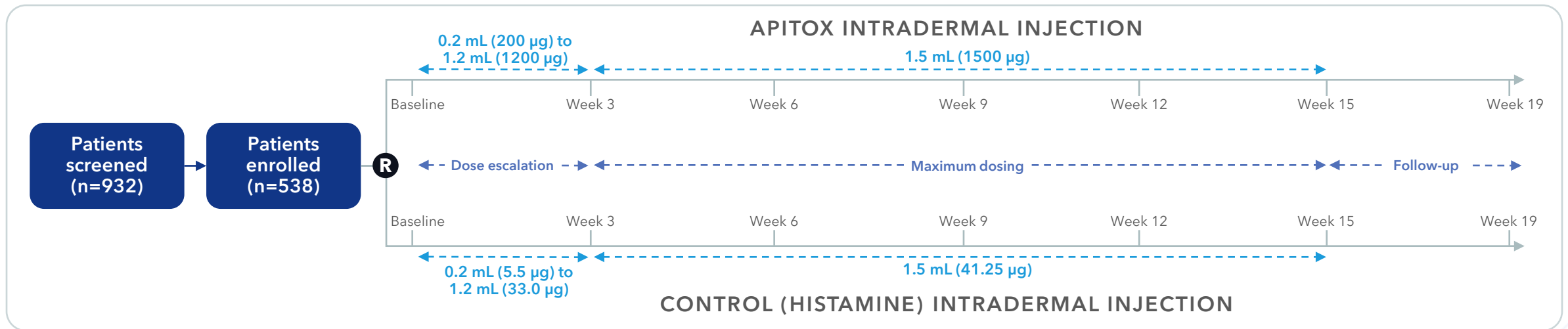
	DRUG CLASS	CONSIDERATION(S)
Strongly recommended	Oral NSAIDs	Risk of systemic side effects and drug interactions
	Topical NSAIDs	Not consistently recommended across anatomical sites
	Intraarticular glucocorticoids	Unclear long-term efficacy; may contribute to cartilage loss
Conditionally recommended	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

 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, multicenter, randomized, double-blind, parallel-group clinical trial evaluating Apitox in subjects with knee osteoarthritis



Key inclusion criteria

- Kellgren-Lawrence radiograph grade 1-3
- Score ≥ 2 on WOMAC question No. 1
- Use of chronic pain medication ≥ 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 β -blockers, chronic oral antihistamines, or cytochrome P450 inhibitors
- Concurrent inflammation or injury to target knee

Primary endpoint

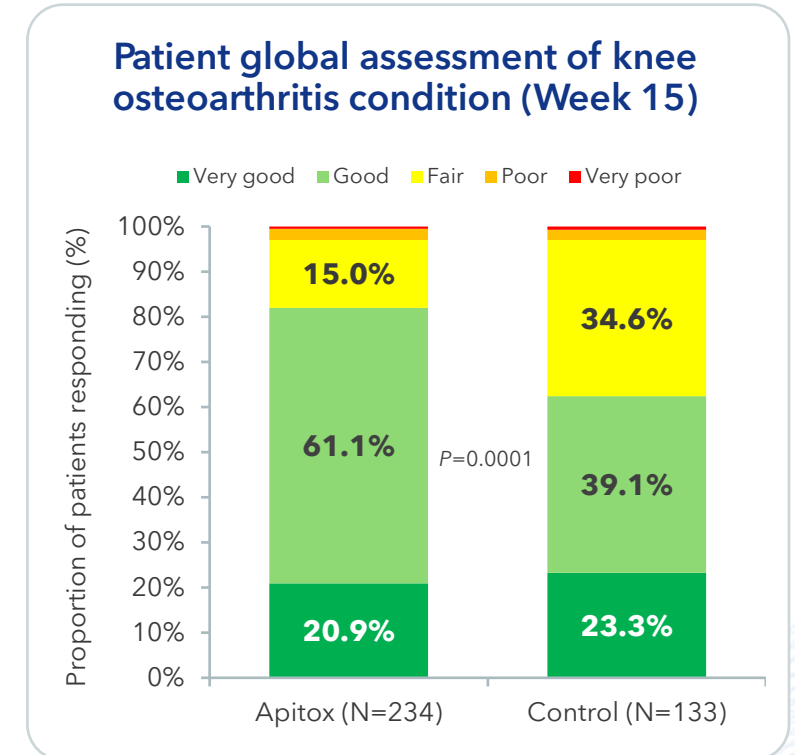
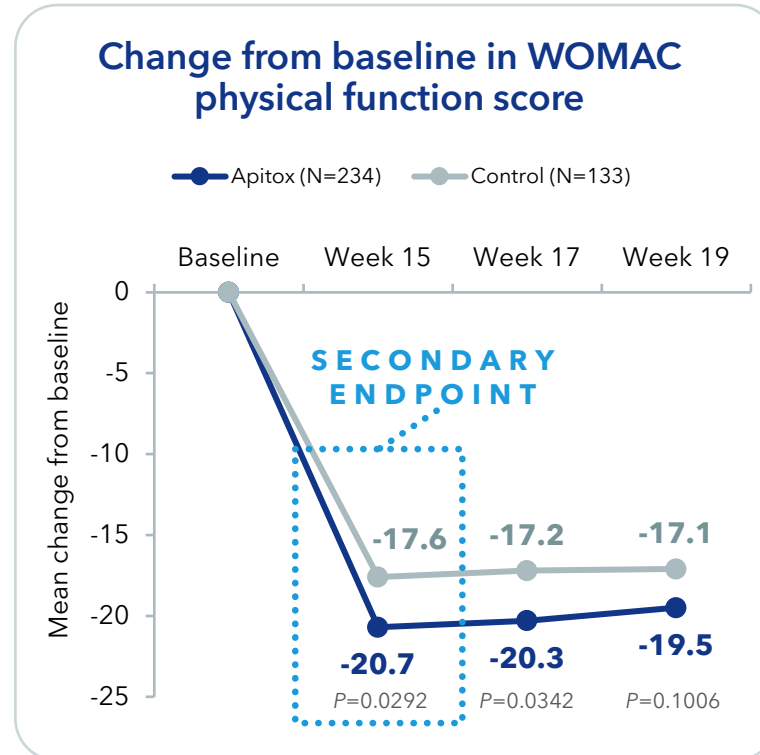
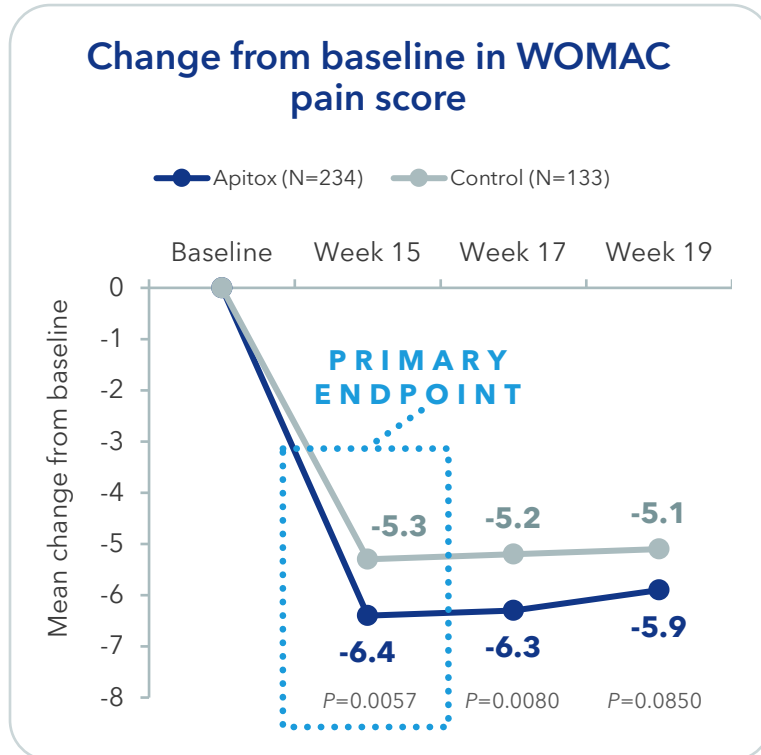
- Absolute change in WOMAC pain subscale score from baseline to Week 15

Secondary endpoint

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



Apitox Was Significantly More Efficacious vs Control at Week 15 and Through Week 19



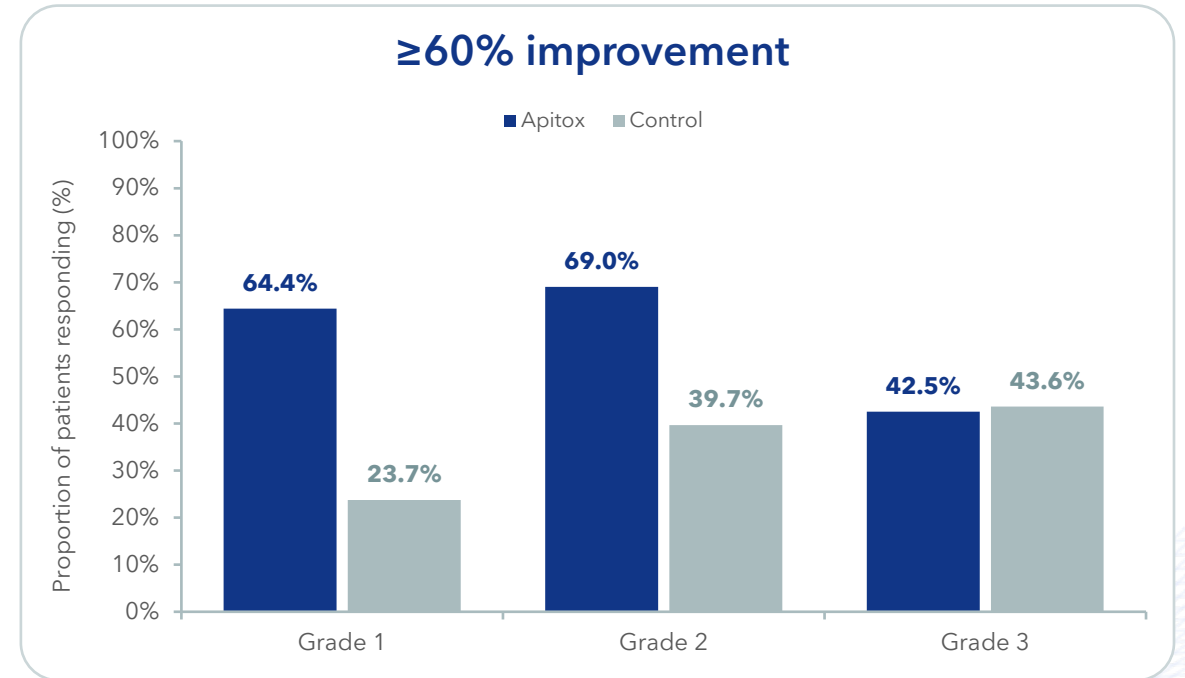
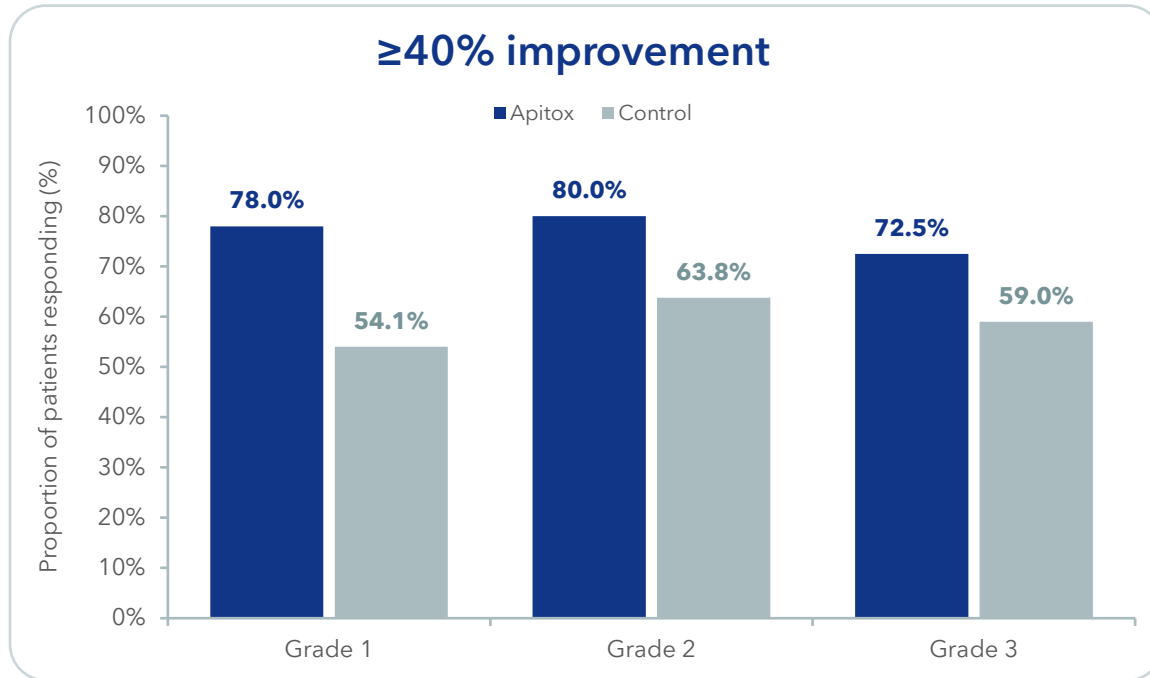
Efficacy outcomes achieved by Apitox at Week 15 were comparable to those achieved with Synvisc-One, an FDA-approved hyaluronan viscosupplement intraarticular injection


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



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
Apimed's Pharmaceuticals. Data on file.



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)





Potential efficacy across multiple indications

Unmet Need in MS Pain Management



MS is an autoimmune disease in which the immune system attacks the central nervous system (CNS)¹

- Primarily affects women between the ages of 20 and 50²
- Causes immune-mediated damage to the myelin sheaths that protect neurons, leading to pain, fatigue and other neurological symptoms¹



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

- However, most patients continue to experience symptoms¹



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^{3,4}

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**^{1,2} that 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 system³; Apitox **may help modulate immune responses**, reducing the severity of attacks^{1,2}



Neuroprotection

- Some studies suggest that Apitox has **neuroprotective effects**, helping to preserve nerve function and reduce tissue damage²



Pain relief

- MS often causes chronic pain³ and Apitox's **analgesic properties may provide relief**, improving patient quality of life²



Natural alternative

- As a naturally derived compound, Apitox offers a **unique mechanism of action** compared with conventional synthetic treatments for MS²

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

Efficacy

Changes in Expanded Disability Status Scale (EDSS) and Multiple Sclerosis Functional Composite (MSFC) through Week 16

Safety

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)

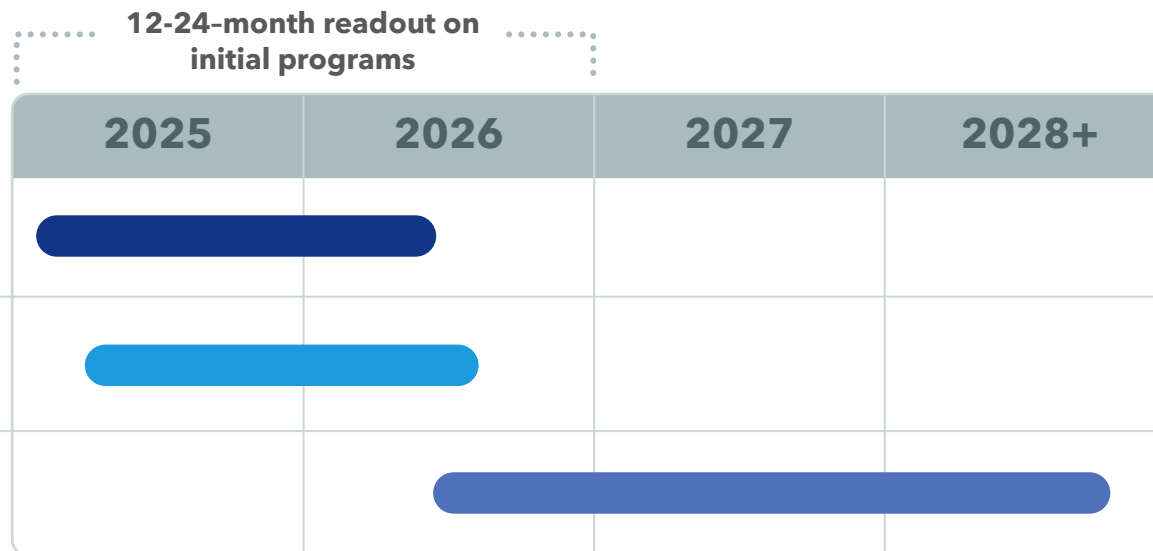
Progression of disability, utilizing the change in EDSS and MSFC

Physician Global Assessment (PhGA)



Multiple Near-term, Value-creating Milestones

Unlocking Significant Opportunities for Investors




Knee osteoarthritis

Phase 3 data; <\$10mm confirmatory trial

Multiple sclerosis pain

early anecdotal data; <\$2mm corporate-sponsored single-site study

Future indications

 **BLA filing to occur post completion of confirmatory trial, assuming positive data**

Structured approach to "stacking" additional indications

- De-risked by initial knee OA approval
- Targeting large underserved markets
- Strong clinical rationale for Apitox usage
- Addressable markets without the need for large salesforces





Untapped market potential

Harnessing Nature's Power

Illustrative Venom-Derived Therapies



Capoten

Derived from the
Jamaican pit viper



Integrilin

Derived from
Southeastern pygmy
rattlesnake venom



Prialt

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



Byetta/Bydureon

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



Botox

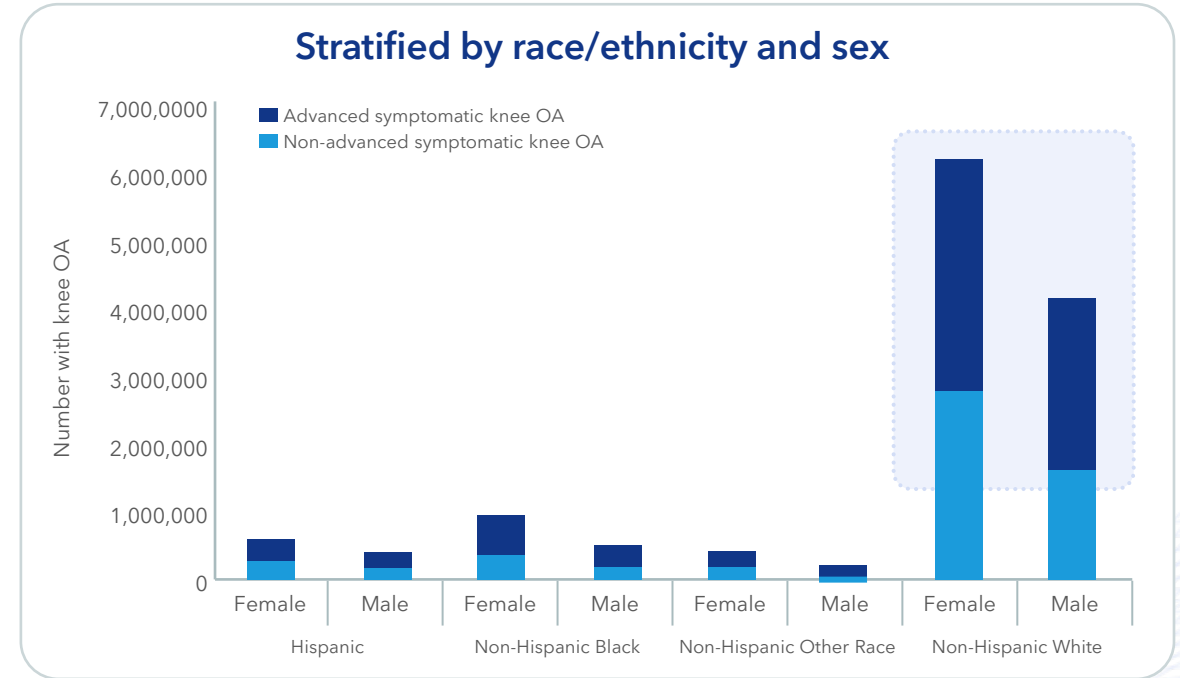
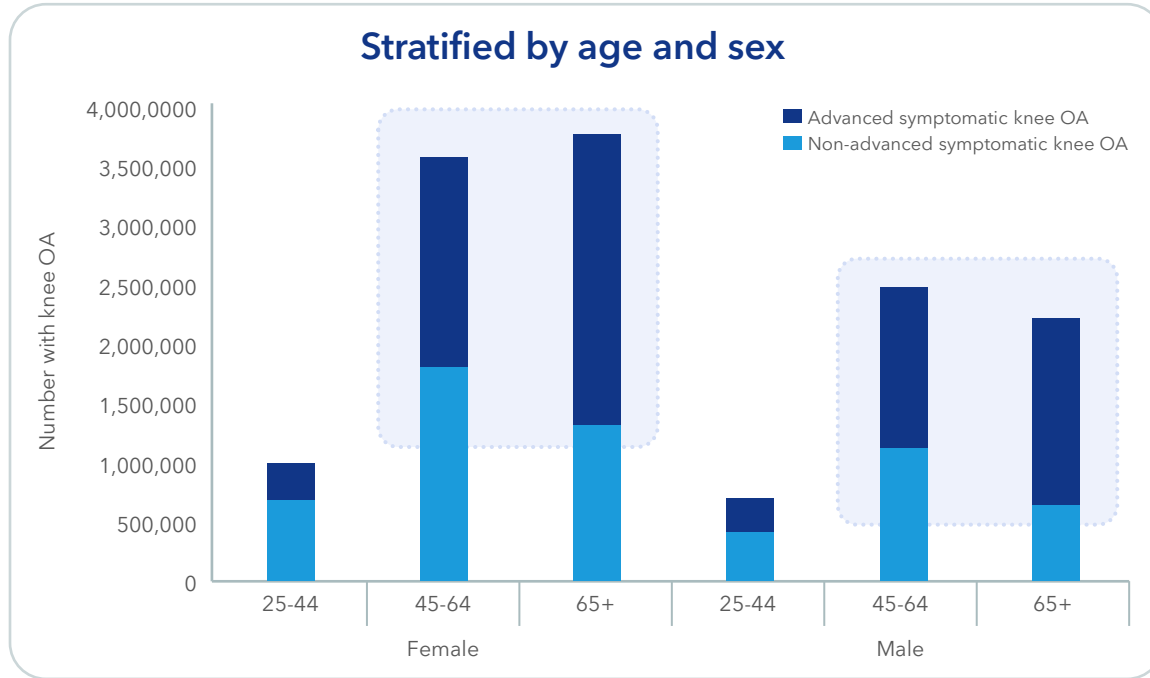
Derived from
Clostridium botulinum,
the bacterium that
causes botulism



Knee OA Affects Millions

Making Personalized, Effective Treatments Crucial

Knee OA in the US by age, sex and race (2007-2008)



 ~7% of the US population age ≥ 25 has symptomatic knee OA, with significant variation across demographic groups



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



The Apimed's Opportunity

The Path to Apitox 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 MS
- 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

