

# **BOME** PHARMA



#### Poison Oak/Poison Ivy Vaccine Individual Investor Presentation (10/17/24)

BOME Pharma, LLC

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1122 N. High Street, Millville NJ 08332-2529 Tel: 856.759.1299 Fax: 856.759.1288 Email: info@BOMEpharma.com Web: www.BOMEpharma.com The world's first and only safe and effective allergy vaccine for poison oak (PO) and ivy (PI) is looking for investors.



\*Details in downloadable Business Proposal.

- •Round 1 (Q1 2025): \$3M to validate commercial scale production technology and prepare vaccine for clinical trials: Company valuation \$50M, each \$1M buys 2% ownership of Co.
- •Round 2 (Q1 2026): Est \$10M for costs of clinical trials. Will have FDA pre-IND meeting. Company valuation \$100M, each \$1M buys 1% ownership.
- •Round 3 (2027) Est \$4-7M: Scale up cultivation and manufacturing facilities for commercial scale production. Register Biologics License and launch the product. Company valuation \$200M. Each \$1M buys 0.5% ownership.
- •Annual dividends from market year 1 will grow by year 5 to:
  - More than \$2 in annual dividends for every \$1 of Round 1 investment.
  - More than \$1 in annual dividends for every \$1 of Round 2 investment.

295M Americans (85% of the population) will become allergic to PO/PI with sufficient exposure.

174M (50%) either have had or will have sufficient exposure to cause clinical disease.

1/3 of these (58M **Americans)** are **VERY SENSITIVE,** and once exposed should want a safe and effective vaccine with annual boosters.



At least half of the VERY SENSITIVE population (28.9M) have already had at least one severe episode. At least 20% of these should want a safe and effective vaccine to prevent recurrence.

These are vaccine candidate Group A.



An unknown % of the 116M with mild to moderate sensitivity have chronic or recurrent exposure they can't reasonably avoid.

These candidates (Group B) have ongoing reactions NOW for which they'll want the vaccine as soon as they can get it. With climate change and suburbanization, Group B may be larger than Group A.

We can't estimate the size of Group B so we based sales and income projections on Group A alone

Demand from Group B will boost sales & profits faster and by more than our financial projections based on only Group A. An allergist may make allergenic products from natural source materials for his own patients without regulatory oversight.

This freedom to innovate and modify let us develop and patent a 100% safe, 90-100% effective hand-made allergy vaccine for PI, that should work for PO as well.



## Novel Vaccine Delivery System

We discovered and patented Vaccine Delivery by Precipitation (VDBP), a novel vaccine delivery system that gave us the world's first and only safe and effective vaccine for persons already sensitized to PO/PI.

In our peer-reviewed human proof of concept series our vaccine had: -No significant adverse effects. -90% response to initial treatment, 100% response of initial treatment failures to a single booster dose. In a pre-IND meeting, the FDA gave us a no-obstacles pathway to biologics licensure with pivotal clinical trials essentially replicating our published 100% safe, 90-100% effective human proof-of-concept experience.

We assembled a team to make a long shelf-life, GMPcompliant vaccine with built-in consistency and industrial efficiency.

# Our Team - 1<sub>of 4</sub>

Robert Coifman M.D. is BOME Pharma CEO, chief science officer, and PI/PO vaccine development program principal investigator. He is an allergist in solo practice in Millville, NJ, an engineer by pre-medical training and orientation. He will provide scientific and medical direction and lead outreach to potential investors.

Eric Feerst is the project manager. He is a retired NJ DEP lab chief. He will be project COO and specifically oversee both process quality control and regulatory affairs.





# Our Team - 2 of 4

Merlin Weaver is a hydroponic Controlled Environment Agriculture grower on whose operation we will build the PI/PO cultivation greenhouse. Merlin will apply standard commercial-scale CEA growing methods to the cultivation of PI and PO, and his staff will provide greenhouse maintenance services.

Catherine Yang, PhD, our chemistry partner and co-inventor of our PI/PO vaccine, is currently Vice President of Academic Affairs and Associate Dean of Medical Education at California Northstate University. She will oversee urushiol assays on samples shipped to her in CA.



# Our Team - 3 of 4

Millan Bhatt is the managing partner of the Molecular Pharma Group, a USP 503b sterile compounding pharmacy in New Providence, NJ. He will perform GMP desiccated vial filling and packaging.

Mel Kornbluh is a serial developer of successful small businesses dependent on various forms of efficient precision technology. He was instrumental in assembling the vaccine development team and will continue to work with us as a consultant and potential provider of sales and distribution services.



# Our Team 4 of 4

Scott Oneto is a University of California Cooperative Extension Farm Advisor and the senior weed scientist at the University of California at Davis College of Agriculture. He was instrumental in the assembly of our cultivation technology protocols and will continue to serve the project as a consultant.



### The FDA Approved Our Proposed Pathway To Biologics Licensure With:

#### No technical obstacles

No need for placebo arms in clinical trials. Each subject is his/her own control with sensitivity measured twice before treatment and once after

A limited set of Phase 2 clinical trials will be accepted as pivotal, with no need for a large and costly Phase 3 clinical trial

With clinical trial vaccine almost identical to our human proof-of-concept vaccines we anticipate similar outcomes in similar subjects

We can request another pre-IND meeting to address investor questions before you commit The antigens in PO & PI are "urushiols." Each exists in 4 forms called "congeners," produced by each plant in genetically determined ratios Protocol Development/ Commercial Scale Vaccine Production 1 of 7

Cultivate and propagate plants selected for identical or near-identical genetically determined urushiol congener production patterns, to build the lot-to-lot and year-to-year vaccine consistency required by the FDA into our crop.

Oven-dry freshly harvested leaves at 50 deg. C. prior to ethanol extraction to remove its 2/3 by weight water content to achieve almost indefinite urushiol stability if desiccation is aggressively maintained.



Protocol Development/ Commercial Scale Vaccine Production 2 of 7

Perform ethanol extraction, vacuum concentration, and final dilution to target vaccine concentration on site, sending samples to Prof. Yang in CA for assay.

Millan Bhatt's Molecular Pharma Group in New Providence, NJ will perform filter sterilization and GMP packaging.

Our vaccines will be unpurified concentrated crude ethanol extracts of oven-dried fresh leaves.

This is allowed by the FDA for allergenic products made from natural source materials.



Protocol Development/ Commercial Scale Vaccine Production 3 of 7 Unpurified extracts were more effective than highly purified urushiol in our published experience, and much less costly to produce

We will compare shelf-life stability at 25 deg and 5 deg C

If equal, we will ask the FDA to allow room temperature storage, reducing costs



# $\begin{array}{c} \mbox{Protocol} \\ \mbox{Development/Commercial} \\ \mbox{Scale Vaccine Production} \\ \mbox{$4_{\rm of 7}$} \end{array}$

We will study the effect of 14 days at each of 40 and 50 deg C before storage at 5 deg or 25 deg. If equal to ask FDA to allow shipping without refrigeration under most (if stable at 40) or all (if stable at 50) weather and climate conditions.

Our plan to select, clone and propagate plants with similar genetically determined urushiol production patterns will automatically give us the lot-to-lot consistency required by the FDA and allow us to use the inexpensive urushiol assay developed by Prof. Yang.



# Protocol Development/Commercial Scale Vaccine Production $5_{of7}$

We will test our vaccine made from PI alone in populations separately exposed and allergic to PI, which predominates east of the Continental Divide, and PO, which dominates in the drier climate of the west.

Because of high cross-reactivity, we expect similar outcomes in both populations.

This will give us the economy of cultivating one crop for a vaccine for both allergens.



#### Protocol Development/Commercial Scale Vaccine Production 6 of 7

In the unlikely event that our vaccine fails to meet efficacy for PO we will license it for PI which is the predominant source of urushiol exposure for 80% of the US population. We can then use profits from its sale to look for more cross-reactive single-source genotypes or make a 2 plantsource vaccine to market for both allergies.

This risk will not derail the vaccine economically.

Protocol Development/ Commercial Scale Vaccine Production  $7_{of 7}$ 

We will validate a multi-step dosing schedule with a safe enough adverse events profile for the FDA to allow administration in retail pharmacies. We will provide a database to let patients get each dose at any participating pharmacy in the US.

The same total treatment dose can be safely given as a one or two step annual booster if given every 12-13 months, which the database will track.





#### **Proposed use of investor funds**

**1** of 3

\$3M of Round One funding will let us perform shelf-life stability testing, clone our greenhouse with genetically selected plants, and validate our industrial production strategy to produce a vaccine for \$30-60 per initial course of treatment or annual booster.

The market analysis in our downloadable Business Proposal predicts maximum profit at a wholesale selling price of \$300 at any production cost from \$30 to \$120.



# Proposed use of investor funds 2 of 3

# \$10M of Round Two investment will cover estimated costs of clinical trials.



# Proposed use of investor funds $3_{of 3}$

We currently anticipate a Round 3 funding need of \$4-7M to cover upscaling of cultivation and production facilities to accommodate commercial scale production, pay Biologics License Application fees, produce enough vaccine to begin commercial distribution, and set up business units to begin marketing, sales and distribution.



# **IP Protection**

- •Our patent for the vaccine expires in 2030.
- •Our application to patent Prof. Yang's FDAcompliant \$50 urushiol assay as an alternative to the "standard" assay costing \$800, is in the final stages of preparation.
- •With numerous assays needed for the production of each lot of vaccine this cost advantage will give us functional market exclusivity until 2044.



# Competition

- •A competing vaccine received media attention. Its Phase One clinical trial results, due in Dec 2021, were never reported.
- •Its developers expressed HOPE that it would protect persons NOT already sensitized.
- •It is NOT delivered to the immune system with the efficiency of our vaccine and its developers have NO data to suggest efficacy in already sensitized persons.
- •Our vaccine is safe and 90-100% effective in persons who are already allergic.

### Investor Summary - 1 of 2)

•Our vaccine is already proven safe and effective.

•FDA approved path to biologics license with no obstacles, estimated \$17-20 million total cost to license and market approval.

•Manufacture vaccine for \$30-60 / course of treatment or annual booster, sell wholesale for \$300.

• Insurance should cover. as cost of vaccine will be less than cost of care of same patient population without vaccine.

## Investor Summary - 2 of 2

•28.9 million very sensitive Americans with one or more severe reactions will want the vaccine to prevent further reactions (Vaccine Group A).

•An unknown fraction of the 116M with mild to moderate sensitivity have chronic or recurrent exposure for which avoidance is not practical and will also want the vaccine (Group B).

•They will jump-start demand as they are having symptoms NOW and will want relief NOW. News of the vaccine's success in Group B will motivate more persons in Group A to want it sooner.

•Patients will have to repeat the initial 7-step dosing schedule for safety if they wait >13 months for a booster. This should motivate patients to get annual boosters on schedule.

# What Are Downside Risks?

- •Either failure to secure investment commitments in time or supply chain delays in equipment availability could cause us to miss a growing season and delay product launch by a year.
- •With no effective competition, we see this as no greater loss than a one-year delay in your receiving annual dividends greater than the amount of your investment.
- •It still sounds too good to be true, but it remains verifiably true. We thank you for your interest in our vaccine.



# **BOME** PHARMA



# Thank you for your interest in this investment opportunity.