



BOME
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Poison Oak/Poison Ivy Vaccine Investor Presentation

BOME Pharma, LLC

Robert E. Coifman MD, CEO & Chief Science
Officer

Eric Feerst, Project Manager, Quality control &
regulatory affairs

1122 N. High Street, Millville NJ 08332-2529

Tel: 856.759.1299

Fax: 856.759.1288

Email: BOMEpharma@gmail.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.**

**290,000,000 (290M) Americans
(85% of the population)
will become allergic to PO/PI
with sufficient exposure.**

**168M either have sought
or will seek medical care for allergy
to PO/PI.**

Prospectus

- Our vaccine is already proven safe and effective
- FDA approved path to biologics license C / no obstacles, est. \$15-20 million **total** cost
- Manufacture vaccine for ~\$30 / course of Tx or annual booster
- Sell same dose for ~\$200
- Insurance should cover vaccine, as cost of the vaccine less than the cost of treatment
- ~112 million Americans meet indications, ~48 million will likely want the vaccine
- Reaching 1/8 of these by year five will generate \$1.2 billion annual revenue, >50% profit
- No safe and effective competition
- Patent protection



56 million Americans are **HIGHLY ALLERGIC** and candidates for a safe and effective vaccine with annual boosters.



Avoidance will not be practical for another 56 million people with chronic or recurrent mild to moderate disease.

Recurring illness from repeated exposures will make this group candidates for a safe and effective vaccine, 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.

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 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

We did not qualify for pre-clinical SBIR funding.

We *MAY* qualify for SBIR clinical trial funding.

Our Team:

- Robert E. Coifman M. D.: Allergy and immunology
- Eric Feerst: Project manager, quality control, and regulatory affairs
- Merlin Weaver: Hydroponic agriculture
- Catherine Yang Ph.D.: Developed and will provide low cost urushiol assay
- Millan Bhatt: USP 503b pharmacy for cost-effective GMP packaging
- Mel Kornbluh: Serial developer of successful small businesses dependent on precision technology, consulting, sales, distribution
- Scott Oneto: Poison oak and ivy agricultural biology, consulting

Protocol development and commercial scale vaccine production strategy -1 of 7

Cultivate and propagate plants selected for genetically determined urushiol congener production patterns to build consistency required by the FDA.

Oven-dry freshly harvested leaves at 50 deg. C. prior to ethanol extraction to remove 2/3 weight water content reported in 1928 to achieve almost indefinite urushiol stability if desiccation is aggressively maintained.



Protocol development and commercial scale vaccine production strategy - 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
and commercial
scale vaccine
production
strategy - 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



Protocol development and commercial scale vaccine production strategy - 4 of 7

- 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 and commercial scale vaccine production strategy - 5_{of 7}

We will compare the efficacy of vaccines containing the major urushiol of PO alone, that of PI alone and a mix in populations exposed and allergic to PI, which predominates east of the Continental Divide, and populations exposed and allergic to PO, which predominates in the drier climate of the west.



Protocol development and commercial scale vaccine production strategy - 6_{of 7}

Because of high cross-reactivity, we expect one or both single plant source vaccines to prove non-inferior to the mixed vaccine in both populations.

This will allow us market a single plant source vaccine for both allergies, significantly reducing production cost.

Protocol development and commercial scale vaccine production strategy - 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 in a different pharmacy if they wish.

The same total treatment dose can be safely given as a one or two step annual booster if given within 12-15 months, which the database will track.





Competition

- A competing vaccine received media attention. Its Phase 1 clinical trial results, due in Dec 2021, were never reported.
- Its developers expressed HOPE that it would protect persons NOT already sensitized.
- They have NO data to suggest efficacy in already allergic persons.
- Our vaccine is safe and 90-100% effective in persons who are already allergic.



Economics - 1_{of 2}

- Projected commercial GMP production cost in low \$10's per course of treatment.
- Anticipated adverse events profile mild enough to allow sale in retail pharmacies.
- Projected 5th year market \$1.2 billion with >50% profit.



Economics - 2_{of 2}

- This is a below-the-radar opportunity to apply the same business model used by manufacturers of COVID vaccines, only more so and without their negative PR:
 - Make it for the low tens of \$
 - Sell it for ~\$200 for a waiting U.S. population of tens of millions with severe or recurrent disease
- Our payers won't be the CDC, which paid for COVID vaccines, but health insurers driven by demand and cost.
- The vaccine's proven safety and clinical effectiveness will drive demand.
- The cost-effectiveness is detailed in our Investor Business Proposal.

Partial Ownership Investment Opportunity – 1 of 3

- We are eligible for a NJ Economic Development Authority Evergreen Fund grant of a dollar-for-dollar match of up to our first \$5M in funds received from outside investor(s).
- An outside investment of \$5M gives us the \$10M needed to set up and validate cost effective production and make clinical trial vaccine. With this grant we can give a first tier (up to \$5M) investor a 1% ownership share in the company for every half million invested up to \$5M.
- Either the same or a different investor can make the second-tier investment of up to \$10M to support us through clinical trials for a 1% ownership share for every \$1M invested. We anticipate zero clinical trial outcome risk as both subjects and vaccines will be identical to those in our human proof-of-concept series.

Partial Ownership Investment Opportunity - 2 of 3

- With 50% from Evergreen Fund match we need total \$3 million at signing and \$1.5 million per 12 months to total \$9 million for non-clinical trial costs and a \$1 million reserve for launch year operations. All payments are subject to annual demonstration of progress.
- Tier 2: Up to \$10 million for costs of clinical trials as required by FDA.
- Investors have the opportunity to ask questions and participate in a pre-IND meeting with the FDA.
- No anticipated need for further outside investment prior to achievement of profitable operations.
- **Key points for investors:**
 - **No current debt**
 - **No ongoing overhead**
 - **No future dilution of proposed investment**

Partial Ownership Investment Opportunity – 3 of 3

- If allocated as planned, \$5 to \$15 million plus the \$5 million Evergreen Fund match should bring the vaccine through clinical trials and to biologics licensure with production facilities ready to begin profitable operations. \$1 million will be in reserve to fund launch year start-up operations.
- We expect the availability of the world's first safe and effective PO/PI allergy vaccine to generate enough media publicity that we do not anticipate a need for an expensive advertising campaign at launch.
- If we decide to reach out for a larger share of our estimated target market of 48 million recipients, we expect profits from sales to cover costs of both marketing to reach that population and increases in production capacity to serve them.

Total Acquisition Opportunity for Big Pharma

- Purchaser option to use our team and resources or manufacture elsewhere.
- Pay a royalty of 50% added to whatever selling price you want for yourself for the life of the product, renegotiable if any true competitor without shared ownership enters the market. Also 5% to patent holders Coifman and Yang.
- Pay \$1.5 million at signing for prior work done plus \$1.5 million per year as an advance of royalty income as an incentive to bring the vaccine to market.
- **Key points for investors:**
 - **No current debt**
 - **No ongoing overhead**

Investor Summary

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