April 22, 2024 **BOME Pharma LLC** tel 856.759.1299
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World's first and only Safe and effective
Allergy Vaccine for Poison Oak (PO) & Poison Ivy (PI)
Investment opportunity (11/1/23)

Wanted: Investors, entrepreneurs, developers to help us commercialize the world's first and only allergy vaccine to safely induce tolerance to PI and (we expect) highly cross-reactive PO

The Business proposal: (Organized in the format of an NIH SBIR Commercialization Plan)

National need for an effective allergy vaccine for PI/PO: Poison ivy (PI), found east of the Continental Divide, and its highly cross-reactive cousin, poison oak (PO), found west of the Divide, are the most common causes of allergic contact dermatitis in the United States (US). Half of Americans will develop a rash from casual environmental contact at some point and 80-90% will become clinically sensitized with higher levels of exposure (1). In a 2006 general review of Toxicodendron dermatitis (2) Gladman points out that even 20% of Americans living in urban environments experience clinical allergic contact dermatitis from PO/PI, that allergy to PO/PI causes 10% of all US Forest Service lost-time injuries, and that approximately one third of forestry workers in California, Oregon, and Washington are disabled by poison oak dermatitis each season. During severe fire seasons in the western United States up to 25% of U. S. Forest Service firefighters must be removed from duty because of this condition (3). In the late 1990's the cost of treating occupational allergic contact dermatitis from PO/PI consumed 1% of the State of California's entire yearly workers' compensation budget (4).

Overall commercial goal. To bring to market the world's first allergy vaccine for the urushiols of poison ivy (PI) and poison oak (PO) that is both safe and effective at a low enough cost of production to achieve all of potential user availability, user and payer affordability, and developer profitability.

Project component goals:

1. Select & clone rapidly growing, high urushiol yield plants with genetically determined congener distributions in a sufficiently narrow range that a standardized vaccine manufacturing process will routinely fall within the lot tolerance limits we can negotiate with the FDA based n what we find it efficient to produce.

2. Employ efficient agricultural and manufacturing methods to optimize the combination of process productivity and economic efficiency.

3. Use a simple, unpurified concentrated crude ethanol extract of fresh leaves as our vaccine, based on our human proof-of-concept experience that an unpurified crude concentrate vaccine was as effective as one made with highly purified urushiol, its much lower cost of production and the key fact that it's allowed under FDA regulations for allergenic products made from natural source materials.

4. Exploit the reported ability of aggressive desiccation to stabilize urushiol under generally adverse storage conditions: to compare shelf life storage stability at 25 deg C as well as 5 deg C and with two weeks of pre-storage thermal shock at each of 40 and 50 deg C: Demonstration of stability under these conditions will support applications to the FDA to let us reduce costs by storing and shipping the vaccines without the need for refrigeration.

5. Exploit the high cross-reactivity of PI and PO by comparing the efficacy of two single plant source vaccines with a mixed vaccines in populations exposed and allergic to each of the two plants. Validation of a single plant source vaccine for both allergies will reduce costs by making it necessary to grow and make vaccine from only one plant source instead of two"

6. Validate initial treatment and booster doses and schedules that are safe, effective, efficient (in

achieving goals of treatment) and convenient for patients: To offer patients the convenience and economy of treatment in retail pharmacies as the FDA allows for flu and COVID vaccines, for example, we'll have to validate a treatment schedule with a sufficiently benign adverse events profile to satisfy the FDA that the vaccine can be safely given in settings without physician supervision or follow-up.

The product: The product will be a 100 mg / ml concentrated crude ethanol extract of PI &/or PO, aggressively desiccated before packaging in sterile injection vials in a dry nitrogen environment. They will be provided with matching vials containing pharmaceutical grade 100% ethanol and instructions for making the 10-fold dilutions needed for the first one or two treatment doses. We will not pre-mix the weaker strength vials as doing so would require shelf life stability testing for the diluted vials and possibly also additional clinical trials.

Our vaccine development team:

Robert Coifman MD 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 leads outreach to potential investors.

Eric Feerst is project manager. He is a retired NJ DEP lab chief. He will perform Prof. John Jelesko's seed germination protocol and oversee both process quality control and regulatory affairs.

Merlin Weaver is a hydroponic vegetable farmer on whose farm the PI/PO cultivation greenhouse will be erected and by whose staff it will be serviced. Merlin will apply standard commercial scale agricultural methods to the cultivation of PI and PO and his staff will provide greenhouse maintenance services.

Catherine Yang Ph D, 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.

Millan Bhatt is 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

Scott Onto 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 future company and its current precursors: We established a NJ limited liability company, BOME Pharma LLC, as the entity hat will ultimately commercialize the vaccine. Up to this time, to minimize overhead and because of evolution in the roles of the various team members while the project remains mostly dormant but ready to roll, it's been most practical for us to work as an informal network of the individuals named in our accompanying science proposal. This leaves individual team members eligible for funding opportunities for the project for which they are eligible because if their individual status. My allergy practice is eligible for certain NIH and state grants, including $3M in NIH SBIR funding for clinical trials when we reach that stage of vaccine development. Team member Merlin Weaver is eligible to apply for a USDA Agricultural Marketing Service Specialty Crop Block Grant. Its purpose would be to facilitate the achievement economic viability for the commercial cultivation of PI and PO, which qualify for that program as "medicinal herbs." Also, purchases of equipment for project use on Merlin's farm are exempt from NJ state sales tax if Merlin is the purchaser of items for use in his farm business. BOME Pharma or a BOME subsidiary entity would be eligible for the same sales tax exemption if it sells dried leaves (an

agricultural product) to another subsidiary for further processing. The second entity would not qualify for the agricultural business tax exemption as its product, the finished vaccine, is not an “agricultural product.”

It’s our understanding that conversion to a C-corp may be the most appropriate vehicle to accept venture capital. If the resulting company wants itself to qualify for the agricultural sales tax exemption it must split into two separate entities as noted above. They can be co-owned or one can be a subsidiary of the other. One would own the greenhouse and leaf drying facility, grow and manage the crops and oven-dry the leaves which qualify as agricultural products. The second entity would purchase the leaves from the tax exempt agricultural business and perform ethanol extraction, vacuum concentration and re-dilution to final vaccine concentration. The vaccine manufacturing entity could lease the rights to do this in the agricultural business’s physical facility and contract for work by the same staff.

U. S. Market analysis:

The medical reference website UpToDate's summary of Poison ivy (Toxicodendron) dermatitis (5), updated 2/11/2022, reports that 10 to 50 million Americans need medical treatment for allergic contact dermatitis to PI or PO every year. Source-tracing leads to a report first published in 2003 (6). The same estimate of 10 to 50 million cases per year is quoted by a public information website (7) and by the most authoritative recent scientific review (8).

CDC national health survey data reviewed by journalist Sammy Fretwell reported a 7% annual increase in number of US ER visits for PI and PO from 2002 to 2012 (9). The factors responsible for this increase, climate change, suburbanization and population growth, persist unchanged. We believe the 7% annual increase in emergency department visits is probably a reasonable surrogate for a similar increase in use of lower level treatment facilities (physician offices, clinics and urgent care centers). The minimum estimated annual number of Americans seeking medical care for PI and/or PO of 10 million in 2003, increasing at a rate of 7% per year, becomes a minimum estimate of 38. million Americans needing care for allergy to the urushiols of these plants in 2029, the earliest year we could have FDA-approved vaccine available for distribution, and 48 million by 2033, our earliest possible 5th year of commercial sales.

50% of Americans, currently 168 million, will require medical care for allergy to PI or PO. William Epstein, one of history's two most recognized experts on urushiol allergy, observed that ~1/3 of clinically sensitive persons (currently 56 million) are "Clinically very sensitive" (4), an estimate corroborated by my own clinical experience. Another third (another 56 million) with mild to moderate sensitivity will Two thirds, 112 million, will have either severe disease or recurrent mild-to-moderate disease and be candidates for a safe and effective allergy vaccine.

Persons with mild PI or PO allergy will often self-medicate and not be included in counts of those seeking medical care. If we can estimate that the number of those seeking first time care for reactions of moderate severity who will not be vaccine candidates without recurrent exposure, is approximately equal to the number with severe or recurrent mild-to-moderate allergy who do not happen to have contact and seek care that particular year, the minimum estimated number seeking care each year, 38M in 2028 and 48M in 2033, is a reasonable estimate of the number of Americans likely to not only meet clinical indications but will actually want the vaccine. These will be 43% of the 112 million vaccine candidates who meet medical indications for the vaccine because of severe allergy on any past exposure or unavoidable recurrent mild to moderate allergy. If, depending on our cost of production per course of initial treatment or annual booster, we can reach from 4% at a production cost of $300 per course to 12.5% (at production costs of $30 to $100 per course of treatment or annual booster), by year 5 post launch we’ll have an annual sales volume of ~$1.2 billion of which a least 50% will be profit.

Customer: If the FDA lets pharmacists supervise vaccine administration as they do for COVID and flu vaccines, our largest volume customers will probably be pharmacy chains, followed by drug distributors. Wholesale and retail distributors will be our major customers if administration is restricted to licensed prescribers. Allergenic products that are further restricted “for use by physicians who are experienced in the administration of allergenic extracts," and require a different supply chain are those that carry a risk of

systemic anaphylaxis. That is not a risk of our vaccine.

Our ability to guide the FDA's approval of vaccine delivery settings, and (per the above) who will be our customers: The FDA will allow administration under supervision by pharmacists if clinical trial adverse effects requiring acute physician care are rare to non-existent. We can control the frequency and severity of adverse effects with our choice of vaccine starting dose and dosing schedule. We can reduce adverse effect frequency and severity with a lower starting dose and a slower dosing schedule with a larger number of steps. We believe we can keep the side effect profile sufficiently benign to allow administration in retail pharmacies with a 6-step dosing schedule for Phase 1 dose ranging recipients of a cumulative 15 mg dose, 7 steps for recipients of a cumulative 25 mg dose, and 8 steps for those receiving a cumulative treatment dose of 35 mg.

Competition: A poison ivy vaccine developed by Hapten Sciences LLC was registered at ClinicalTrials.gov to enroll patients beginning in April 2021 with an estimated completion date of 12/1/22. However, the sponsors have posted no status updates since August 2021. The vaccine to be studied was a water-soluble urushiol acetate ester that the company's scientific founder, Dr. Mahmoud ElSohly, has been studying at the University of Mississippi since the 1970's. It does not precipitate in its target tissue like our water-insoluble urushiol vaccine, and it had not previously been studied in humans. Dr. ElSohly's published scientific data and the fine print on the Hapten Sciences website indicate a HOPE (with no confirming evidence) that their vaccine MAY induce tolerance if given to genetically susceptible persons BEFORE they're exposed and sensitized to PI or PO. ***We do not see this vaccine as a serious competitor to our vaccine with its proven record of safe and effective induction of tolerance in persons who are already allergic.***

Additional markets. PI and PO evolved in North America. Related Toxicodendron species exist in enclaves in South America. The Chinese / Japanese lacquer tree is a member of the family that crossed the former land bridge between Alaska and Asia. Other trees of the Anacardiaceae family produce urushiols that can cross-react, including mango, poison sumac, Peruvian pepper, pistachio, and cashew. The urushiol content is usually higher in the skin or shell than in the flesh of the fruit. Cashews are typically sold shelled (to eliminate most of their urushiol) and roasted (to degrade what remains). Urushiol-allergic persons with occupational exposure to these non-PI or PO urushiols are future candidates for the vaccines of the present project. PI and PO are slowly spreading world-wide, from seeds transported in global commerce.

Intellectual Property (IP) Protection: Drs. Coifman & Yang's US Patent 9,107,901 for VDBP for the urushiols of PI, PO and related plants, expires in 2030 (10). They have broader patents for VDBP in Great Britain, Germany and India. A provisional patent application is currently in preparation for Prof. Yang's low cost urushiol assay. Having exclusive access to an assay that costs $25 when the assay cost for potential competitors is `$800 will give us a functional monopoly on vaccine production until 2044.

Finance option A, Partial ownership investment opportunity:

We are eligible for a grant of up to $5M from the NJ Economic Development Authority Innovation Evergreen Fund as a dollar-for-dollar match of VC investment. $5M of VC funding in return for a 10% interest in the company will give us the $10M needed to fine-tune, integrate and validate the different elements of our cultivation and manufacturing processes and prepare sufficient GMP vaccine for clinical trials to follow. We will want $3M at signing comprising E$1.5M for work already done + $1.5M per year going forward to prepare for clinical trials with the final $1M to cover post-launch operations until they become self-sustaining.

A second solicitation for $10M in return for an additional 10% interest in the company will pay for clinical trials and leave us with a $1M reserve to fund operations from launch until they are covered by operating income. We do not anticipate any need for further dilution of investment.

The FDA confirmed that they do not foresee any reason to ask for Phase 3 clinical trials. It is not yet clear whether they will require one or two sets of pivotal Phase 2 trials.

If they decide to require 2 sets, the second should only cost 1/3 of the cost of the first. In the first set we will study the efficacy of 3 separate vaccines (PI alone, PO alone and a mix). Their outcomes will tell us which one of the 3 vaccines to develop further. If the FDA decides to require a second set of Phase 2 pivotal clinical trials they will only ve needed for the one of the three vaccines (from PI alone, PO alone and a mix of the two) that we decide to bring to market based on results of the first set.

Finance option B, Total ownership investment opportunity:

Candidate investors for total ownership are established pharmaceutical or vaccine manufacturers with their own capability to manage projects such as this.

1. The purchaser will have the option to contract with us for our team to perform whatever components of vaccine development it wishes to hire us to do &/or to consult as it chooses if it elects to have the vaccine development work done elsewhere.

2. The purchaser will increase whatever selling price it would want for itself by 50% as a royalty payable to us, for the life of the product. This will give us 1/3 of the final selling price at which the vaccine leaves the last entity in the chain from manufacturer to recipient that has any shared or overlapping ownership with the purchaser. The royalty % may be renegotiated if there is mutual agreement to do so, if a separately owned competitor ever appears in the market and creates true price-based competition. .In the absence of price competition we do not see this royalty on top of a reasonable return on investment for a ig Pharma purchaser of the vaccine as likely to adversely impact sales. We also see this as a reasonable way for a Big Pharma purchaser to pay us on the basis of the actualrevenue it generates for the purchase.

3. The purchaser will pay us $3M at signing, consisting of $1.5M for work previously done and a @1.5M advance of post-marketing royalty income.

4. The purchaser will pay us an additional $1.5M every 12 months thereafter until a royalty stream is established that catches up with cumulative advances.

5. If the vaccine has not entered clinical trials within 5 years from the date of signing or achieved biologics licensure within 10 years from date of signing, the seller (us) will have the option to reclaim the company for a price of one dollar, with no obligation to repay advances.

6. The purpose of the above advances and option to reclaim is to incentivise the purchaser to proceed expeditiously with the vaccine development project, which will then be under its total control.

Investor opportunity to validate our claims and ask its own questions to the FDA:: The investment value of our vaccine development project depends on the accuracy of our claims about the pathway to licensure given to s by the FDA. When a serious investor or consortium or investors are otherwise ready to commit, we'll be happy to request another pre-IND meeting with the FDA in which they can participate and for which they can submit questions. The FDA will probably let us do this only once, so we must reserve this opportunity for an investor, investors or Big Pharma potential buyer who is otherwise ready to sign on the dotted line.

Estimated clinical trial costs: (based on my estimates of what a biostatistician may recommend and what the FDA is likely to require)

FDA Phase 1, initial round: The fastest path through Phase 1 will be to concurrently treat 10 subjects exposed and allergic to PI with each of 15, 25 and 35 mg of PI vaccine at a single center in the eastern US, and 10 subjects exposed and allergic to PO with the same 3 doses of PO vaccine at a single center in the West. If these studies do not confirm doses that are both safe and effective, additional dose ranging studies can be performed with either higher or lower doses, as directed by outcome.

To accommodate an up to 50% drop-out rate without loss of study validity I'm budgeting for 60 subjects for each of the PI and PO study groups, each of whom will require 2-4 visits (budgeting for 4) for testing & grading for each of 2 sets of tests before treatment and 1 set after treatment. We're budgeting for a payment of $100 for each of 12 budgeted testing visits per study visit to the test site and an honorarium of $25 to the study subject/patient. The small honorarium should not e a deterrent as every study subject will receive a vaccine of a class already proven to be safe and effective. Recruitment should be easy if each study subject who experiences an unsatisfactory initial response to a smaller dose than what we determine to be optimal is offered enough additional vaccine to bring them up to the final cumulative dose determined to be optimal, and each subject who still has an unsatisfactory response is offered a single booster dose as was proven effective in our human proof-of-concept experience.

Costs per study subject will be $125 for each of 12 visits for testing and grading. I want to pay study sites the same $100 per visit when the patients will only require injections, in return for their agreement to manage any adverse vaccine reactions and document any late adverse reactions. The treatment schedule for subjects randomized to 15 mg will require 6 treatment visits, those randomized to 25 mg will require 7 treatment visits, and those randomized to 35 mg will require 8. Average total incremental cost per Phase 1 clinical trial subject will be $125 for each of 12 visits for testing & grading plus 7 visits for treatment = 19 x $125 = $2,375. For 60 Phase 1 subjects treated with different doses of either PI or PO this totals $142,500 in addition to costs of organization, administration and data analysis. I don't know if it will be cost-effective to hire a Contract Research Organization (CRO) to manage this study as it is sufficiently non-standard that no CRO is likely to be able to plug it into one of their standard protocols. The alternative would be my personally recruiting study centers through personal contacts and the communications resources of one of the allergy specialty scientific societies and either personally managing the clinical trials or contracting with a trusted associate to do so. Estimated total cost including IRB services and setting up the data collection and analysis system to be used for Phase 2, should not exceed $1 million.

Additional FUTURE Phase 1 testing: We determined in our human proof-of-concept experience that urushiol is not the only vaccine ingredient essential for optimal efficacy, another being an unidentified component of crude ethanol extracts. For this reason we will have to demonstrate efficacy up to whatever use life we ask the FDA to let us apply to our vaccines. We plan to perform initial clinical trials with vaccine between 27 and 30 to 33 months old, to validate assignment of an initial use life of 27 months from date of manufacture. Once the vaccine is on the market, generating profits sufficient to fund additional clinical trials, we will ask the FDA to let us perform small Phase 1 clinical trials with vaccines 30-33, 33-36 months old, etc., to validate increases in approved use life on a stepwise basis.

Phase 2 clinical trials will each randomize 30 subjects to treatment with each of 3 different vaccines (PI, PO and mixed), at doses selected on the basis of Phase 1 dose-ranging outcomes as optimally safe and effective.. Each course of treatment will require the same up to 12 visits for testing and 6-8 visits for treatment (budget based on 8). We again budgeted $100 for the study site and $25 for the subject/patient for each visit. Depending on how easy it is for the two Phase 1 clinical trial sites to each recruit 60 subjects and complete 30 we will recruit 3 sites to each recruit the same number of subjects for Phase 2 trials for each of subjects exposed and allergic to PI in the eastern US and PO in the West, two sites in each area to each recruit 90 subjects and complete treatment of 45, or 6 sites in each area to each recruit 30 subjects and complete treatment of 15. If the FDA will accept one set of the above pivotal clinical trials we will budget for 180 study subjects each having the same $2,375 subject + subinvestigator site cost = $427,500. Adding costs of study management, data analysis and IRB services may push the cost of a complete set of Phase 2 clinical trials to an estimated $2 million. If the FDA elects to require replication to accept the proposed Phase 2 clinical trial as pivotal, the cost of the second set of trials should not exceed $1M, as the outcomes of the first set will let us choose a single formulation to advance to the second set and subsequent commercialization.

Possibility of NIH SBIR clinical trial funding: We failed to qualify for NIH SBIR pre-clinical funding because NIH reviewers insisted on laboratory demonstration of our postulated mechanism of action that we didn't have the resources to perform, and that the FDA does not require for allergenic products derived from natural source materials. Once we already have a vaccine with FDA approval to take to clinical trial

those objections will become moot and we will be eligible if the applicant entity is a US-owned SBA-defined small business not majority owned by private equity and that employs its principal investigator at least 50% of full time. If the project receives the investor funding we are currently seeking my work coordinating clinical trials will be sufficient to satisfy the 50% of full time equivalent requirement.

Clinical Trials to support annual booster dosing schedule: These studies will recruit from subjects of the clinical trials for initial vaccine approval, as they will be the first persons to reach our target 15 month interval for booster doses. We plan to begin with a small (10-12 subject) initial study of patient tolerance of a one-step booster. If successful, we will then conduct a pivotal safety/efficacy booster study with a one-step booster. If a one step booster is not well tolerated, we will then repeat a similar small study to validate the safety of a 2-step course of booster treatment. We think it extremely unlikely to have to go to a 3 step booster schedule.

Pivotal booster interval clinical trials will require patch testing to document reactivity both before and after treatment, for a total of up to 10 visits per subject. At a per-subject cost of $1,250 per subject, treatment of 30-60 subjects will have a direct cost of $37,500 to $75,000. Adding indirect costs for study coordination, IRB and data analysis could inflate total costs to $250,000 to $500,000.

Production: Strains of PI &/or PO selected for rapid growth, high urushiol content and genetically determined urushiol congener distribution pattern will be grown in a dedicated greenhouse on Merlin's farm in Pittsgrove NJ. Harvested leaves will te oven-dried in a modular building adjacent to the greenhouse where their urushiol will then be extracted with ethanol. The ethanol extracts will be concentrated by evaporation under vacuum to slightly more than our vaccine target concentration of 100 mg /ml to permit precise dilution to that strength as guided by assays of samples sent to Prof. Yang in CA.. Final strength vaccine will be shipped to Molecular Pharmagroup, Inc., in New Providence NJ, where it will be filter-sterilized and packaged in injection vials under desiccating conditions. The nature and location of storage and shipping facilities will depend on outcomes of the storage stability studies and whether the FDA will allow storage and shipping without refrigeration

Marketing efforts will depend on who is our customer, as discussed above. Marketing will include efforts to generate positive media exposure as the vaccine approaches its launch date for commercial sale. We expect media publicity of vaccine availability and advertisement by pharmacies to use vaccine availability as a bait to bring customers to their stores to make other purchases will generate enough interest among the 36M Americans we estimate to be vaccine seekers in launch year 1 to generate enough revenue to support whatever additional marketing the Board and advisors ay then deem worth while.

Revenue Stream:

Revenue will come from sales of our vaccine, for which 112 million Americans either do now or in the future will meet clinical indications.. Of these, we believe the projected 36M seeking medical care for PI or PO in our earliest projected launch year of 2029 and 48 million in our earliest projected sales year #5 in 2033 are reasonable estimates of the number who both meet clinical indications and are likely to actually want a safe, effective, affordable and conveniently available vaccine.

Projection for high ($300 per course of Tx) total cost of production, wholesale sale for $600, end user or payer cost of $1,200:.

A minimum of 1/3 of the 38M vaccine candidates in 2029 and 48M in 2033 will be highly sensitive and a minimum of 1/4 both highly sensitive and unable to avoid repeated exposure and illness. Their total cost of care is likely to exceed $2,000 per episode making vaccine coverage cost-effective for insurers even at an end user or payer cost of $1,200.

If we penetrate 1% of this 25% of our total estimated market of 38M potential vaccine candidates in launch year #1 we will generate $56+M in first year revenue of which ~50% will be available to divide between investment to increase production capacity and profit. If our fraction of market penetration doubles every year, by post-launch year #5 we will reach 15% of the highly sensitive repeatedly exposed 25% of the total of 48M potential vaccine candidates or 4% of the total pool of vaccine candidates. This limited market penetration will still give us post launch year #5 sales of $1.2B, of which 50% will again be available for division between reinvestment and profit.

Projection for mid-range ($100 per course of Tx) total cost of production with end user or payer cost of $400:

Medical care of a non-trivial mild episode of PI or PO dermatitis will usually require one level 3 physician or urgent care office visit. Treatment of a moderate episode usually requires 2 office visits and treatment with a short course of high dose corticosteroid, which is not benign particularly if frequently repeated.. At an end-user or payer vaccine cost of $400 per course of treatment plus ~$30 per dose for vaccine administration for vaccines of It becomes cost-effective for insurers to pay for treatment of all highly allergic patients (with any history of severe reactions) plus mildly and moderately allergic patients with chronic and recurrent exposure and illness. These patient groups collectively comprise ~50% of the 38M potential vaccine candidates in projected launch year 2029 and 48M in projected post launch year #5 in 2023

First year penetration of 1.5% of this 50% subset of the total potential market of 38M vaccine candidates in 2023, doubling annually to 25% of this 50% subset or 12.5% of the total vaccine candidate pool of 48M in 2033, will yield the same sales revenues and profits as those projected above for a vaccine production cost of $300 per corse of treatment and sale to 4% instead of 12.5% of the same total market.

Projection for low ($30 per course of Tx) total cost of production:

If we achieve our cost-containment production goal of ~$30 per course of treatment and sell wholesale for 2X cost of production with an additional 2-fold cost increase for the end user or payer it will be cost-effective for insurers to pay for vaccine for the full 100% of the projected 48M persons potentially interested in receiving the vaccine. Income and profits will 40% less than if we reach only the more severely affected half of that number with a 3x higher priced vaccine. Our take home message here is that even if we achieve our cost-containment goal of production in the los 10's of dollars per course of treatment we should target a smaller and sicker recipient population for whom it will be cost-effective for insurers to pay a higher price.

As the PR effect of reducing a drug cost is much more favorable than the PR effect of a price increase I think it best serves our overall interest to launch at a wholesale price significantly greater than twice production cost if we achieve our cost-containment goal of production in the low 10's of dollars per course of treatment. A reasonable wholesale selling price might be in the range of $200-$300 before adjustment for inflation, If negotiations with insurers yield willingness to expand indications for coverage in return for price cuts that will increase rather than decrease net revenue and profits those accommodations will also give us the PR benefits of reducing the cost of a high volume health care service when so much of the health care economy is moving in the opposite direction.

Ask your own questions to the FDA:

For a serious investor otherwise ready to sign a contract we can request another FDA pre-IND meeting for which we can discuss and jointly prepare our lists of questions to be addressed. We will list you as members of out meeting team and you'll be able to participate in the video conference meeting. (This is an option we can only offer to an investment partner who is otherwise ready to sign a contract, as it's something we don't believe the FDA will let us do more than once.)

We thank you for your interest in this product and this project.

Robert E. Coifman, M. D.

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Market projection table:

PI/PO urushiol allergy vaccine marketprojections		Low	Mid	High		
Single pt Tx kit production cost		$30	$100	$300		
Single pt Tx kit wholesale selling price		$60	$200	$600		
Market share & $$ goals for:		2029	2030	2031	2032	2033
Market #	Low mft cost	36,063,854	38,678,778	41,483,306	44,491,185	47,717,160
	Med mfg cos	18,031,927	19,339,389	20,741,653	22,245,592	23,858,580
	High mft cost	9,015,963	9,669,694	10,370,826	11,122,796	11,929,290
Mkt # if cost $30, sell @ $60		36,063,854	38,678,778	41,483,306	44,491,185	47,717,160
Target mkt penetrance		0.015625	0.03125	0.0625	0.125	0.25
Projecteed # sales		563,498	1,208,712	2,592,707	5,561,398	11,929,290
Projected gross revenue		$33,809,863	$72,522,709	$155,562,397	$333,683,886	$715,757,396
Proheted profit		$16,904,931	$36,261,354	$77,781,198	$166,841,943	$357,878,698
Mkt # if cost $100, sell @ $200		18,031,927	19,339,389	20,741,653	22,245,592	23,858,580
Target mkt penetrance		0.015625	0.03125	0.0625	0.125	0.25
Projecteed # sales		281,749	604,356	1,296,353	2,780,699	5,964,645
Projected gross revenue		$56,349,771	$120,871,181	$259,270,661	$556,139,810	$1,192,928,993
Proheted profit		$28,174,886	$60,435,591	$129,635,331	$278,069,905	$596,464,497
Mkt # if cost $300, sell @ $600		9,015,963	9,669,694	10,370,826	11,122,796	11,929,290
Target mkt penetrance		0.010416666667	0.020833333333	0.0416666666667	0.0833333333333	0.1666666666667
Projecteed # sales		93,916	201,452	432,118	926,900	1,988,215
Projected gross revenue		$56,349,771	$120,871,181	$259,270,661	$556,139,810	$1,192,928,993
Proheted profit		$28,174,886	$60,435,591	$129,635,331	$278,069,905	$596,464,497