Orchard Cottage, Bintree Road,
Billingford, Dereham,
Norfolk,
NR20 4AJ
ENGLAND

T: +44 (0)1362 668358
F: +44 (0)1362 668834
E: lee@bulbrook .com
W: www.bulbrook.com

Bulbrook Associates Product Design and Development

October 12th 2012

Impopharma Inc., Unit 6,
255, Spinnaker Way,
Concord, Ontario,
Canada
L4K 4J1

For the attention of Harold Wulffhart.

Dear Harold,

Re: Development Program for a Generic Reservoir based Dry Powder

I have pleasure in attaching a proposal, for the design and pilot manufacture of a generic reservoir based dry powder inhaler – as discussed.

Please note that this proposal outlines the stages of development for an inhaler in advance of a formal presentation only. Please give us the opportunity to amend these proposals if the content does not align with the customers needs.

These proposals terminate at single impression steel tooling. Tooling will be suitable for supplying final quality devices to cover studies, clinical trials and commencement of pilot production.

We constantly endeavour to circumvent existing patents known to us and brought to our attention, but it will be the responsibility of the client to verify and ensure the intellectual property status of all aspects of the design at the appropriate time.

It must be acknowledged that a successful product requires the integrated development of powder, device and filling means. It should be noted from the outset that the final performance of the device is determined from an iterative development program and cannot be assumed to be resolved at the inhaler component design stage. Therefore, early access to the powder intended for use is required to ensure an efficient development program.

All estimates shown do not include the following:

Validation documentation; Travelling expenses, Travelling time outside UK; Shipping and transport costs; Mold tool set-up costs; Device component costs; Powder filling means; labelling and packaging; raw materials costs; Printing costs and/or Legal fees relating to patents.

Intellectual Property rights will become the property of the client when Stage 1 payments have been made in full. Tooling will become the property of the client when tooling payments have been made in full.

Payment terms half in advance and half on completion for each stage.

I trust this information meets with your client's approval and look forward to further communications in due course.

Yours sincerely,

Lee Bulbrook
For and on behalf of Bulbrook Associates

Development Program for a Generic Reservoir Type Dry Powder Inhaler October 2012

The design of the Dry Powder Inhaler will comprise a single user, disposable, breath-actuated inhaler incorporating a single bulk powder reservoir able to contain (say) 200 milligrammes of powder from which individual doses can be extracted and introduced into the device airway. The volume of powder dispensed in each dose will be intended to match the innovator. The device will include a counter mechanism to indicate the number of doses taken or remaining. We will also allow for the incorporation of a desiccant inside the device.

Stage 1. DESIGN Timescale: Approx. 12 weeks

Deliverable: Detailed design of device to define method of construction, appearance, concept method of filling and method of operation. Since the filling of the device is an integral requirement of its construction, the design program will include outline design only of the powder filling system. Bulbrook Associates to present the design for appraisal and discussion. At key stages during the design process the client will be presented with progress presentations and design considerations.

$120,000 US

Stage 2. PROTOTYPES / AIRWAY TEST MODEL Timescale: Approx. 5 weeks

Deliverable: Three working models to demonstrate unit size, presence and potential usability sufficient to inform all interested parties how the final device is intended to work; one model for customer, one for use by us and toolmakers and one for Impopharma. These will allow appraisal of the unit airflow pressure drop to ensure the device conforms generally to customer specifications, as well as confirming the size of the powder reservoir and dose well(s).

$20,000 US

Stage 3. INITIAL MANUFACTURE Timescale: Approx. 16 weeks

Deliverable: Complete device engineering detail design for mold making and initial manufacture, i.e. construction of single impression and/or family impression mold tools. Cost estimates only for tooling, actual costs will depend on the complexity of the final design. Cost includes invigilation and management of tooling program. Samples will be molded to prove assembly, fit and function. (Iterations are expected to progress snap fits etc. to suit final product assembly).

$400,000 US

Stage 4. FIRST TEST AND PERFORMANCE Timescale: Approx. 8 weeks

Production quality devices must be available alongside filling means that can be adjusted for filling those devices. The target at this stage will be to achieve consistency of operation only of

both filler and device. Access to the intended powders at this time is critical and usually requires changes to the powder to modify its handling characteristics.

It is not predicted that the inhalers will consistently deliver those doses at a required pressure drop without iteration. Also, the filling machine cannot be developed and calibrated in isolation without having units available.

Typically, the filling environment can affect the characteristics of the powder and that control of static charge may require dedicated anti static and humidity controlled environments and protocols.

It will be important at this stage to define a comprehensive test protocol where the device, filling machine, powder formulation and powder management will require combined iterations to establish successful filling and performance parameters.

$35,000 US

Stage 5. **PRODUCT DEVELOPMENT** Timescale: Approx. 5 weeks per iteration

It is not possible to fully predict costs since the procedures will be iterative. However, we would anticipate perhaps 2-3 iterations to establish good working parameters for the device and powder. Costs include modifications to mold tools and Bulbrook Associates involvement with molders and Impopharma only.

Following these iterations it is predicted that the device and filler performance will be well established and that the dispensation of precise doses will have been achieved.

Per iteration: $35,000 US

Summary:

Stage 1.	DESIGN	12 weeks	$ 120,000
Stage 2.	PROTOTYPE / TEST MODELS	5 weeks	$ 20,000
Stage 3.	INITIAL MANUFACTURE	16 weeks	$ 400,000
Stage 4.	TESTING & PERFORMANCE	8 weeks	$ 35,000
Stage 5.	PRODUCT DEVELOPMENT	15 weeks	$ 105,000 3 iterations
	TOTAL…	56 weeks	$ 680,000 US