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Bulbrook Associates

Product Design and Development

October 16th 2013

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 Multiple Fixed Dose Dry Powder Inhaler

I have pleasure in attaching a proposal, for the design and pilot manufacture of a generic multiple dose dry powder inhaler – similar to the Advair device – 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 prototype (single impression steel) tooling. Prototype 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. All intellectual property rights associated with the project shall become the sole property of the client when stage 1 payments for designs have been made in full.

It must be acknowledged that a successful product requires the integrated development of powder, device and dose containment 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:

Tool Validation and associated documentation; Travelling expenses, Travelling time outside UK; Shipping and transport costs; Mould tool setup costs; Device component costs; Dose containment pack prototyping or manufacture; labelling and packaging; raw materials costs; Printing costs and/or Legal fees relating to patents.

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 Multiple Fixed Dose Dry Powder May 2013

The design of the Dry Powder Inhaler would comprise a single user, disposable, breath-actuated inhaler incorporating a strip of compartmented doses. The device will include a counter mechanism to indicate the number of doses taken.

This program does not include full design or manufacturing means for the dose strip, other than for mechanical handling inside the unit. We would work alongside the strip supplier to influence the strip design and ensure that mechanical considerations for strip management in the device would be correctly integrated.

Stage 1. DESIGN Timescale: Approx. 14 weeks

Deliverable: Detailed design of device to define method of construction, appearance, concept design of dose strip and method of operation. 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.

Approx. $130,000 US

Stage 2. PROTOTYPES / AIRWAY TEST MODEL Timescale: Approx. 6 weeks

Deliverable: Two 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 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 usage of the dose strip. It is assumed that a dose strip resembling the final design will be made available for test.

Approx. $30,000 US

Stage 3. MANUFACTURER SOURCING Timescale: Approx. 4 weeks
(To run concurrently with stage 2).

Deliverable: Component manufacturers, assembly, filling and packaging providers sourced and short-listed to suit customer requirements for high volume production. A design and development program will be outlined to define an approved high volume assembly, filling and sealing environment along with associated quality control systems.

Approx. $10,000 US

Stage 4. INITIAL MANUFACTURE Timescale: Approx. 16 weeks

Deliverable: Complete device engineering detail design for mould making and initial manufacture, i.e. construction of single impression and/or family impression mould 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 moulded to prove assembly, fit and function. (Iterations are expected to progress snap fits etc. to suit final product assembly).

Approx. $450,000 US

Stage 5. **FIRST TEST AND PERFORMANCE** Timescale: Approx. 10 weeks

Production quality devices must be available alongside production quality dose strips and powder. The target at this stage will be to achieve consistency of operation only. It is not predicted that the inhalers will consistently deliver those doses at a required pressure drop without iteration.

Approx. $50,000 US

Stage 6. **PRODUCT DEVELOPMENT** Timescale: Approx. 4 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. Costs include modifications to mould tools and Bulbrook Associates involvement with moulders and Impopharma only.

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

Per iteration: Approx. $50,000 US

Summary:

Stage 1.	DESIGN	14 weeks	$130,000
Stage 2.	PROTOTYPE / TEST MODELS	6 weeks	$ 30,000
Stage 3.	MANUFACTURER SOURCING	----------	$ 10,000
Stage 4.	INITIAL MANUFACTURE	16 weeks	$450,000
Stage 5.	TESTING & PERFORMANCE	10 weeks	$ 50,000
Stage 6.	PRODUCT DEVELOPMENT	12 weeks	$150,000 3 iterations
	TOTAL…	49 weeks	$820,000 US