

Business Plan for Sublime Stericeuticals Corporation

April 8, 2021

Executive Summary

Freeze-drying is a commonly used approach to stabilize drugs & vaccines. Traditionally, industrial-size freeze-dryers sold for the pharmaceutical industry incorporate an inefficient and expensive, decades old shelf-freezing design. Through a development and marketing agreement with our Fortune 500 strategic partner, Sublime is introducing a novel continuous freeze-drying machine (aka lyophilizer) that will provide pharmaceutical manufacturers with freeze-dried drug & vaccine products at one fourth ($\frac{1}{4}$) of the capital costs of traditional processing, while increasing process throughput up to ten times (10X).

Opportunity

The Problem

Pharmaceutical lyophilization is typically an expensive process that involves high operational costs, high energy consumption, high capital investment, and lengthy processing times. Old-school shelf-type freeze-dryers in mainstream use by drug manufacturers are extremely inefficient, have a tremendous capital cost (~ \$9M/machine), have a very large operational footprint, and often deliver drug products with inconsistent quality attributes resulting in millions of doses of unsalable drug products needing to be destroyed.

The Solution

Sublime incorporates a liquid nitrogen based, instant freezing method into our continuous freeze dryer design. Our unique freezing and drying system can be made available to our pharmaceutical manufacturing customers at about 25% of the capital cost they would have expended on a traditional lyophilizer, while increasing their product throughput up to ten times (10X) the commonplace freeze-drying process.

The Opportunity

The global pharmaceutical freeze-drying equipment market is expected to reach over \$6.2B in 2023 and continue to grow at a CAGR of 8.2%.

As part of our development agreement, our machines will be marketed by our Fortune 500 development partner, Air Products, in addition to Sublime's own sales and



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marketing team. This partnership is mutually beneficial in that Sublime, through the sales of its machines, will provide Air Products with a lucrative avenue for increased sales volume of liquid nitrogen.

- ⌚ Air Products is a worldwide supplier of liquid nitrogen, and has established itself as the main supplier to US drug manufacturers.

With Air Products as a partner in our marketing effort, Sublime expects to take a 0.5% share (\$39M) of the lyophilization new equipment market within 5 years, and 5-8% (\$580M to \$930M) within 10 years.

- ⌚ We know of only one competitor, IMA Life, that is pursuing development of a commercial continuous lyophilizer, though using a completely different drying technology.

Why Us?

The founders of Sublime Stericeuticals have over 44 years of experience in the pharmaceutical and biotech industries. The majority of that time has been spent as consultants to the industry. Our services have been contracted at numerous US manufacturing facilities from coast to coast, and we have identified countless quality, compliance, and manufacturing efficiency issues (i.e. problems) at every single site we have visited.

One particular issue kept popping up... the inefficiencies and inconsistencies of operating the conventional lyophilization process. Sublime Stericeuticals' Cryophilizer delivers equivalent or superior drug product while significantly increasing factory throughput. This allows our customer to rapidly upgrade their sterile freeze-dried drug manufacturing operations to be efficient and compliant, *every single time*.

We know what can go wrong, *will go wrong*, so we endeavored to greatly reduce the opportunities for error through our system design. With this, we elevate our customer's ability to achieve right-first-time manufacturing. *Every single time*.

Expectations

Early Forecasting



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	Y1 (begin Q2'21)	Y2 (begin Q2'22)	Y3 (begin Q2'23)
SALES REVENUE	\$ 0	\$ 13,563,036	\$ 33,372,207
NET INCOME (Loss)	\$ (1,795,063)	\$ 4,699,030	\$ 19,237,426
	Year 1 End	Year 2 End	Year 3 End
CASH ON HAND	\$ 54,065	\$ 4,765,095	\$ 24,002,520

Financing Needed

We will need an initial minimum raise of \$275K to take us through comprehensive prototype testing. Following successful prototype testing, we will extend our raise another \$975K to support funding of our first commercially salable model. We intend to use an SEC approved crowd-investment platform to initiate and manage our fundraising efforts.

Product Development Status

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Mass transfer and thermodynamic calculations were completed February, 2021 with results indicating process feasibility.

Assembly of our initial prototype is underway, with a target completion date of May, 2021, followed immediately by comprehensive testing.



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Target Market

Initial Target Market:

1. Global lyophilized drug manufacturers.
2. Global freeze-dried food processors.

Customers:

- ⌚ Existing Air Products pharmaceutical and food manufacturing customers.
- ⌚ Up and coming startup pharmaceutical manufacturers looking for an edge over the competition.
- ⌚ Institutional research and development centers.

Feasibility and Competitive Analysis

Advantages and Disadvantages of Conventional Lyophilization

The Sublime Cryophilization System

Advantages of Sublime's Continuous Lyophilization and Filling System

- Lower manufacturing costs
 - Equipment/facility footprint is relatively small.
 - Lower operational costs (utilities, labor, maintenance, validation).
 - Relatively low capital investment costs as compared to traditional technology.
- High manufacturing throughput
 - Continuous lyophilization and filling process.
- Better product
 - Shorter drug reconstitution times .
 - Higher assurance of product sterility by using a sterile, closed system.
- We anticipate the system design will easily lend itself to turn-key delivery or portability.



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Execution

Marketing Plan

Our Fortune 500 development partner, Air Products, will begin approaching their current pharmaceutical customers upon completion of our prototype testing. We expect this early marketing effort to stimulate conversation within these drug companies, create buzz in big pharma, and likely fuel the first order of our commercial product.

At the same time, Sublime's own sales and marketing team will be introducing our continuous lyophilizer to small and mid-size drug producers as an expedient way to become an industry game changer. Sublime will leverage its access to Zoominfo.com to obtain current contact information for our target market.

To further stimulate industry buzz, Sublime will embark on a social media marketing campaign through an established social media management agency.



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Production Operations

Location & Facilities

Sublime's facility in Ames, IA will be used to complete the testing of our prototype and to build our first commercially available machines. We anticipate our current facility to accommodate assembly of two lyophilization units concurrently.

Our location at Iowa State University's Research Park is adjacent to US Highway 30, and 4 miles from entry onto the interstate highway system at I-35.

People

Currently the key leadership and management positions are occupied by the Sublime cofounders, Joel Lennon-Meyer (President) and Shawn Stimson (Vice President). We anticipate hiring a marketing/sales manager in Q4'21, and contracting a controls engineer in the same timeframe.

Skilled and non-skilled labor will be hired as necessary for office work and machine assembly.

Technology

Our novel equipment is patentable intellectual property. A provisional patent application was filed in November of 2020. Ancillary off-the-shelf technology will be integrated where advantageous.

Equipment & Tools

Our cryophilization machine will be automated from start to finish, and incorporate fully FDA compliant electronic systems that provide real time feedback and process control.



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Significant Activities and Milestones

Year 1			
Q2-21	Q3-21	Q4-21	Q1-22
Meet Minimum Raise Goal to Release Crowd Funds	Develop Full User Requirements for Commercial Machine	File Full Patent Application	Begin Machine Hardware Assembly
Install Liquid Nitrogen Tank	Prove Prototype w/Multiple Drug Products	Draft System Technical & Build Documents	Develop Controls Integration Training Plan
Publish Prototype Initial Test Results	Release Second Round of Crowd Funds upon Completion of Prototype Testing	Develop Controls Integration Plan	Integrate/Automate Equipment
	Establish Safety Program	Establish GMP/ISO-9001 Quality Systems	

Year 2	
Q2-22	Q3-22
Develop Validation Protocol Package for Sale	Deliver, Install, and Test 1st Commercial Machine
1st Commercial Machine Ready for FAT	\$0.9M Payment Upon Acceptable FAT (SN: 2)
\$1.3M Upon Acceptable FAT (SN: 1)	\$0.9M Upon Successful Install/Test (SN: 1 & 2)
\$1.0M Upon Order of SN: 2 & 3	



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Company

Overview

Ownership & Structure

Sublime Stericeuticals is registered as a C corporation in the state of Iowa. Joel Lennon-Meyer and Shawn Stimson currently have equal controlling shares (50:50) in the corporation.

Company History

Shawn and Joel have known and worked with each other for 15+ years. They met in 2006. Joel was the Director of Technical Services at what was Fort Dodge Animal Health at the time, and Shawn was hired to perform autoclave qualifications as a contractor. Several years later their paths crossed again when both were on separate projects as consultants for the same client. Upon the end of their respective projects at this client Joel and Shawn both went to work for another client, this time Shawn was hired by Joel to work as an independent contractor. They have been working together whenever possible ever since.

In 2016, Shawn had an idea for a way to produce lyophilized product both at a higher quality and less expensively and approached Joel for his thoughts on the viability of such a company. After kicking around the idea for a couple years whilst continuing our consulting careers, we founded Sublime Stericeuticals Corporation in October 2018. We then set out together to make our idea a reality. Shawn discovered the Startup Factory at Iowa State University, which accepted Sublime into Cohort 6 in January 2019. We gained an immeasurable amount of entrepreneurial knowledge during our time at the Startup Factory and have made many valuable connections. The Startup Factory prepared us for the next steps in our entrepreneurial quest.

During the summer 2020, while searching for possible components for our lyophilization system, Joel discovered that Air Products and Chemicals, Inc. was marketing a cryogenic spraying system to assist in cooling during certain powder coating processes. He made an inquiry into use of a similar system for cryogenic



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freezing of drug products and discovered through telephone conversations that Air Products had already completed research and development into a system for this type of application in nutraceutical production. In the fall of 2020, Air Products approached Sublime with an opportunity for a joint development agreement, which would join our two technologies into a single, commercializable system.

Team

Management team

Joel Lennon-Meyer, a.k.a “the voice of reason”- Cofounder, President and CEO with over 28 years of pharmaceutical experience in roles of Management, Qualification, Business, and Aseptic Manufacturing.

Shawn Stimson, a.k.a “the visionary”- - Cofounder – 15 years of pharmaceutical experience with roles in Qualification, Aseptic Manufacturing, and Sterility Assurance

Advisors

Pharma Industry Advisors:

Jeff Haughey – Pharmaceutical facility design, construction, and qualification

Maria Banach - Pharmaceutical operations and startup experience

Anita Sabourin – Industry certification in regulatory affairs

Jake Johnson - Marketing and sales professional

Legal Advisors – Todd Van Thomme and Dan Blakesly, Nyemaster Goode, Ames, IA

Financial and Tax Advisor – Brett Moellers, CPA, The Bookkeepers, Inc., Des Moines, IA

Business Advisor - Bill Adamowski, Executive Director of Entrepreneurship, Innovation, and Human Centered Design, Drake University, Des Moines, IA.



Financial Projections

Key assumptions

Sublime has been bootstrapped from inception to prototype. Angel and/or crowd investment is critical to building our first commercial machine and bringing it to market.

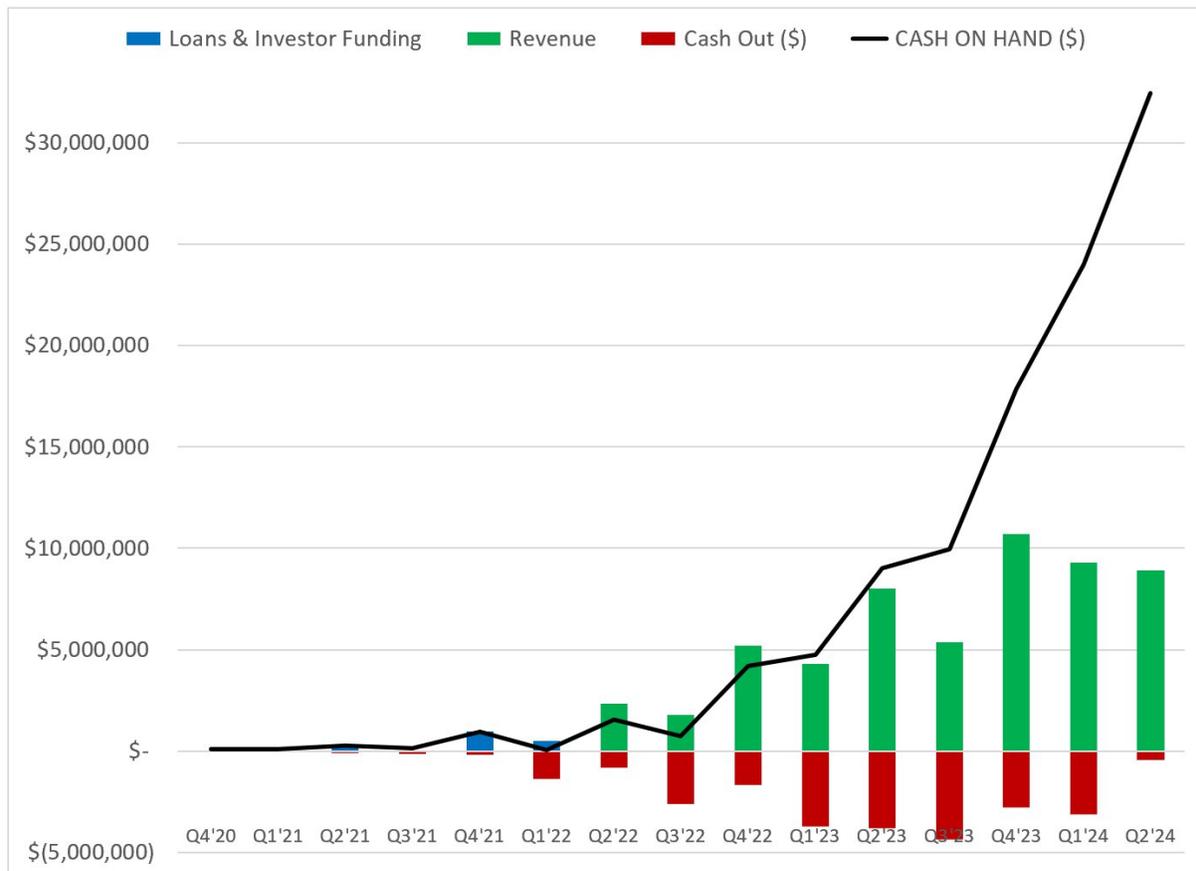


Chart Summary

1. Expenses will be incurred immediately to establish manufacturing operations as expeditiously as possible.
2. The majority of cash out is COGS.
3. Revenue begins at the sale of our first commercial machine in Q2'2022.
4. Cash on hand begins to accumulate very quickly in Q3'2023