



Contact

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Company Milestones

2015 Successful Completion of Artemether-Lumefantrine PK/BE Study

US Patent US20150366998 A1

2016: NIH Phase I Grant awarded

2016 ODS Adherence Study Completed at California Lutheran University

2017 Successful Completion of Isoniazid PK/BE Study

Patent WO 2018236729A1

2019 Successful Subcontract for AZT-NVC Study by University of Kansas Medical Center

2020 First Commercial Contract for Development of Maropitant ODS

2020 Grant Received from Kansas Department of Commerce

2020 NIH Phase II Grant Application Submitted

2021 Commercial Contract for Development of Dry Mouth ODS for use in Cancer Patients

Business Summary

At Oak, we have big goals - **global health, dignity, and sustainability for underserved populations.** With our innovative drug delivery platform, Oral Dissolvable Strips (ODS) and a unique distribution model we can make medicines that are safe, affordable and available globally regardless of geography or economic status. Drugs can now be administered to millions of people of all ages; arguably our products could service the widest demographic population in recent decades, including our beloved pets. Our therapeutic products address some of the most devastating diseases worldwide. We place special emphasis on markets in the developing world and niche populations such as pediatric and geriatric patients.

The Problem: Medicines don't work in people who don't take them

Globally, people are suffering from diseases with relatively simple cures, simply because things like tablets, capsules, and liquids, can be difficult to take and things like Injectables require special training and equipment to administer. Almost **6 million children under five years of age die annually, more than 2 million of them from only a few diseases.** Worldwide, millions of people – children and adults alike - die or suffer long-term consequences of illness because they simply do not have access to the right medicines.

Our Solution

A drug delivery platform called Oral Dissolvable Strips (ODS, sometimes also called Oral Thin Film or OTF). These are very thin, stamp-sized, flavored strips of a carrier matrix in which active ingredients are embedded. When put on the tongue, the inside of the cheek or the roof of the mouth, they hold in place while rapidly and completely dissolving and releasing the active ingredients. All of this is usually a matter of seconds, although the dissolution time can be tailored to fit the treatment or patient need. We also mask the often extremely bitter or unpleasant taste of active pharmaceutical ingredients with customized flavoring – compare that with a large pill that is bitter and difficult to swallow or with a liquid formulation that has the potential to spill or be expelled. Other advantages of ODS include bypassing of the first pass effect, avoidance of pre-systemic elimination within the GI tract, and, depending on the particular medication, a better enzymatic flora for medication absorption. **By drastically improving the patient experience, we create a clear marketing advantage and – more importantly - increase patient adherence to treatment regimens and therefore clearly improve health outcomes.**

Market

In 2018, total spending for pharmaceuticals in the United States was \$482bn (Statista). While the share of ODS among overall spending is still relatively small with an estimated US\$1.435 bn in 2017, interest in ODS as an alternative is rapidly growing. The overall market for ODS is projected to grow at a CAGR of 13% until 2026. We believe that the need in niche populations will be even greater. Between 16-23% of the adult population in the United States suffers from dysphagia, a condition that makes it difficult to swallow tablets or capsules. For stroke patients, the prevalence of dysphagia increases to 50-75%, to 35- 83% for Parkinson's patients, to 75% for people in nursing homes, it is estimated to be between 30-80% for children with developmental disorders, and as high as 99% for children suffering from cerebral palsy. It is forecast that one of our key markets, the global market for pediatric medications will grow from approximately \$92.6 billion in 2019 to reach \$116.6 billion by 2024 at a CAGR of 4.7% for the period of 2019-2024 (BCC Research).

The Oak Team

Dr. Edward Maliski, PhD
CEO

Dr. Gerhard Apfelthaler, PhD
Chairman & Chief Strategist

Zachary Nicolai, B.S., B.A.
Senior Scientist

Cameron McFarlane
Business Development &
Director of Manufacturing

Kassra Homayounfar, B.S.
Corporate Development

Advisory Board

Dr. Lisa Y Armitige, MD, PhD,
FACP, FAAP, FIDSA
Pediatric Infectious Diseases, TB

Dr. Sarah Finocchiaro Kessler,
PhD, MPH - Reproductive Health
& HIV Intervention

Dr. Michael Hageman, Professor,
School of Pharmacy, University of
Kansas.

Dr. Sally Maliski, PhD, RN,
FAAN
Clinical Healthcare and Outreach

Dr. Carol Nacy, CEO, Sequella -
Microbiology

Competition

There are approximately 20 players in the ODS market globally, but only a handful with the technical and scientific capabilities to manufacture strips that extend beyond the novelty category. Notable competitors at this stage are; Adhesive Research, Biofilm, CL Pharma, Intelgenix, LTS Lohman, Aquestive Therapeutics and Zim Labs. **The average loading capability amongst our competition is 15 mg/in²**

Competitive Advantage

Oak's ODS platform has a number of major technological advantages over our competitors:

- **Significantly more active ingredients** (more than 60% / **300 mg**) per strip.
- **Targeted dissolution time** through advanced encapsulation technique.
- **Tailored degree of muco-adhesion.**
- **Customization of the absorption point** for the active ingredients.

Ability to produce **multi-layer strips for combination therapies, mixed release rates and properties.**

Objectives & Products

In the next three years, we will move products along the development pipeline, develop new products, work on essential improvements to our drug delivery platform, expand our IP portfolio, and begin small batch manufacturing. We will start business development for commercially ready products, and are planning to enter the market via licensing agreements in the North American market and via smaller caregiving organizations in our target markets in the developing world via US-based NGOs. Our main activities for the next three years will be as follows:

Research and Completion of ongoing product development

- Isoniazid (INH): GLP-Bioequivalence Study and Clinical Trial
- Amoxicillin: Non-GLP Bioequivalence Study
- Maropitant: Non-GLP Bioequivalence Study

Business & Corporate Development

- Acquisition of key clients in the U.S.
- Development of Relationships with US-based NGOs
- In-country field tests with NGO partners
- Fundraising
- Build out of lab infrastructure
- Development of manufacturing capability
- Hiring of key personnel

Testimonials

"I think Oak's medication strips are the most exciting advance in the delivery of medications to patients who need them that I have seen in my 20 years of practice."

Michael Neely, MD, MSc, FCP
Director, Laboratory of Applied Pharmacokinetics and Bioinformatics.
The Saban Research Institute, Children's Hospital L.A.

"I see Oak's technology, when applied to the needs of children, as having the potential to address the gap in pediatric care globally."

Ashley Margol, MD, MS Attending Physician Pediatric Neuro-oncology Division of
Hematology/Oncology and Blood & Marrow transplant.