



DESTINATION STARTUP

Ezalife, LLC

One-Sentence Summary of What You Do: Ezalife, LLC designs and develops medical devices that make life easier for infants, children and adults with complex medical needs. Our first product, the Button Huggie, is a precision-designed, low profile gastrostomy button securement device.

Affiliated Institution: University of Colorado Anschutz Medical Campus

Have you formed a company yet? Yes

Funding/Financing: Grant Funding, Direct/Indirect University Support

Please describe your company and the problem you are trying to solve: Ezalife, LLC (www.ezalife.com) is an early stage company that is actively being spun out of the University of Colorado and Children's Hospital Colorado. Ezalife designs and develops medical devices for infants, children and adults with complex medical needs. Our mission is to improve overall health and safety, by developing products that simplify the lives of those with complex medical issues, so that they can live with dignity and greater independence.

A gastrostomy button is a surgical device that is inserted through the abdominal wall and into the lumen of the stomach. Gastrostomy button placement is the third most common non-cardiac, inpatient surgical procedure performed in children in the US. In fact, more than 2.5 million low profile gastrostomy devices are placed or replaced throughout the world each year, including more than 750,000/yr in the US. These low-profile devices help children and adults maintain body weight, correct nutritional deficiencies, hydrate, provide medication(s), and improve overall quality of life. Unfortunately, a variety of distressing problems often complicate healing and maintenance of the gastrostomy tract, due to excessive movement of the g-button in the tract.

There are no g-button securement devices on the market. The "Button Huggie" is uniquely designed and clinically tested in two small clinical trials; a 200 patient RCT will start in fall 2019.

Three provisional patents and one PCT application have been filed with the USPTO. Licensing discussions with CU have started. Trademark applications for "Ezalife" and "Button Huggie", and a logo have been submitted to the USPTO.

What is/was your go-to-market strategy? According to "Markets and Markets", more than 2.5 million low profile gastrostomy devices are placed or replaced throughout the world each year, including more than 750,000/yr in the US. The international market is expected to exceed 3M and the US market more than 1M devices per year by 2021.



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No company, including those that manufacture g-buttons, offers an external securement method for these devices. To create a barrier to market entry, we have submitted three provisional (CU4335H, CU4613H, CU4913H) and one full PCT (62/636,536) application (and soon a second) to the USPTO via CU TTO for national and international patent protection.

Value Proposition: ED visits and hospital readmissions are common after gastrostomy placement in children due to infection (26.6%), mechanical complication (22%), or replacement (19.4%). Landisch et al noted that early laparoscopic g-button dislodgement (< 6wks) occurred in 7.6% of patients, with an average cost for IR (interventional radiology) replacement of \$7,105. We will soon start an IRB approved, multicenter randomized controlled trial comparing g-button related complications in patients who use the standard tic-tac-toe (tape and gauze) dressing versus the Button Huggie for a 12-week period, to prove clinical effectiveness and parental adoption.

The FDA categorizes the Button Huggie is a Class II, 510(k) exempt medical device, subject to General Controls under Product Code PLI, regulated by 21 CFR 876.5980). We plan to begin online sales once we complete the 200 patient clinical trial and make any final design modifications to the device.

How will/do you generate revenue? We are employing a razor-razorblade revenue business model. We plan to sell 12 week Button Huggie kits online via the Ezalife.com website. We also plan to market and sell to hospitals. Discussions with Children's Hospital Colorado have helped outline the following process. Patients will receive a Button Huggie starter kit at the time of g-button placement. This kit will include one reusable lid, 12 disposable base layers and 120 gauze pads (a 12-week supply). The surgeon who places the initial g-button will apply a sterile Button Huggie at the time of initial gastrostomy button placement and then give the kit with 11 remaining weeks of dressings to the parents. The nurses on the ward will reinforce use of the device by teaching the parents how to change the gauze pad and/or base layer as needed. At home, parents and caregivers will be able to access the Ezalife.com website for replacement products, including brightly colored thematic lids.

There is great potential to develop additional, related product lines for gastrostomy buttons made by other manufacturers, as well as gastrojejunostomy, cecostomy and vesical (bladder) access devices in current use. Each will have a slightly different shape and profile, but all will have the same basic three component design (reusable lid, absorbent gauze layer and base layer).

Dr. Moulton was recently awarded a \$25,000 grant to develop a securement method for external tunneled catheters. This device will adopt similar design features of the Button Huggie and could be added to Ezalife's product portfolio.

How will this showcase benefit your company or technology? Ezalife, LLC is Dr. Moulton's third startup. The company has raised nearly \$300,000 in grant funding from the following organizations:



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1. CU Department of Surgery, AEF grants: \$75,000 (2016- 17, 2017- 18 and 2018- 19)
2. First Place, \$40,000, 2019 Children's Hospital Colorado Innovation Challenge
3. First Place, \$50,000, 2019 UCSF- Stanford, Pediatric Device Accelerator
4. 2019- 2021 CU Spark Grant, \$108,000
5. Second place, \$25,000, 2019 CU Boulder New Venture Challenge

Ezalife is actively seeking \$300,000 from an angel investor to hire a sales and marketing team. We are especially interested in speaking to those who are drawn to the idea of joining and building an early stage company that is poised to launch a national, followed by international marketing and sales plan for a series of thematic gastrostomy button and other medical securement devices.

A likely exit scenario is to sell the company to an existing medical device manufacturer, such as Applied Medical Technology (Brecksville, OH), Halyard Health (Alpharetta, GA), C. R. Bard (Tempe, AZ) or Boston Scientific (Marlborough, MA). We believe that if one of these companies were to acquire Ezalife and the Button Huggie product portfolio, it would gain a competitive advantage over its competitors in the gastrostomy button marketplace (current global sales > 2.5 units/yr). We believe there are several avenues that will lead to significant Button Huggie sales in a short period of time, followed by a relatively quick and successful exit.

Who are the members of your team and why is this the right team to get the job done?

Steve Moulton MD is a Professor of Surgery at the University of Colorado and pediatric surgeon at Children's Hospital Colorado, where he directs the Trauma/Burn Program and holds the Colorado Firefighter Endowed Chair for Burn and Trauma Care.

Dr. Moulton is a surgical entrepreneur. He founded 10Blade, Inc. in 2001, shortly after 9/11. 10Blade was funded by the NIH and US Army to develop small lightweight sensors and big data methods to merge pre-hospital vital sign and field treatment data with disparate hospital database systems, to provide incoming patient situational awareness in real-time. This work evolved into the Medical Hands-Free Unified Broadcast (MEDHUB) battlefield communication system that is being developed by Sierra Nevada Corporation for the US Army.

In 2010 Dr. Moulton and Greg Grudic PhD co-founded Flashback Technologies, Inc., based on technology they co-invented at CU. Flashback developed and now markets the first FDA cleared medical monitor (CipherOx® CRIM1) for continuous, beat-to-beat non-invasive assessment of acute blood loss on the battlefield and in pre-hospital and hospital settings. This work was supported by nearly \$10M in funding from the NIH and the US Army (including SBIR Phase I, II, and III grants) and several million dollars in private capital.

Ezalife, LLC is Dr. Moulton's third startup. He is actively working with New Media on branding, marketing and website design. He is in the team building phase and is actively hiring.



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Dr. Moulton is an inventor on four issued US patents, two European patents and 12 pending US/European patents.

