BioLargo

Healthcare & industrial services

3 October 2018

Incubating innovation in iodine

BioLargo is a chemical innovation company developing and marketing novel products for a range of industries. Its core competency is the unique chemistry of iodine, which it has leveraged to develop an industrial odor control agent (currently marketed as CupriDyne Clean), an irrigation solution for chronic wounds and a wastewater treatment solution. The goal is to build independent companies around each of these products, which can then be spun out, with the BioLargo acting as a development engine. The company has expressed the intent to uplist to NASDAQ.

CupriDyne: Safely oxidizing odors and VOCs

CupriDyne Clean is an odor control agent marketed to the solid waste management and water treatment industries, with potential inroads into other industries such as composting and animal waste. Its unique property is that it is capable of generating molecular iodine, which oxidizes odorants and other volatile organic compounds (VOCs). This is accomplished with a highly dilute solution that is safe for humans and does not interfere with the natural processes important for these industries.

Clyra: An independent wound care company

Using a technology inspired by the CupriDyne technology, albeit at higher concentrations and with other ingredients, the company has developed a wound irrigation product that can provide disinfection by generating iodine without the risk of tissue damage. Historically, iodine has been widely used in the medical setting, but is not ideal for wounds given the potential of harming exposed tissue. The product is awaiting a response from the FDA, expected in H218, on an outstanding 510(k) application. BioLargo also recently entered into an agreement to acquire the SkinDisc technology developed by Scion Solutions, a proprietary therapy for chronic wounds utilizing the patient's own bone marrow cells. The goal is to spin off Clyra as an independent wound care company in 2019.

AOS: Water purification with new science

As part of its investigation of iodine chemistry, BioLargo experimented with the electrochemical generation of iodine species. It was found that a high capacitance cell doped with iodine which it has named the Advanced Oxidation System (AOS) can both kill biological threats and break down organic contaminants. The cell generates a number of oxidative molecules including highly reactive iodine oxyanions, which can break down contaminants missed by other systems. The first pilot programs will process poultry waste and oil sands process affected water.

Historical financials

Year end	Revenue ($m)	PBT ($m)	EPS ($)	DPS ($)	P/E (x)	Yield (%)
12/14	0.1	(3.7)	(0.05)	0.0	N/A	N/A
12/15	0.1	(5.1)	(0.06)	0.0	N/A	N/A
12/16	0.3	(8.1)	(0.09)	0.0	N/A	N/A
12/17	0.5	(9.5)	(0.10)	0.0	N/A	N/A

Source: Company filings

Price	US$0.29
Market cap	US$38m

Share price graph

Share details

Code	BLGO
Listing	OTCQB
Shares in issue	130.5m
Net debt ($) at 30 June 2018	1.4

Business description

BioLargo has a number of subsidiaries and products focused on using iodine chemistry. CupriDyne is a product that is currently on the market for industrial odor control. The subsidiary Clyra Medical is a wound care company with an iodine-based irrigation solution and SkinDisc, a cell therapy for wounds. It is developing the AOS as a low-cost water purification device. Finally, the company has a full service environmental engineering team.

Bull

- Diversified portfolio of products.
- Unique technology with broad applications.
- CupriDyne gaining market share.

Bear

- Additional capital needed.
- Sales ramp has been slow.
- Regulatory and development risk for Clyra and AOS.

Analysts

Nathaniel Calloway +1 646 653 7036

Maxim Jacobs +1 646 653 7027

healthcare@edisongroup.com

Edison profile page

Investment summary

Company description: Iodine and beyond

BioLargo is a diversified science and technology company developing and commercializing products in the healthcare, water treatment and waste handling industries. Its core development expertise is in novel products leveraging the unique chemistry of iodine, but it is also engaged in opportunistic business development to cultivate independent subsidiaries specializing in different markets. Its most commercially advanced product is CupriDyne Clean (under the Odor-No-More subsidiary), an industrial odor control product marketed to the waste management and water treatment industries (among others). Its medical subsidiary, Clyra Medical, is seeking approval for its iodine-based wound irrigation product, which has a 510(k) application submitted to the FDA. BioLargo is also in the process of concluding an acquisition of Scion Solutions, the developer of an autologous tissue therapy called SkinDisc for treating chronic wounds. It is also developing its Advanced Oxidation System (AOS) through the BioLargo Water subsidiary as a low-cost solution to industrial water treatment. The system is an electrochemical cell of unique design and is entering the pilot stage. Finally, these efforts, as well as other contracts, are supported by an in house environmental engineering services company, BioLargo Engineering Science and Technology.

Financials: Revenue generating, but more cash needed

BioLargo is revenue generating ($327,000 in Q218) and growing ($100,000 in Q217), but outpaced by expenses. The net loss for Q218 was $3.6m, of which $1.7m comprised non-cash payments associated with convertible notes. The majority of these notes have been recently converted ($2.0m vs $6.8m at year-end 2018), so we expect this expense to go down significantly.

Sensitivities: Risks unique to each program

Given the diverse operational focus of the company, it faces a diverse and unique set of risks. Although adoption of CupriDyne Clean is progressing steadily, it is entering a highly fragmented market. Given the lack of low-cost, effective options, we expect customer confidence in new solutions initially to be low. Gaining momentum in this environment may be difficult. The company has initial inroads with some of the largest players in the solid waste industry, but these need to be further developed before broader adoption. Adoption in other industries (such as water treatment, composting, or animal waste) remains exploratory, and these channels will likely be commercialized through distributers. The company's medical subsidiary, Clyra, faces the risks typical of pre-commercial healthcare companies, both regulatory and clinical. The ongoing 510(k) application is lower risk than other regulatory pathways, but not completely without risk, and the company will have to perform clinical trials for both its irrigation product as well as SkinDisc to support marketing claims. The company's water treatment program, AOS, is just entering the pilot stage, and all devices produced to this point have been small prototypes. The company will have to establish that this technology is scalable to address real-world industrial water treatment needs. This will be tested in the first pilot programs for poultry waste and oil sands processing. If the product is successful on this score, it will face certain commercial risks, including establishing an attractive value proposition over well-entrenched existing technology. The risks to each subsidiary are unique but, given this diversity, there is proportionally less risk to the parent company. The biggest risk to the parent is financial as we expect the company to require additional capital, which may result in dilution. This is a risk shared by pre-commercial companies, but we expect at least part of these financing needs to be satisfied through the licensing or potentially spinning-out of its technology.

An industry-agnostic innovator

BioLargo is a chemical technology company based in Westminster, California, which is developing a suite of products across a range of industries, including healthcare, waste management and water treatment. Instead of focusing on a particular industry, the company opportunistically develops new technology from its core expertise, and develops this technology though the use of operationally focused subsidiaries (Exhibit 1). Historically, this expertise has focused on the chemistry of iodine, although it has expanded beyond this original platform and includes in-licensed technology as well as a service business. It plans to continue to operate as a developer of new platforms and products that it can both integrate into its existing businesses and develop into new companies. The company maintains a team of PhD research scientists to drive this process.

BioLargo's most commercially advanced technology is CupriDyne Clean, a product marketed for odor control through the Odor-No-More subsidiary. CupriDyne is currently commercially available and marketed to waste management and water treatment industries. The company's healthcare subsidiary, Clyra Medical Technologies, is focused on developing products for topical disinfection and wound care. The company has submitted a 510(k) application to the FDA for an antimicrobial iodine product for wound irrigation, and a response is expected in H218. BioLargo is in the pilot stages of developing a water treatment technology through its BioLargo Water subsidiary with the so-called Advanced Oxidation System (AOS). The company has the BioLargo Engineering, Science and Technologies (BLEST) subsidiary, which is a full service engineering company. Finally, BioLargo previously licensed the iSAN iodine delivery system under to Clarion Water, although this product is currently on commercial hold at the company and is not covered in this report.

Exhibit 1: BioLargo subsidiaries and products

Subsidiary	Product(s)	Description
Odor-No-More	CupriDyne Clean	The CupriDyne technology has been applied to a number of different products, including consumer products, but it has found the most traction as an industrial odor solution as CupriDyne Clean. Potential markets in this setting include waste management, water treatment and agriculture, among others.
Clyra Medical	510(k) wound irrigation product, SkinDisc	Developing iodine-based products with improved safety and biocompatibility for wound care. Clyra is also developing the technology as an oral rinse (following oral surgery) and for sterilization during orthopedic procedures. To enhance the company's wound care offering it recently initiated an acquisition of Scion Solutions for its SkinDisc technology, a cell therapy technology for wound void filling. The goal is to spin out Clyra as an independent company in 2019.
BioLargo Water	Advanced Oxidation System	AOS is an electrochemical purification system centered on iodine chemistry. The product has several potential advantages over currently available technology, such as operational costs, and the most immediate applications are for waste water treatment. There are currently two ongoing pilot projects.
BioLargo Engineering, Science and Technologies (BLEST)	Contract engineering services	BLEST provides contract services across a range of sectors and functions including regulatory compliance, waste control and process engineering. It also installs and supports CupriDyne delivery systems, and is involved in piloting the AOS system.
Clarion Water (licensee)	iSAN	iSAN is an iodine delivery technology for water sanitation and providing nutrients for agriculture. The program is currently deprioritized.

Source: BioLargo

CupriDyne

CupriDyne Clean represents the technology developed at BioLargo that has driven the majority of its commercial and development efforts. It is currently being marketed as an odor control solution for various industrial applications such as waste management and water treatment in US markets, but historically the company has examined the technology in an array of products including consumer products such as diapers, deodorizers, and cat litter (which are currently deprioritized, but available for partnering). It was launched as an industrial odor control product in 2016 and remains in the early stages of commercialization, with $190,000 in sales in Q218 ($327,000 in total sales for all odor products). In addition to the product, the Odor-no-More subsidiary also installs and maintains the systems used to deliver CupriDyne Clean.

The product is used by dissolving it in water, which is then aerosolized in the vicinity of the odor needing control or sprayed directly onto surfaces responsible for the odor. Unlike other odor solutions, it does not mask or bind odorants, but destroys them in the air. Additionally, in a detail that is important for many of its applications, CupriDyne does not destroy the source of the odor, for instance by killing microorganisms. This is key for waste management, water treatment and other industries because these microorganisms are important to the industrial process. The Water Environment Federation recently highlighted the product at its 2018 Odors and Air Pollutants Conference as a best practice for odor control. Additionally, the California Department of Pesticide Regulation has independently determined that CupriDyne does not have the properties of a pesticide, which is important for widespread use.

Iodine chemistry

At its core, CupriDyne Clean is a product designed to generate low levels of molecular iodine (I_2). I_2 is generated through a chemical reaction with copper (hence the “Cupri” in CupriDyne) that occurs when the components of the product are mixed. The I_2 is produced at very low doses that do not pose a threat to safety or have toxicity against other organisms, and infact is considered nutritive at these concentrations (as are the other reaction byproducts).

The chemistry of I_2 is very well understood, but the innovation of this product was the determination that this chemistry could be leveraged for the elimination of airborne odors. Iodine is a reactive molecule with a significant oxidizing potential. Moreover, in solution, I_2 can react (dissociate) in water in a pH-dependent manner to generate hypoiodous acid (HIO), which has a further increased oxidizing potential. In addition to the aforementioned salts, CupriDyne contains pH buffering agents to control the rate at which I_2 is converted into HIO. We believe that both of these molecules contribute to the activity of the product.

Oxidizing potential is the capacity of this species to remove electrons from other molecules, which typically destroys them in the process. The oxidizing potential of I_2 and HIO is tied to antiseptic properties, which is why aqueous iodine has been widely utilized for water purification in a number of different contexts. This is commonly recognizable in water purification tablets. Importantly, once CupriDyne is diluted in water, it is not concentrated enough to have antiseptic activity, but its oxidizing potential is significant enough to destroy a wide range of the volatile compounds that typically constitute odors. I_2 alters the chemical structures of these volatile organics to odorless molecules.

Iodine has several unique properties that lend themselves to this application. First, I_2 has a relatively high vapor pressure, which allows it to be easily volatilized at the concentrations used for CupriDyne to oxidize airborne molecules. The other halogens, chlorine and bromine, could hypothetically be more effective on this score because they have higher oxidation potentials and are more volatile (chlorine for instance in a gas at room temperature), but they are both highly toxic. By comparison, iodine is biologically benign at the concentrations present in CupriDyne (although there are adverse biological impacts at the concentrations used historically in medical preparations, see below).

Markets

CupriDyne Clean is marketed for any large-scale odor control application, but this lends itself naturally to certain industries. The product has had the most successful traction so far in the solid waste management industry, and the company is currently working with four of the top seven largest companies in the space (although details have not been released), and management has stated that it expects more contracts with top players shortly.

Despite the ever-increasing waste disposal needs of Americans, the municipal solid waste (MSW) industry has become increasingly concentrated. The US Environmental Protection Agency (EPA)

estimates that in 2010 there were approximately 250 million tons of MSW, up 20% from 1990.[1] However, the estimated number of landfills was significantly down over roughly the same period: 1,900 in 2009 vs 7,900 in 1988.

Waste transfer stations are an additional market for CupriDyne Clean. These are the facilities where MSW is unloaded from collection trucks and placed into long-distance transport vehicles. Because of this, unlike landfills, transfer stations need to be close to collection sites and therefore population centers, and have significant odor control needs. There are no statistics on the precise number of transfer stations operating in the US, but the company estimates that there are approximately four transfer stations servicing each landfill on average. Materials recovery facilities (MRFs), where recycling is sorted, represent a similar market to transfer stations, and many of these facilities are operated by the same companies that operate landfills and transfer stations.

The industry has become increasingly vertically consolidated, with the largest companies controlling all aspects of the waste stream from collection to disposal. However, significant fragmentation remains. The largest MSW companies are Waste Management Inc and Republic Services, which together only control approximately 25% of operational landfills. Moreover, the operational structure of these large waste companies is highly stratified, with a large number of both regional and local operations that must be engaged separately. We believe that penetration into a given waste management network can facilitate cross-pollination and allow scale up. Management states that over 500 landfills and 600 transfer stations are operated by the company's current clients and, although a small fraction of these are already ordering product, these represent the lowest hanging fruit.

Exhibit 2: Largest solid waste operators

Company	Landfills	Transfer stations	Recycling/MRFs
Waste Management	249	305	102
Republic Services	194	209	92
Waste Connections	90	146	66
Advanced Disposal	40	73	22

Source: Company reports

Another major market that the company is targeting is wastewater treatment. According to the American Society of Civil Engineers (ASCE), there are 14,748 water treatment facilities in the US, and wastewater treatment demands are steadily increasing. Approximately 24% of the country relies on septic treatment systems and is not serviced by these facilities, but that number is steadily decreasing. The ASCE estimates that wastewater treatment demands are expected to increase 23% by 2032 as regions shift to centralized wastewater treatment. These facilities are generally located just outside population centers and therefore face significant pressure to maintain odor control. The company has a limited penetration into this market to date and is currently servicing a small number of pilot customers in Southern California. The company's longer-term strategy is to use distributors to facilitate entering this market.

Based on the company's experience with its current clients, it estimates that landfills will provide the largest revenue per client at an average of $120,000 per year. It is reasonable that landfills would use the largest amount of product given their larger footprint and the lack of potential physical containment solutions. Transfer stations and water treatment plants, by comparison, are smaller and odors can be physically controlled via barriers (building walls or pool covers for instance) more easily. However, despite this, given the larger number of these facilities, they represent greater market opportunities (Exhibit 3).

1 EPA (2014) "Municipal Solid Waste Landfills; Economic Impact Analysis for the Proposed New Subpart to the New Source Performance Standards".

Exhibit 3: Market size estimates

Facilities	Number	Est. revenue per year per site ($)	Market size ($m)
Landfills	1,900	$120,000	$228
Transfer stations	7,600	$48,000	$365
Water treatment plants	14,748	$48,000	$708

Source: EPA, ASCE, BioLargo

Although landfills, transfer stations and water treatment plants represent the biggest market opportunities, CupriDyne is being explored in other markets. Municipal composting is a relatively small but growing industry where CupriDyne Clean has been successfully tested. The product naturally lends itself to this market considering it does not kill bacteria and does not interfere with decomposition. Finally, the company has identified livestock production as a potential market, which is under increasing pressure to control its emissions and odors. As an example, there have been a number of high-profile lawsuits in the US against pork producers citing the nuisance produced by odor (as well as other factors), with settlements ranging from the tens to hundreds of millions.

Headwinds and competition

The single largest headwind limiting the adoption of CupriDyne Clean or any other odor control product is that facilities in these industries have been constructed with odor in mind. Landfills are built away from habitation; transfer stations and water treatment plants are at the edges of communities and have physical controls. Simply said, odor control is not an issue for a large number of facilities. These industries also employ a number of standardized practices that limit odor emissions. For instance, the practice of daily cover in landfills substantially limits the amount of malodorants released into the air. However, as communities expand, these historic measures to limit the impact of odors may become insufficient.

There are a number of capital improvements that can be utilized to control odors with varying degrees of success depending on the parameters of the facility. Transfer stations are the most amenable to capital solutions, given that they are typically partially or fully enclosed. One of the simplest measures is mixing malodorous air with large volumes of fresh air to dilute any released scents. Chemical scrubbers are utilized for odor control in manufacturing and other settings but require complete control of airflow and have high capital costs that limit their application to waste processing. CupriDyne Cleanhas the potential to be used in such scrubbers, although ozone generators provide a solution not wholly unlike CupriDyne Clean in that they provide a method of chemically oxidizing odorants. However, ozone itself has a strong scent and potentially negative health effects, so its implementation must be made carefully with the welfare of workers in mind.

Competing chemical odor control products can be roughly divided into three categories: fragrances, barriers and adsorbents. Fragrances are straightforward and mask odors. Barriers are products that form a layer of material that traps odorants. These include products like RusFoam, which forms a foamy layer of material applied as a daily cover in landfills and prevents the escape of odors. Adsorbents are products that bind odor molecules and sequester them from the air. These come in two subtypes: solid mineral granules that are typically placed at the perimeter of facilities or solubilized absorbents that are dissolved in water and sprayed into the air to remove airborne scents. The Ecosorb product from OMI Industries is an example of a chemical adsorbent. Generally speaking, the market for these chemical solutions is highly fragmented and penetration is low.

Clyra Medical

Clyra Medical is a subsidiary (46.3% owned by BioLargo) established to explore the medical applications of BioLargo's technology, with a particular focus on wound care. This is being pursued through two independent products. First, the company has adapted its iodine technology (similar to how it is used in CupriDyne) for use as a wound irrigation solution. This product has been submitted to the FDA for 510(k) approval, and there is the potential to adapt the technology to other products

such as wound dressings. Second, the company recently announced the planned acquisition of Scion Solutions and its SkinDisc technology. SkinDisc is an autologous cell therapy product intended for the treatment of chronic wounds, which the company intends to advance to clinical trials. The strategic goal of the Scion acquisition is to establish Clyra with a sufficient platform to operate as an independent company, with a spin-out planned for 2019. Clyra will be raising capital independently towards this goal (as per the contingencies on the acquisition discussed below).

Iodine in medicine

Iodine has a long history of use in the medical setting and is indispensable in current medical practice as a topical antiseptic. Tincture of iodine was developed as a pre-surgical antiseptic in the early 20th century. Currently, the most widespread iodine formulation is povidone iodine (eg Betadine), which is an iodophore that slowly releases the molecular iodine (I_2) responsible for these products' antiseptic properties.

As previously discussed, I_2 is an oxidizing agent which reacts with a range of organic and non-organic molecules. At the high concentrations used in medical preparations of iodine, this reactivity is sufficient to chemically modify proteins, lipids and nucleic acids. This indiscriminate reactivity is responsible for the broad-spectrum antimicrobial activity of iodine, which is excellent against Gram-positive bacteria and many Gram-negative bacteria, viruses and other microorganisms. Additionally, given this mechanism, microorganisms are generally unable to develop strategies to mitigate the damage and acquired resistance is not observed.

However, the reactivity of iodine with biologic molecules, which is responsible for its efficacy as an antiseptic, also limits its applicability in the medical setting. Iodine will similarly react with tissue that it can penetrate and can cause irritation to mucous membranes and exposed tissue. This is why iodine is limited to topical skin use, but even in this case irritation and skin reactions are not unheard of, albeit rare.

The goal with BioLargo's wound irrigation product is to provide sufficient antisepsis while avoiding the limiting irritation of other iodine preparations. The precise formulation of the company's medical products has not been released. However, we are aware that it relies on the same basic technology as CupriDyne: copper-mediated in situ generation of I_2. Based on the information provided, it is unclear how the product can achieve these stated goals, although the company has provided a series of claims regarding the product (Exhibit 4). However, we are aware that the company has performed a series of studies in pigs to support the safety and activity of the product. In addition, a potential ancillary benefit is that the product is capable of delivering antiseptic levels of I_2 without the risk of staining associated with other iodine products.

Exhibit 4: Antiseptic product claims

100% killing of bacteria in suspension (planktonic kill)	Sustained activity at three days
2.5 log kill in biofilms	Anti-inflammatory

Source: BioLargo

The company's wound care program is its most advanced for the product, and it has submitted a 510(k) application to the FDA for marketing approval. This is a typical pathway for approval of wound dressings and irrigation solutions, and no clinical studies are needed for the initial application if it is found to be "substantially equivalent" to existing products, ie not sufficiently different to warrant safety or efficacy risks. However, we do expect the company to perform post-approval studies to support claims that the product improves healing, etc. A response from the FDA on the initial application is expected in H218. In addition to irrigation solution, the technology could also be integrated into other wound care products such as dressings.

The company has also identified a series of follow-on indications where it believes the product could be useful and has provided basic timelines for these programs (Exhibit 5). However, we believe these will be predicated on the approval and success of the irrigation product.

Exhibit 5: Clyra indications and timelines

Product	BioLargo market estimates	Timeline
Wound Irrigation	$75m	510(k) submitted, response H218, launch H119
Oral rinse	$264m	Planned study results H219, launch H120
Orthopedic revisions	$35m	Institutional Review Board results in H119, launch in H120
Primary orthopedics	$350m	Planned study results H220, launch H121

Source: BioLargo

SkinDisc

On 2 October 2018, the company announced that it had entered a definitive agreement to acquire Scion Solutions, a developer of cell therapies for the treatment of chronic wounds. As part of the deal, Scion will receive 20% of Clyra stock (half vested on closing the deal, and the remainder tied to performance milestones), 7.1m shares of BioLargo stock (with the same provisions as the Clyra stock), and a promissory note for $1.25m. The whole deal is contingent on Clyra raising an initial minimum capital of $1m within the following 120 days. The technology developed by Scion is unrelated to the iodine-based technology developed by BioLargo, but the acquisition is being pursued to position Clyra as a diversified wound care company.

Scion's primary development program was the so-called SkinDisc technology, a therapy that uses a patient's own plasma and bone marrow to make a cell-rich biogel for use in chronic wounds. The product is delivered as a kit intended for use in the operating room, which enables the production of a biogel generated by the patient's own tissue. This biogel can act as a scaffold for additional cells to migrate into the healing environment to promote healing. This process is designed to be completed in less than 30 minutes, so that a patient's cells can be extracted and the wound treated in a single procedure.

The product has been tested in over 250 patients and the company reports that no adverse events were observed and that the product successfully aided in the salvage of limbs that would have otherwise been amputated. We expect a formal clinical trial will be required to support an application to the FDA. The company's current timeline is to launch the product in 2022 following completion of such a study and FDA approval. If the product can successfully prevent amputations in clinical trials, this could significantly improve outcomes (given the high mortality in these patients) and we believe it will be an attractive value proposition to payers (given the high costs of these procedures).

The wound care market

The majority of development in the wound care space is devoted to addressing difficult-to-heal chronic wounds. Chronic wounds consist of four basic subtypes (Exhibit 6), but the common unifying factor in all chronic wounds is reduced blood flow to the site of injury. The initial lesion can be any sort of superficial tissue damage, but lack of blood flow triggers progressive tissue degeneration due to the restriction of necessary white blood cells and oxygen to the wound site. Increased inflammation causes the destabilization of the extracellular matrix under the skin, preventing the migration of new cells into the wound.[2] Additionally, healing is further frustrated by the growth of biofilms, which proliferate in the absence of immune cells to protect the wound site.[3]

2 Agren MS, et al. (1999) Proliferation and mitogenic response to PDGF-BB of fibroblasts isolated from chronic venous leg ulcers is ulcer-age dependent. *J Invest Derm* 112, 463-469.

3 Bader MS (2008) Diabetic foot infection. *Am Fam Phys* 78, 71–79.

Exhibit 6: Chronic wound types

Wound type	Prevalence[4]	Cause
Pressure ulcers	9-24% (hospital in-patients)	Restricted blood flow due to lack of movement
Diabetic ulcers	8.1% (Medicare beneficiaries)	Deterioration of vascular structure secondary to diabetes
Venous leg ulcers	2.5% (long-term care facility)	Peripheral vascular disease
Artery insufficiency ulcer	0.3% (general population)	Peripheral vascular disease

Source: Graves and Zheng (2014)

The total addressable market for chronic wounds is very large given the high prevalence of the disease. A recent analysis estimated an existing annual cost to Medicare alone of $6.9bn for diabetic foot ulcers and $4.6bn for pressure ulcers.[5]

There is a wide range of products for use in the treatment of chronic wounds. This includes preparation materials, fillers, wound dressings, debridement aids and medical devices, among others. The irrigation solution will compete most directly with antimicrobial preparation and dressing products. Smith & Nephew currently has an iodine-based wound dressing and preparative gel called Iodosorb (cadexomer iodine), and we expect this product to be the primary competition for the wound irrigation solution. It uses a polymer-based system to slowly release stored iodine. To our knowledge, it is the only iodine-eluting wound care product currently available. There are a number of other competing technologies including silver and chlorhexidine washes and wound dressings. This includes Tegaderm from 3M and Acticoat from Smith & Nephew, among others. By comparison, the SkinDisc product does not have direct analogs on the market, although we expect it to compete primarily with other procedures, for example those treated by negative pressure therapy and skin grafting. It may also compete with wound care biologics such as Regranex (becaplermin; Smith & Nephew), as well as biomembranes such as Epifix (amniotic membrane, MiMedx).

The Advanced Oxidation System

The BioLargo Water subsidiary was formed to investigate applications of some of the company's discoveries to water treatment. The company is developing a water treatment device, which it has termed the Advanced Oxidation System (AOS). As the name implies, it is intended for use in the oxidation step of water purification when biological contaminants are destroyed. The system is still in the prototype stage of development as the company investigates its mechanism and applicability.

Like much of the other technology at BioLargo, the AOS is centered on the chemistry of iodine. Iodine has a long history in water purification (as discussed above) based on the oxidative potential of iodine itself as well as the hypoiodite ion. However, the AOS is designed to further enhance the oxidative potential of iodine by electrochemically generating more highly reactive molecules. Water entering the device is lightly doped with iodine, and it flows through an array of alternating electrodes. These electrodes then generate a variety of oxidative species, which include high-order iodine oxyanions. These molecules are extremely reactive and some such as periodate (IO_4-) can break a wide array of chemical bonds and are highly cytotoxic. The fact that this type of system could generate iodine oxyanions was a discovery made at BioLargo and the company is currently studying the mechanism of their generation. It has generated data, which support that the system can disinfect water from a range of microorganisms. A benefit of the system is that the high reactivity of the species generated can also remove a range of organic contaminants.

This process is superficially similar to electrochlorination, which is another electrochemical water purification process employing chlorine. Electrochlorination generates sodium hypochlorite (NaOCl)

4 Graves N and Zheng H (2014) The prevalence and incidence of chronic wounds: a literature review. *Wound Pract Res* 22, 4–19.

5 Nussbaum SR, et al. (2018) An Economic Evaluation of the Impact, Cost, and Medicare Policy Implications of Chronic Nonhealing Wounds. *Value Health* 21, 27–32.

from sodium chloride (NaCl) and is the main method of "chlorinating" drinking water. However, there are a number of differences in the systems and their purpose. First off, although both systems employ halogens in their operation, electrochlorination uses ionic chloride, whereas the AOS uses the more reactive and oxidizing molecular iodine as its feedstock. The chemistry of ionic halides is fundamentally different from molecular halogens, and as a result the products of these two systems are different, and the AOS generates more reactive, higher-order oxyanions. Moreover, due to the different chemistry, as well as aspects of the cell design (the AOS is designed to produce a high capacitance), the electrical needs of the systems are significantly different. The company is positioning the AOS as a potential low-energy solution for water purification. A final difference is that the end-product of electrochlorination is chlorinated water, which retains some resistance to further contamination. This is important for municipal water systems, where there is potential for contaminants to enter the water stream between treatment and use, and chlorination is used to limit these risks. We do not expect the AOS to generate long-living reactive species, and therefore the product of the system is functionally purified water.

Exhibit 7: Comparison of electrochlorination and the AOS

Property	Electrochlorination	AOS
Starting material	Chloride (Cl-)	Iodine (I_2)
Reactive species	Hypochlorite (-OCl)	High-order iodates (eg IO_4-)
Reactivity of products	Moderate	High
Cell design	Electrolytic	Capacitive
Energy use	High	Low
Product	Chlorinated water	Purified water

Source: BioLargo, various

There are several technologies that can be employed in the oxidation step of water purification. Instead of generating hypochlorite in an electrochlorinator, it can be added directly to the waste stream as a solid. This requires very little capital investment, but has higher operating costs. Similarly, gaseous chlorine can be used, although it is poisonous and requires safety controls. UV and ozone systems operate by generating oxygen and hydroxyl radicals ($O^{\cdot}$, $HO^{\cdot}$). These systems are better at removing organic contaminants, albeit with limitations. UV treatment is ineffective in turbid water, as the light cannot penetrate. Also, ozone requires both high capital costs and high energy costs. The AOS is positioned as a solution that can disinfect and remove organic contaminants from potentially turbid water with lower energy and capital costs than ozone or UV.

We expect the AOS to be employed predominantly at the point of waste generation. Current prototypes of the device can purify approximately four gallons or less per minute. However, given its simple solid state and lateral flow design, BioLargo believes that it can be highly scalable and modular in nature. Hypothetically, a particular throughput could be reached by the placement of multiple individual units in parallel, with few other capital costs. It is applicable to a range of industries and the company has initiated a series of pilot programs to test its real-world feasibility with the first applications being the processing of poultry waste and the treatment of oil sands process affected water (Exhibit 8). All of these pilot efforts are grant supported, and pose little financial risk to the company. Given the potential environmental benefits of the system, the company has received over 60 separate grants to support its development.

Exhibit 8: AOS pilot programs

Industry	Program
Agriculture	C$250k grant received for Canadian poultry pilot
Food and beverage	Grant received for pilot for Joshua Tree Brewery
Chemicals	Shortlisted for C$600k grant for pilot at Tianjin Industrial Chemical Park
Oil and gas	Shortlisted for C$1.5m grant for pilot to process Alberta oil sands water

Source: BioLargo

BioLargo Engineering

BioLargo Engineering, Science and Technologies (BLEST) is unlike the other subsidiaries of BioLargo in that it is a service company specializing in environmental engineering. It has a staff of six professionals, and there are currently 14 clients under contract. The unit is close to break-even, and BioLargo has previously stated that it expects it to be profitable in the near term.

BLEST's operations are functionally independent of the rest of BioLargo, although there are a number of synergies. The team has been involved in the design and installation of CupriDyne capital systems, and we expect this revenue stream to scale with the advancement of the product in general. Additionally, the team is involved in setting up the pilot operation for the AOS, and we expect the team to be the primary professionals used for this purpose once the product enters the market. Moreover, BLEST's engineers are well seasoned in the solid waste and wastewater markets, whose knowledge we expect to aid in CupriDyne and AOS sales.

Sensitivities

BioLargo faces a series of risks as diverse as its various businesses. We expect CupriDyne Clean to remain the company's core product and the primary growth driver going forward. However, it faces a series of commercial challenges. The odor control market is poorly developed and highly fragmented, which may make marketing the product more difficult despite its efficacy. There are a large number of available products with marginal effectiveness, which has reduced the expectations of potential customers, and the company faces an uphill battle in changing perceptions. We believe this is at least in part responsible for the slow rate of adoption to date. The company's strategy is to target the largest companies in the industry to establish credibility. Implementation of CupriDyne Clean requires some capital expenditure in most cases, which is a potential barrier for a product that has not been proven on the market yet. Additionally, the customer base for the product is highly distributed, and there are a large number of independent operators in the waste industry. Even in the case of the larger consolidated companies in the space, sales contracts tend to be site specific. The product also faces the risks inherent in technology. There is a degree of IP risk, and a competing product with very similar technology may be able to enter the market if the company cannot defend its patents.

Clyra faces the risks typical of a development-stage healthcare company. These include both clinical and regulatory risk. The wound irrigation product may receive marketing authorization in the absence of a clinical trial, but the company will have to perform these studies post approval to support marketing claims. We expect SkinDisc to also require a clinical study before approval, which carries associated risks. Historically, there have been a large number of products that have failed clinical studies in the wound care space. These products also face commercial risks, given the large number of wound care products available, and the fact that many are marketed by some of the largest healthcare companies.

The AOS is the earliest-stage program at the company and still carries significant development risk. To date, only prototypes have been developed. The company is initiating a series of pilot studies, which it hopes will elucidate some of the real-world strengths and limitations of the product. The prototypes that the company has developed have all been relatively small in scale, with relatively low flow rates. However, many of the potential customers the company has identified will require high throughput solutions, and the scalability has not been tested. These customers, similar to and in part overlapping with CupriDyne customers, are frequently independent operators, and there is therefore significant legwork to gain market share, even if the product delivers on its promises.

Finally, BioLargo as a whole faces risks common to pre-profit companies. It ended Q218 with $651,000 in cash. In the same quarter it had an operating loss of $1.6m, so we expect the company

to require additional cash to cover these losses until profitability. Raising this capital may result in future dilution.

Financials

BioLargo is a revenue-generating company, albeit in the early stages of commercialization. The company had revenue of $327,000 for Q218, which was a substantial increase year-on-year ($100,000 in Q217). The net loss for the period was $3.6m, although a large fraction of this was driven by non-cash interest expense ($1.7m). Company debt is largely held as convertible notes. It has been pursuing reduction in this debt load through conversion to equity, and reduced it to $2.0m from $6.8m at year-end 2017. We expect the company to require additional capital to reach profitability, although we expect a portion of this to be met through business development activity, either the licensing or spinning out of its various products and subsidiaries. However, in the near term, the company has stated the intent to uplist to NASDAQ (or equivalent national market), which will require a capital raise to satisfy the exchange's $5m equity listing requirement. In a special shareholder meeting on 26 September 2018, a reverse stock split was approved (at a rate between 1:4 and 1:40) to be completed sometime in the following year, in order to meet the NASDAQ minimum bid requirement of $4.00.

Contact details	Revenue by geography
14921 Chestnut Street Westminster, California 92683 US (949) 643-9540 http://biolargo.com	N/A

Management team

Dennis Calvert: Chairman and CEO of BioLargo

Mr Calvert started his corporate career at a Fortune 500 chemicals company, and moved on to become the VP at a leading physician recruiting firm. Before his work with BioLargo, he participated in more than 300 consulting projects and more than 50 acquisitions. He was appointed a director in June 2002, and has served as president and CEO since June 2002, corporate secretary from September 2002 until March 2003, and CFO from March 2003 through January 2008. Mr Calvert holds a BA degree in Economics from Wake Forest University.

Charley Dargan: CFO

Mr Dargan has been a member of the board of directors of InterSearch Group, an American stock exchange-listed provider of search and advertising services for the internet, since May 2006. Since January 2003, he has served as founder and principal of CFO 911, a provider of operational and managerial expertise, specifically in accounting and finance, to middle-market companies. From March 2000 to the present, Mr Dargan has been the CFO of Semotus Solutions, an American stock exchange-listed wireless mobility software company.

Steve Harrison: President of Clyra Medical

Mr Harrison has also served as director of international ventures for BioLargo since 2008. From 2003 to 2008 he served on BioLargo's board of directors as chairman of the audit and compensation committees. In 2001-02, he was an investor and advisor to healthcare and consumer products companies including Beep for Free.com. From 1996 to 2001, he was the founder and CEO of InTouch Communications, a Competitive Local Exchange Carrier (CLEC), guiding the firm from authoring the business plan and managing it to profitability on annual revenues of more than $20m after 2.5 years.

Joseph Provenzano: President of Odor-No-More

Mr Provenzano was a co-developer of the CupriDyne product, and has become an odor control industry expert over the past eight years. He has been a director since June 2002 and assumed the role of corporate secretary in March 2003. He began his career in April 1988 as a personnel manager and recruiter for First American Travel, a marketing company in Southern California. From June 1991 to September 1995 he worked as a technician in the commercial and residential security industry. From September 1995 to September 1996 he was head of marketing at two major Southern Californian moving and storage companies.

Randall Moore: President of BioLargo Engineering

Mr Moore is an engineer/executive with more than 30 years' industrial commercial experience. Most recently he served as manager of operations for consulting and engineering at the Knoxville, Tennessee office of CB&I Environmental & Infrastructure. Prior to that, from February 2013 to May 2017, he was manager of operations at Integrated Environmental Solutions, a consulting and engineering group within CB&I, Environmental and Infrastructure.

Shan Yong, PhD: Director of Business Development

Shan Yong has more than 14 years' experience in international business development and technology consulting in the water and environmental sector with companies like Veolia Water Technologies North America, SembCorp Industries Singapore, SafBon Shanghai Water Holding, Nanostone and Aquafortus. Notably, she had dual roles in Veolia, managing new technology developmental projects with the Americas technology team at Veolia Water Technologies North America while concurrently working with open innovation at Veolia Environment Research and Innovation.

Richard Smith, PhD: President of BioLargo Water

Dr Smith oversees R&D efforts at BioLargo Water, and has been integral to the vision of the AOS from the beginning. He is recognized as an expert in the navigation of public funding resources and networks, and in his career at BioLargo alone has succeeded in securing over 60 research grants. Dr Smith has over 10 years' experience as the Research Development and Industrial Relations Co-ordinator at the University of Alberta Department of Agricultural, Food and Nutritional Sciences, where he oversaw the administration of grants totaling over $10m. He has over 15 years' experience in industry, having worked with several biotech companies in Alberta, including ChemBioMed, Alberta Reseach Council, AltaRex and VirRexx.

Tanya Rhodes: Senior Strategy Advisor for Clyra Medical Technologies

Ms Rhodes is former Smith & Nephew VP of Innovation and VP at Smith & Nephew Wound Management. She spent 15 years at Smith & Nephew US, and more than 20 years in the wound management and skin care industry globally. She has established a broad base of expertise that includes a concept-to-commercialization philosophy using product design, strategic marketing and evidence-based trials, as well as reimbursement and regulatory compliance strategies. During her career, Ms Rhodes has played an instrumental role in bringing a number of staple wound care technologies to market around the globe. She holds a Master's in Technology Management from the University of Miami and graduated with honors in Chemistry from Hull University, UK. She also completed the full research for PhD in Molecular Orbital Computational Stereochemistry before relocating to the US.

Principal shareholders	(%)
Kenneth Code	17.2%
Dennis Calvert	6.4%
Jack Strommen	3.3%
Joseph Provenzano	1.1%

Companies named in this report

3M (MMM), Advanced Disposal (ADSW), Republic Services (RSG), Smith & Nephew (SNN), Waste Connections (WCN), Waste Management (WM)

Edison is an investment research and advisory company, with offices in North America, Europe, the Middle East and AsiaPac. The heart of Edison is our world-renowned equity research platform and deep multi-sector expertise. At Edison Investment Research, our research is widely read by international investors, advisers and stakeholders. Edison Advisors leverages our core research platform to provide differentiated services including investor relations and strategic consulting. Edison is authorised and regulated by the Financial Conduct Authority. Edison Investment Research (NZ) Limited (Edison NZ) is the New Zealand subsidiary of Edison. Edison NZ is registered on the New Zealand Financial Service Providers Register (FSP number 247505) and is registered to provide wholesale and/or generic financial adviser services only. Edison Investment Research Inc (Edison US) is the US subsidiary of Edison and is regulated by the Securities and Exchange Commission. Edison Investment Research Pty Limited (Edison Aus) [46085869] is the Australian subsidiary of Edison. Edison Germany is a branch entity of Edison Investment Research Limited [4794244]. www.edisongroup.com

Frankfurt +49 (0)69 78 8076 960
Schumannstrasse 34b
60325 Frankfurt
Germany

London +44 (0)20 3077 5700
280 High Holborn
London, WC1V 7EE
United Kingdom

New York +1 646 653 7026
295 Madison Avenue, 18th Floor
10017, New York
US

Sydney +61 (0)2 8249 8342
Level 12, Office 1205
95 Pitt Street, Sydney
NSW 2000, Australia