

CollPlant Holdings

Initiation of coverage

Solid foundations with potential for growth

CollPlant's investment story is built on the versatility of its plant-based technology, rhCollagen, and its application in regenerative medicine. It has strong potential across various subsectors, initially focusing on orthobiologics and advanced wound care. Two products have recently been launched: VergenixFG, targeting chronic and acute wounds, and VergenixSTR, targeting tendinopathy. CollPlant has recently postponed its NASDAQ offering and raised c \$2m on TASE. Our rNPV prior the funding requirement is \$61m (NIS225m), or 48c (NIS1.77) per share.

Year end	Revenue (NISm)	PBT* (NISm)	EPS* (NIS)	DPS (NIS)	P/E (x)	Yield (%)
12/14	0.0	(13.0)	(16.19)	0.0	N/A	N/A
12/15	0.0	(18.7)	(22.03)	0.0	N/A	N/A
12/16e	0.1	(25.1)	(25.36)	0.0	N/A	N/A
12/17e	1.3	(16.4)	(12.75)	0.0	N/A	N/A

Note: *PBT and EPS are normalised, excluding amortisation of acquired intangibles, exceptional items and share-based payments.

Tendon repair and wound care entry point

VergenixSTR received its CE approval in October 2016, and recently entered into an exclusive distribution agreement with Arthrex to commercialise in EMEA. VergenixFG (treatment for chronic and acute wounds) is the most commercially advanced product, having been on the market since mid-2016; the first commercial patients were treated in August 2016. The primary focus at this time is for both products to gain traction in Europe and build end-user experience and clinical data. We expect CollPlant to consider a launch in the US (via a partner/distributor respectively) in c 24 months, depending on the rate of commercialisation.

Investment highlights

CollPlant has a versatile technology, rhCollagen, with potentially a broad clinical application. According to the company, rhCollagen offers a number of advantages, in particular that it is identical to type I human collagen. Alongside the potentially superior technology, it is close to generating revenue (we forecast revenue CAGR of 224% from 2016 to 2021, including a US launch in both products). It is important to note that CollPlant has a funding requirement in FY17 (cash at Q316 NIS8m), despite having raised NIS 7m in Feb 2017, to deliver on its current plans. We have modelled illustrative long-term debt of NIS16m in 2017, which on our current forecasts would give CollPlant a cash horizon to 2019.

Valuation: Risk-adjusted NPV \$61m/NIS225m

Our rNPV is \$61m (NIS225m), or 48c (NIS1.77) per share. We include each of CollPlant's current product lines: VergenixSTR (rNPV \$48m) and VergenixFG (rNPV \$24m). We note that this excludes a contribution for the earlier R&D programmes and the inherent value of the rhCollagen platform technology. We forecast cash reach into 2017. The company has a strong track record of raising capital in Israel, and we expect upside potential as it progresses the application of its rhCollagen. Other potential catalysts include finding a partner or raising additional funding to develop its bone void filler and/or additional applications of its technology and sales traction in Europe.

Healthcare equipment & services

9 March 2017

Price* NIS0.25

Market cap NIS32m

*Priced at 06 March 2017

	\$1:NIS 3.69
Net cash (NISm) at 30 September 2016	8.0
Shares in issue	128m
Free float	80.6%
Code	CLPT
Primary exchange	TASE
Secondary exchange	OTCQ

Share price performance



%	1m	3m	12m
Abs	(26.4)	(39.2)	(81.0)
Rel (local)	(27.8)	(39.7)	(81.2)
52-week high/low	NIS1.46	NIS0.25	

Business description

CollPlant is an Israel-based regenerative medicine company. It is focused on developing and commercialising tissue repair products with its plant-based technology, rhCollagen. It has two products on the market, VergenixSTR and VergenixFG.

Next events

FY16 results	March 2017
First commercial patients treated with VergenixSTR	H117
Earlier stage applications of its technology developments	2017/2018

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[Edison profile page](#)

Investment summary

Company description: Versatile regenerative technology

CollPlant, an Israel-based, regenerative medicine company, is focused on developing and commercialising tissue repair products with its plant-based technology. The company's genetically engineered plants produce human recombinant collagen, which is initially targeted for use in orthopaedic and wound healing products. Current products on the market include a soft tissue repair matrix for treating tendinopathy and a wound repair matrix to promote rapid optimal healing of acute and chronic wounds. Additional applications, at an earlier stage, include bone void filler for spine fusion and Trauma and rhCollagen-base Bioink for 3D printing of tissues and organs. CollPlant conducts its product research and development work at offices and research laboratories in the Weizmann Science Park in Ness-Ziona, Israel. The agricultural research and development and extraction activities for its rhCollagen are conducted in North Israel. The company became public in May 2010 through a reverse merger with Portfolio Green. It trades on the Tel Aviv Stock Exchange (TASE) and has raised c \$56m to date.

Valuation: Risk-adjusted NPV \$61m

We value CollPlant at \$61m, or 48c per share, based on a risk-adjusted NPV analysis, with a 12.5% discount rate. We model cash flows for each of the current product lines, VergenixSTR and VergenixFG, from their current stages through to potential expiration of market exclusivity (ie patent expiry in 2032). We note this excludes a contribution for the earlier R&D programmes and the inherent value of the rhCollagen platform technology, which has the potential to be developed into a number of other applications. This offers upside potential if the programmes progress into the clinic and/or CollPlant secures partners or funding. We also employ relatively conservative assumptions, which could bring further upside as we get more clarity on uptake and spread.

Financials: Fund-raising requirement in 2017

We forecast FY16 net cash of NIS3m and a funding requirement in FY17, despite CollPlant raising c.NIS 7m on TASE in Feb 2017, for which we model an illustrative loan of NIS15m. In the absence of a significant fund-raising (although including the illustrative NIS15m long-term debt in FY17), we expect the main areas of spend to be its R&D activities during FY17 and FY18. We forecast R&D spend of NIS13.3m and NIS15.3m and an SG&A spend of NIS3.6m and NIS4.0m in 2017 and 2018 respectively. This is lower than preceding years as its main products have moved into the commercialisation stage (via distributors and partnerships) and now that the NASDAQ offering has been abandoned, as there was an increase in costs associated with this.

Sensitivities: Innovative approach to regeneration

Key sensitivities include funding requirements and execution of the tendinopathy and wound care product sales (including reimbursement) and the rate of clinical progress in orthobiologics. Commercial success in each area will depend on the success of the regulatory process, reimbursement and surgeon uptake. Development of the pipeline and technology is subject to additional funding and/or partnerships to conduct further studies and/or to grow salesforces that could prove dilutive to current shareholders. CollPlant has received government grant funding to develop its technology, which comes with various stipulations on the return of the funding amount and location of manufacturing and knowledge. Finally, while CollPlant performs the extraction process from the tobacco plant, the purification process that produces rhCollagen is carried out by a subcontractor in Israel (in-house capability being developed) and the end products are manufactured by a subcontractor in the US. Although strict protocols are in place, it should be noted that the process is not completely in house and there could be risks in execution and delivery.

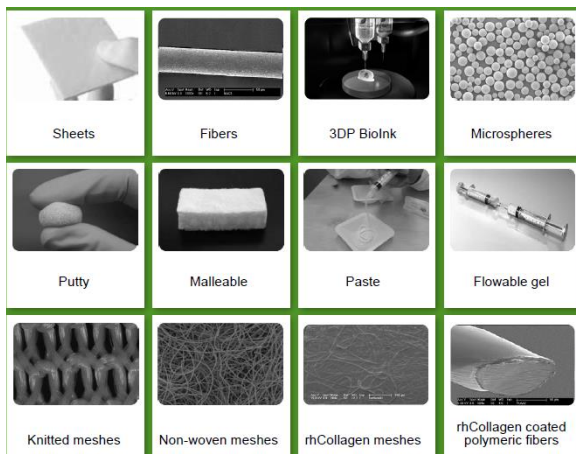
A plant-based approach to regeneration

CollPlant is a regenerative medicine company. It develops and commercialises medical devices for regenerating human tissues based on a proprietary plant-based genetic engineering technology to produce recombinant human collagen (rhCollagen) from tobacco plants. Initially, CollPlant introduced five human genes encoding heterotrimeric type I collagen to tobacco plants. Once this is achieved the ongoing production process has four broad steps: growing the tobacco plants that contain the type I collagen genes in greenhouses, harvesting them, extracting the collagen and purifying it.

The resulting rhCollagen is, according to the company, identical to type I human collagen, which can then be used in a number of biological applications in particular tissue repair. Tissue engineering and regenerative medicine is an advancing therapeutic area, which is generating demand for collagen fibres that mimic native collagen fibre structure and function and can then be produced in large quantities and processed effectively. CollPlant's rhCollagen reportedly offers this and has a number of features¹ that we believe could differentiate it from existing animal and human tissue options, including:

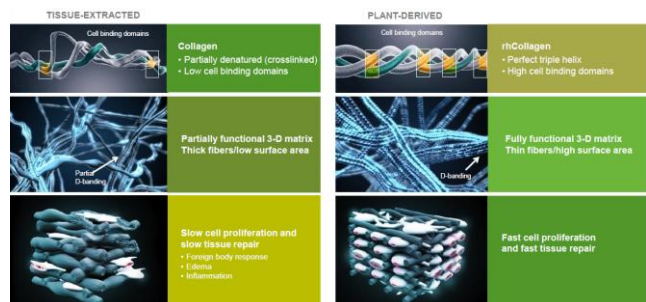
- Improved biological function (over animal and human tissue). As rhCollagen is identical to human collagen, it is recognised by the body and potentially induces and supports cellular infiltration (eg endothelial, fibroblast and keratinocyte) and ultimately promotes healing.
- High structural integrity with superior homogeneity, which enables a consistent, repeatable product with a high molecular order (oriented in the same direction). This is important because it can then be made into scaffolds with distinctive properties, such as thermal stability, improved tensile strength and compression resistance.
- Reduced risk of immune response (innate and due to reduced risk of pathogens).
- Ability to create different forms and shapes (gels, pastes, sponges, sheets, membranes) for different applications (see Exhibit 1).
- Potential for scale, ease of sourcing and lower-cost processing.

Exhibit 1: Potential forms and shapes for different applications



Source: CollPlant presentation

Exhibit 2: Advantages of CollPlant's technology



Source: CollPlant presentation

The investment story is built on the versatility of the technology described above. The potential application is broad and the adoption of biological, as opposed to standard treatments such as

¹ Majumdar, S., Guo, Q., Garza-Madrid, M., Calderon-Colon, X., Duan, D., Carbajal, P., Schein, O., Trexler, M. and Elisseeff, J., 2016. Influence of collagen source on fibrillar architecture and properties of vitrified collagen membranes. *Journal of Biomedical Materials Research Part B: Applied Biomaterials*, 104(2), pp.300-307.

synthetic implants, is driven by the need for earlier intervention and cost savings for longer-term healing solutions. CollPlant is initially focused on the wound care and orthobiologics markets, but also has a potential pipeline of other applications including cardiovascular, ophthalmic, 3D bio-printing and other extracellular proteins (such as elastin, fibronectin). We estimate that the current target market for CollPlant is c \$15bn. This is based on Smith and Nephew's estimate that the advanced wound care market is \$8.5bn (CAGR 4-5% 2015-18) and Transparency Market Research's estimate of the global orthobiologics market of \$5.5bn in 2019 (CAGR 5.9% from 2013 to 2019). A significant commercial advantage of CollPlant's products is that they can be stored and transported cost-effectively as many potential competitor products are cryopreserved, which is more costly and can create structural integrity problems. CollPlant is operating in highly innovative areas where commercial traction could make these products attractive to larger medical devices companies that need to enhance their portfolios.

Exhibit 3: CollPlant's pipeline

Product	Indications	Description	Status/estimated launch date
VergenixFG	Surgical wounds and chronic wounds, eg diabetic ulcers	Wound-filling flowable gel composed of rhCollagen. Once applied, it forms a scaffold that covers the wound site. Wound closure is achieved via scaffold degradation and growth of new tissue.	CE mark achieved Q116. Commercialisation initiated via a distributor in Europe. Initial focus is Italy.
VergenixSTR	Tendinopathy, eg tennis elbow, rotator cuff, patellar tendon	Soft tissue repair matrix composed of rhCollagen and platelet-rich plasma (PRP). Once injected to the site of injury, it forms a viscous gel matrix that serves as a scaffold. Platelets in the PRP provide sustained release of growth factors.	Completed open-label, single-arm, multi-centre clinical trial to support CE marking application. Reported positive results August 2016. CE marking achieved Oct 2016. Commercialisation through a partnership with Arthrex (announced November 2016).
Bone void filler	Trauma and spinal fusion	Resorbable scaffold composed of rhCollagen and synthetic materials, which can be seeded with growth factors (autologous or recombinant) to heal and create new bone.	Looking for a strategic partner to progress through the regulatory pathway and commercialise.

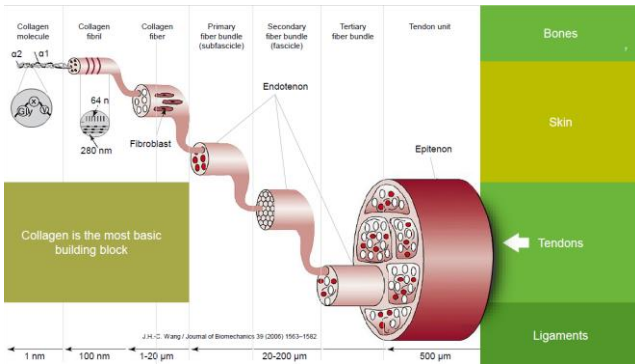
Source: Edison Investment Research and CollPlant

Technology and production

Type I collagen is the most abundant form of collagen in the human body. It is the dominant constituent of connective tissue and is best suited for applications associated with regenerative medicine because of its essential role in the healing process of bones, skin and tendons. Type II and type III collagen are primarily found in articular cartilage and granulation tissue (artery walls, skin, intestines, uterus) respectively.

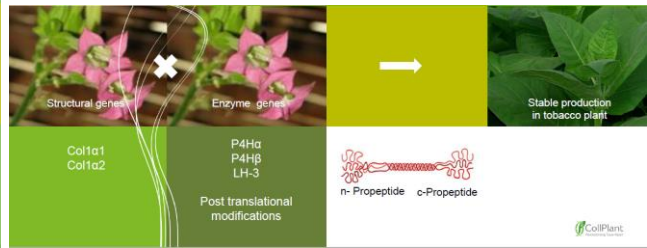
The human body has five genes that encode heterotrimeric type I collagen: two are structural genes (collagen $\alpha 1$ and $\alpha 2$ protein chains) and three are enzyme genes (prolyl-4-hydroxylase [P4H α and P4H β] and lysyl hydroxylase 3 [LH3] enzymes). CollPlant introduces the two structural genes into one tobacco plant and the three enzyme genes into another. These are cross-bred to obtain a parent plant that contains the five genes. The plant essentially becomes a biofactory, able to synthesise the proteins. The plant produces procollagen, which is extracted, then the c and n propeptides are cleaved, mimicking the process in a human, and are enzymatically converted to atelocollagen using a plant-derived protease. The protein is purified through a cost-effective industrial process, taking advantage of collagen's unique properties that make it soluble at a very low pH.

Exhibit 4: Role of type I collagen



Source: ColiPlant presentation

Exhibit 5: Starting point for ColiPlant's technology



Source: ColiPlant presentation

Tobacco plants have been chosen for the medium for production because they:

- have a well-understood genetic structure so can be manipulated effectively;
- offer the ability to control the growing process to maximize yields;
- are not part of the food chain so there are no concerns about cross-contamination of the food supply that could result from genetically modified plants, which eases the regulatory burden; and
- can be grown in very large volumes and reach maturity in a short time frame (eight weeks).

The production process is outlined below in Exhibit 6. ColiPlant conducts the growing and extraction part of the process in house and currently subcontracts the purification and product manufacturing. The company has indicated that scale-up is easily achieved and that the in-house purification capability will be implemented in 2017.

Exhibit 6: Production process



Source: ColiPlant presentation

Orthobiologics

Orthobiologics uses cell-based therapies and biomaterials to help musculoskeletal injuries heal more rapidly. These products are made from substances that are naturally found in the body, which dynamically interact with the musculoskeletal system to facilitate the healing of bone, cartilage, meniscus, tendons and ligaments affected by disease or injury. Key market players include DePuy Synthes, Medtronic, Sanofi, Stryker and Zimmer Biomet, although unusually for orthopaedics the market is highly fragmented with a number of small players. According to GlobalData, the worldwide orthobiologics market is currently \$6.7bn, which is growing (CAGR 7% 2016-20), driven by an

ageing population, obesity, active demographics, innovative technology and emerging geographic areas. The orthobiologics market can be split into five broad segments: bone allografts, bone graft substitutes, growth factors, stem cell therapy and viscosupplementation. CollPlant is targeting the bone graft segments with its bone void filler and the growth factor segment with VergenixSTR, its tendinopathy treatment with PRP. Bone grafting is the predominant segment of the orthobiologics market. According to a Global Industry Analysts report, it is valued at \$850m and is forecast to grow to \$3.2bn by 2022. The PRP market was reported by Transparency Market Research as \$160m in 2015 and is expected to grow to \$452m by 2024, a CAGR of 12.5%.

VergenixSTR: Tendinopathy treatment

VergenixSTR is a soft tissue repair matrix intended for the treatment of tendinopathy (micro tears in collagen fibres in the tendon) by promoting healing and repair of tendon injuries in a variety of tendons including the elbow, rotator cuff, patellar, Achilles and hand. The product combines cross-linked rhCollagen with autologous (extracted from the patient) PRP. The platelets contain growth factors that stimulate tissue generation and repair.

Exhibit 7: VergenixSTR



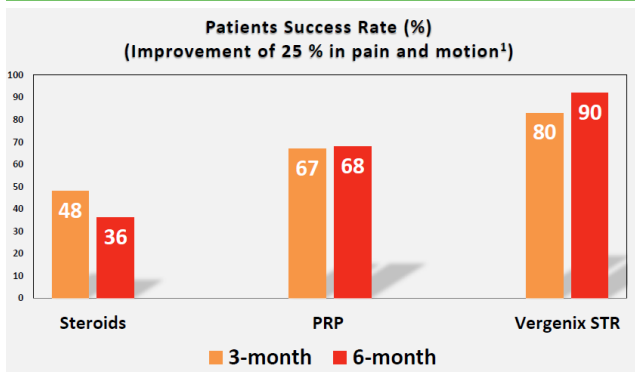
Source: CollPlant presentation

The predominant approach to tendinopathy is rest and physiotherapy. In approximately 5-10% of cases an intervention is needed. Current treatments offered for tendinopathy include a local steroid injection, which is the standard of care, shock wave therapy and injection of PRP alone. Steroid injections have been shown to damage the tissue, so repeat injections are not recommended. Equally, PRP alone requires more than one injection due to an issue relating to platelets localisation: it tends to dissipate quickly.

The main advantage of VergenixSTR over PRP alone is its ability to localise platelets in the vicinity of the injured tissue. VergenixSTR is injected into the tendon, where it forms a viscous gel matrix. This provides a temporary reservoir and scaffold for PRP. It essentially holds the PRP in place at the point of injury and potentially supports cell proliferation via sustained release of growth factors. The company indicates that, rather than being rapidly degraded (within 24 hours), VergenixSTR remains in place for up to a month. This issue of localisation, where the viscous gel matrix remains in place at the point of injection for a longer period of time, becomes increasingly important with the extension of VergenixSTR's indications to its application in joints as opposed to tendons. This is because there is a large amount of synovial fluid in joints, which increases the problem of the injected substance remaining in situ as it is more easily 'washed' away. Exhibit 9 shows in vivo data demonstrating the clot degradation, comparing steroids with VergenixSTR.

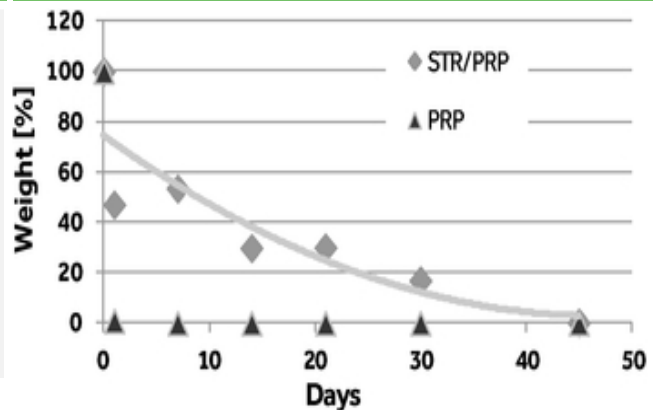
Direct competition with VergenixSTR comes from companies that specifically sell steroid and PRP kits. These include Biomet, Harvest Technologies Corporation, MTF Sports Medicine and Arterioocyte Medical Systems.

Exhibit 8: Comparison to standard of care



Source: Company presentation. Note: Data from separate studies.

Exhibit 9: Clot degradation



Source: Company presentation

VergenixSTR received its CE approval in October 2016 and CollPlant announced in November that it had signed an exclusive distribution agreement with Arthrex to commercialise in Europe, Middle East and Africa (EMEA). We believe there are two possibilities for commercialising this product in the US. CollPlant could introduce it there alone, or it could secure a commercialisation partner in the US, possibly via an extension of the partnership announced with Arthrex in EMEA or with another player. We assume launch in the US c.24 months following the launch in Europe via a partner. We do not currently include commercialisation costs in our model if CollPlant were to commercialise in the US alone. For an overview of the clinical data and commercialisation steps, see Exhibit 10.

Exhibit 10: Overview of clinical data and commercialisation

	Description
Patients	40 patients, prospective, open-label, single-arm trial.
Objective	Safety and performance.
Structure	Patients with inflammation of the elbow tendon (tennis elbow). Patients were followed for a total of six months after a single treatment.
Outcome measures	Assessed by a measuring improvement of pain and recovery of motion using the Patient-rated Tennis Elbow Evaluation (PRTEE) questionnaire.
Results	Three months: average PRTEE score improvement of 51% over baseline. Using a threshold of at least 50% improvement in PRTEE score, 62% achieved. Six months: average PRTEE score improvement of 59% over baseline. Using a threshold of at least 50% improvement in PRTEE score, 64% achieved.
Comment	Positive result demonstrating improvement, particularly when compared with improvement figures in the literature for corticosteroid injection (standard-of-care therapy).
Status	CE mark received October 2016.
Commercialisation route	- Targeting Europe initially. - Signed an exclusive distribution agreement with Arthrex to commercialise in EMEA.

Source: CollPlant

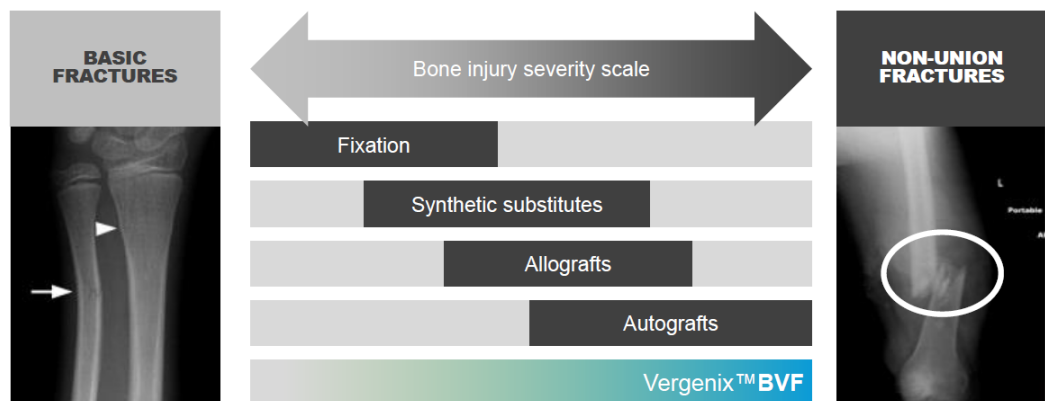
Bone void filler

This is at an earlier stage of development and CollPlant are currently seeking a partner (following the recent discontinuation of its joint development with Bioventus) to develop any product along the regulatory pathway and to commercialise. Bone grafts are pieces of bone or bone substitute that can replace damaged or diseased bone in a number of joints and bones in the body. Bone grafts have four mechanistic functions: structural, osteoconduction, osteoinduction and osteogenesis. These provide mechanical support and scaffold for bone formation, induce differentiation of progenitor cells into bone-forming cells, or osteoblasts, and directly contribute cells for bone formation respectively. Bone grafts can be autologous (graft taken from the recipient), allogeneic (grafts from cadaveric donors), xenogeneic (animal) or synthetic:

- Autologous grafts work well, have demonstrated good results and are considered the ‘gold standard’ of treatment. The disadvantages include donor site morbidity, restriction of potential sites in the body, efficacy dependent on age and health of patient and cosmetic issues from harvest sites.
- Allogeneic grafts provide an osteoconductive scaffold, are weakly osteoinductive and have no osteogenic potential. An example is demineralized bone matrix (DBM).
- Xenogeneic grafts are potentially popular due to unlimited availability. However, they have to be processed at very high temperatures to avoid the potential for immune rejection and contamination. Equally, they only provide an osteoconductive scaffold and therefore lack any potential bone-forming properties.
- Synthetic bone graft substitutes are an attractive option as they could be easily processed (once a suitable quality substitute that effectively mimics natural bone is produced), offer minimal batch-to-batch variability and their mechanical and chemical properties can be tailored. The downside is that they can lack the signalling cues present in naturally derived materials for cell repopulation and cause inflammation, so they are only osteoconductive, although there is potential for them to be charged with cells or growth factors.

CollPlant’s bone void filler is a novel resorbable scaffold composed of rhCollagen and synthetic minerals that mimic bone structure. It is osteoconductive, but designed to be charged with a growth factor, which will create an osteoinductive/osteogenic implant, so it will stimulate bone and tissue growth. It is intended to be used as a one-time, easy-to-use treatment.

Exhibit 11: Approaches to treating a range of fractures



Source: CollPlant presentation

The initial target markets for its bone void filler will be in trauma and spinal fusion. GlobalData indicates that in 2013 there were 1.8 million bone-grafting procedures performed worldwide, c 400 million related to trauma and one million related to spinal fusion. The market is very fragmented with, according to CollPlant, over 50 DBM products currently available. Interestingly, however, GlobalData also indicates that fewer than 10 have shown clinical evidence of their benefits.

Advanced wound care

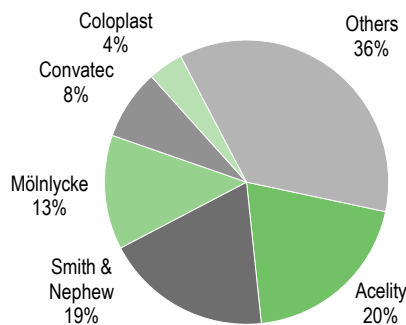
There has been a shift in treatment from traditional wound dressings towards advanced therapies that aim to optimise the wound healing environment. Advanced wound care products include products such as bioengineered skin and skin substitutes, along with dressings incorporating growth factors. In a healing wound, a cascade of events occurs that includes platelet accumulation, inflammation, fibroblast proliferation, cell contraction, angiogenesis and re-epithelization, ultimately leading to scar formation and wound remodelling. Collagen plays an important role in each of these

phases of wound healing and, as a result, there are a number of biological wound care dressings available that incorporate tissue-derived collagen.

The overall wound care market is \$14bn, according to Derma Sciences. The size of the advanced wound care market, according to Smith & Nephew, is \$8.5bn. The wound care market remains dominated by basic products, such as gauze and bandages. This part of the market is low margin and experiencing price erosion. Innovative, new products such as dermal substitutes, growth factors and debridement agents have pricing power and are the growth part of the market. The wound care biologics market is a small but fast-growing segment of the wound care treatment landscape, forecast (according to Research and Markets) to grow at c 21% (CAGR) from 2016 to 2020. The primary market drivers are the ageing population and an increasing emphasis on earlier intervention and cost reduction. The US is expected to lead the market for the foreseeable future due to the high incidence of chronic and acute wounds, favourable healthcare reimbursement policies and an ageing population. In addition to this, there is a more conservative use of tissue-derived products, greater hurdles in the production of processed human tissue, and religious and sociological considerations, which have an impact on the use of, for example, porcine-derived products.

The major players in the advanced wound care market include Smith & Nephew, Acelity, Covidien, and ConvaTec. However, the remainder of the market is the largest segment (36%) and very fragmented.

Exhibit 12: Advanced wound care market



Source: S&N

Wounds are generally classified as acute or chronic. Acute wounds progress through the normal stages of wound healing and demonstrate definite signs of healing at approximately the four-week mark. Chronic wounds do not progress in this manner and ‘stall’ at one of the stages of healing. The value of the products currently used for acute wounds is low. Chronic wounds, such as diabetic foot ulcers, vascular ulcers and pressure ulcers by definition do not heal easily and as such there is an unmet medical need. Alongside the unmet medical need is the significant cost to the healthcare system of chronic wound treatment. This is mainly associated with nursing resources, hospital admittance and complications such as infection.

CollPlant indicates that it will target a broad number of indications including chronic wounds, diabetic foot ulcers (DFUs), pressure, venous and surgical wounds. DFU and venous leg ulcers (VLU) are particularly difficult and expensive to heal. Pressure ulcers are also prevalent, developing in 15-30% of all hospital patients (acute and chronic), and cause a 7% increase in mortality.²

² Sen, C.K., Gordillo, G.M., Roy, S., Kirsner, R., Lambert, L., Hunt, T.K., Gottrup, F., Gurtner, G.C. and Longaker, M.T., 2009. Human skin wounds: a major and snowballing threat to public health and the economy. *Wound Repair and Regeneration*, 17(6), pp.763-771.

Fragmented market makes commercialisation challenging

Wound care is a complex market, primarily because it is not usually the focus of any single physician speciality but is handled in and as part of other specialities such as vascular surgery, gynaecology and dermatology. As a result, consensus about treatment protocols is challenging and exacerbated by variations in reimbursement and budgets. More importantly, patients often have co-morbidities and are affected by adverse socioeconomic factors, which can undermine compliance and effectiveness.

Wound care procedures are predominantly performed in an outpatient setting in Europe, with a well-developed system of specialised wound nurses. In the US, it tends to be in wound care centres and Healogics and Restorix are the largest commercial operators. However, procedures are also performed in surgery centres and physicians' offices.

VergenixFG: Wound filler

CollPlant's advanced wound care product (VergenixFG) is intended for the treatment of surgical incisions and wounds, including diabetic ulcers, burns, bedsores and other chronic wounds that are difficult to heal. It is in a form of a dry powder that creates a gel when mixed with saline. This is applied to the wound after debridement, via a cannula. Once applied, a standard secondary dressing is applied to cover the wound. The gel is applied once and is intended as a single treatment, which potentially reduces follow-up visits. The gel provides a scaffold of collagen, which is thought to provide the wound with collagen to initiate healing by enabling cellular infiltration and capillary growth. The Vergenix-provided collagen degrades, leaving the endogenous native collagen to continue normal wound healing.

Exhibit 13: Application of VergenixFG



Source: CollPlant presentation

Exhibit 14: VergenixFG



Source: CollPlant presentation

VergenixFG is the most commercially advanced product, having been on the market since mid-2016 with the first commercial patients treated in August 2016. For an overview of the clinical data and commercialisation steps, see Exhibit 15 below. The next steps for this product include developing traction in Europe via the establishment of a distribution network. As the product gains traction in Europe, the company will build up its clinical data then intends to find a collaborator to enter the US market. We expect this could be in c.24 months.

Exhibit 15: Overview of clinical data and commercialisation

	Description
Patients	20 patients, open-label, single-arm study
Objective	Safety and performance
Structure	Received a one-time treatment, followed by four-week follow-up
Outcome measures	Percentage of wound closure achieved
Results	<ul style="list-style-type: none"> - Average wound closure rate of 80% - 100% wound closure nine patients (45%) - Median wound closure 94% - Safe and effective for human use
Comment	Positive result, particularly when compared with current standard of care resulting in complete wound closure in 24% patients*
Status	<ul style="list-style-type: none"> - CE mark approval February 2016 - Commenced a post-marketing surveillance study with KOLs
Commercialisation route	<ul style="list-style-type: none"> - Targeting Europe initially - Distribution agreement signed June 16 with an Italian distributor (exclusive, two-year agreement, with an option to extend) - First commercial patients treated early August 16, reportedly with positive feedback

Source: CollPlant. Note: *Compared to a separate standalone trial.

Intellectual property

CollPlant protects its proprietary technology via a combination of patents, trade secrets and trademarks. Its global patent portfolio comprises eight patent families. The [patents](#) cover methods of creating collagen-producing plants and processing recombinant collagen. Core patents around processing start to expire in 2025; however, CollPlant states that protection extends until 2032. It is important to note that in addition to IP there are other significant barriers to entry to compete with a like-for-like product due to the level of knowledge required to be able to replicate the technology and the significant infrastructure requirements. For example, there are restrictions on genetically engineered tobacco plant growth in places such as the US.

Sensitivities

Key sensitivities include funding requirements and execution of the tendinopathy and wound care commercial strategy, and the rate of clinical progress in wound care and orthobiologics. Commercialisation of the tendinopathy and wound care products is dependent on raising the visibility of VergenixFG among key opinion leaders (KOLs), which are typically conservative in adopting new technologies. While existing study data demonstrate promising results, larger studies may be needed to differentiate the wound care product from the range of advanced wound care products available. CollPlant's other recently marketed product, VergenixSTR, is in an area where standard treatment is not to intervene as injection can cause unwanted side effects. Earlier uses of its technology such as the bone void filler potentially address a significant innovation gap; however, its development requires a partner to move forward, which is less assured following the announcement that Bioventus recently discontinued its joint development agreement. Development of the pipeline and technology is subject to additional funding to conduct further studies and/or to grow salesforces that could prove dilutive to current shareholders. We are not aware of any competitors that produce human collagen from plants or recombinant type I human collagen. The industry is characterised by rapidly evolving technology and intense competition, and its products will compete with several alternative tissue-derived or synthetic products. CollPlant has received government grant funding to develop its technology, which comes with various stipulations on the return of funding amounts and location of manufacturing and knowledge. As a result, the company could be affected by any change in governmental regulations or conditions. Finally, while CollPlant performs the extraction process from the tobacco plant, the purification process that produces rhCollagen is carried out by subcontractors in Israel (the in-house capability is being developed)

and the products are manufactured by a subcontractor in the US. Although strict protocols are in place, it should be noted that the process is not completely in house and there could be risk in execution and delivery.

Valuation

We value CollPlant at \$61m, or 48c per share, based on a risk-adjusted NPV analysis. The breakdown of our rNPV valuation, which uses a 12.5% discount rate, is shown in Exhibit 16. We model cash flows for each of the current product lines: VergenixSTR and VergenixFG from their current stage through to potential expiration of market exclusivity (ie final core patent expiry in 2032).

Exhibit 16: Valuation assumptions and rNPV					
Product	Status	NPV (\$m)	rNPV (\$m)	rNPV per share (c)	Key assumptions
VergenixSTR: Tendonopathy	Europe market	48	48	37.08	Peak sales \$97m, Europe launch end 2016 (via partnership with Arthrex), US launch 2019 (assumed also via a partnership on similar terms to Arthrex deal) (tennis elbow incidence 1% of population, growing to include other tendonopathies), 5% addressable, 7% growth, peak penetration 25%, pricing based on the lower end of the PRP pricing point c \$475, partnership margin 50% (we expect it to be higher than through a distribution agreement), one application, Gross margin based on 50% inline with woundcare assumptions), improving to 45% with volume and efficiencies
VergenixFG: Woundcare	Europe market	24	24	18.54	Peak sales \$71m, Europe launch (distributor model) 2016 (VLU incidence 1.3m, DFU incidence 650k, Other vascular conditions 1.2m), US launch 2019 (distributor model) (VLU incidence 856k, DFU incidence 528k, Other vascular conditions 1m), 50% addressable, 4% growth, peak penetration 3%, pricing in-line with the lower end of the biologics pricing point c \$350, 30% distributor margin, one application. Gross margin based on 50% as reported by DermaSciences for its Advanced Woundcare products), improving to 45% with volume and efficiencies
Portfolio total		71	71	55.61	
R&D			-9	-6.76	2016-18 expenses (risk-adjusted)
SG&A			-2	-1.91	2016-18 expenses (risk-adjusted)
Cash (FY16e)			1	0.56	
Overall valuation			61	47.50	

Source: Edison Investment Research

We do not yet include the potential of VergenixFG for other applications such as for the treatment of surgical incisions, which the company has indicated it may target. There is also potential uplift to the selling price once a reimbursement code is established in each jurisdiction. We also note that rhCollagen is a platform technology and there are a number of other potentially valuable applications. We do not currently ascribe a value to CollPlant's other R&D activities based on its rhCollagen such as 3D bioprinting; however, any future developments and progress into the clinic would offer additional upside to our base case valuation.

CollPlant could be an acquisition target either on a product-line basis or for its platform technology as a whole. M&A has been a significant factor in the orthopaedic sector, which has led to considerable consolidation. For example, LifeCell was acquired by Allergan for \$2.9bn in 2016, Synthes was acquired by J&J/DePuy (\$21.3bn in 2011), alongside other large deals such as Zimmer Biomet (\$13.4bn in 2014) and Wright Medical and Tornier (\$3.3bn in 2014). We expect a gradual shift away from these scale-based acquisitions towards transactions that enhance value through innovation and enable a focus on category leadership and portfolio depth. In the longer term, as CollPlant gains sales traction and builds an evidence base around its technology, it could attract M&A value. This could be enhanced as a result of the high barriers to entry due to IP protection, internal knowledge and regulatory restrictions on infrastructure and location. We note that the average price paid (we have removed deals that were significantly higher outliers) in recent orthopaedic deals is four times sales (see Exhibit 17 below). We have specifically selected deals that were in the orthobiologics and/or spine space.

Exhibit 17: Orthopaedic deal metrics

	Acquirer	Target	Deal value (\$m)	Last 12 months (\$m)	Price/sales (x)
Orthobiologics					
Sports medicine	Smith & Nephew	Arthrocare	1,500	373	4
	Medtronic	Osteotech	135	96	1.3
Bone graft	Wright Medical	BioMimetics	190		
Spine					
	Royal DSM	Kensey Nash	360	90	4
	Bioventus	Spin-off from S&N	506	223	2.3
	Stryker	Orthovita	304	95	3.2
	J&J	Synthes	19,300	4,371	4.9
	Zimmer	Abbott Spine	360	109	3.3
	Integra	Theken Spine	75	34	2.2
	Medtronic	Kyphon	3,235	444	7.3
	Orthofix	Blackstone Medical	333	60	5.5
				Average	4x

Source: Edison Investment Research

Financials

CollPlant reported net cash of NIS8m at Q316. We forecast FY16 net cash of NIS3m and a funding requirement in FY17, (despite raising NIS7m in Feb 2017) for which we model an illustrative loan of NIS16m, which on our current forecasts gives a cash horizon to 2019. We expect CollPlant to carry out a significant round of fund-raising in 2019, if not earlier, to drive the business towards profitability. In the absence of a significant fund-raising (although including the illustrative NIS16m debt financing in FY17), we expect the main areas of spend to be its R&D activities during FY17 and FY18. This could include expansion of its product pipeline, additional indications for existing product candidates and improvement in yield and process. We currently forecast SG&A spend to return to lower levels now that the NASDAQ offering has been abandoned, as there was an increase in costs associated with this. We forecast R&D spend of NIS17.8m, NIS13.3m and NIS15.3m and an SG&A spend of NIS 7.3m, NIS3.6m and NIS4.0m in 2016, 2017 and 2018 respectively. It should be noted that the SG&A spend does not include the increased cost that would be necessary if CollPlant decided to take steps to commercialise VergenixSTR or VergenixFG itself rather than with a partner or through a distributor respectively.

CollPlant has received R&D grants from the Office of the Chief Scientist (OCS) of the Ministry of Economy and Industry. Up to June 2016 it received \$7.2m. In turn, CollPlant has to pay a royalty of 3-5% of any revenues derived from products that resulted wholly or in part through the grant money. This is up to a total of the money received. An additional stipulation is that CollPlant is restricted in terms of manufacturing and transferring know-how outside Israel. The company would need to gain approval from the authority (OCS) if it were to do this.

We forecast revenue of NIS1.2m in 2017 and NIS2.9m in 2018, broadly split between VergenixFG and VergenixSTR. We expect VergenixSTR to achieve a higher portion of the revenue split as it is being sold via a partnership with an orthopaedic company (Arthrex), which has an established sales team in place across Europe. VergenixFG will be commercialised via distributors, which can take longer to get in place and is more segmental in terms of geographic coverage. Our current forecasts do not include any potential milestone payments from its current partnerships, potential OCS grant awards or potential future partnerships. We do not include any tax in our forecasts as the company has indicated that for the foreseeable future there will not be a requirement to do so. We incorporate the payment of tax in four years' time (2020), at the Israeli tax rate of 25%. We expect to review this as we gain greater clarity on the progress of product commercialisation.

The company announced at Q316 that it was enacting a reverse share split of 3:1. We have restated the number of shares in the model to reflect this. Also, it is worth noting that it has a

number of warrants and options, currently an additional 31.8m at an average exercise price of NIS1.9, and as such out of the money. It also has 10.96m options at a range of NIS0.9-3.9. If all warrants and options were exercised, the maximum dilution would c 25%.

Exhibit 18: Financial summary						
	NIS'000s	2014	2015	2016e	2017e	2018e
Year end 31 Dec		IFRS	IFRS	IFRS	IFRS	IFRS
PROFIT & LOSS						
Revenue		0	0	0	1,260.6	2,948.8
Cost of Sales		0	0	0	(630)	(1,474)
Gross Profit		0	0	0	630	1,474
R&D expenses,net		(9,734)	(11,864)	(17,796)	(13,347)	(15,349)
SG&A expenses		(3,906)	(6,950)	(7,298)	(3,649)	(4,014)
EBITDA		(12,838)	(18,026)	(24,571)	(15,809)	(17,346)
Operating Profit (before GW and except)		(13,640)	(18,814)	(25,093)	(16,365)	(17,888)
Intangible Amortisation		0	0	0	0	0
Exceptionals		0	0	0	0	0
Operating Profit		(13,640)	(18,814)	(25,093)	(16,365)	(17,888)
Other		0	0	0	0	0
Net Interest		617	164	40	14	71
Profit Before Tax (norm)		(13,023)	(18,650)	(25,053)	(16,351)	(17,817)
Profit Before Tax (FRS 3)		(13,023)	(18,650)	(25,053)	(16,351)	(17,817)
Tax		0	0	0	0	0
Profit After Tax (norm)		(13,023)	(18,650)	(25,053)	(16,351)	(17,817)
Profit After Tax (FRS 3)		(13,023)	(18,650)	(25,053)	(16,351)	(17,817)
Average Number of Shares Outstanding (m)		80.4	84.7	98.8	128.3	128.3
EPS - normalised (NIS)		(16.19)	(22.03)	(25.36)	(12.75)	(13.89)
EPS - FRS 3 (NIS)		(16.19)	(22.03)	(25.36)	(12.75)	(13.89)
Dividend per share (NIS)		0.0	0.0	0.0	0.0	0.0
BALANCE SHEET						
Fixed Assets		4,348	4,971	5,143	5,072	5,356
Intangible Assets		1,725	1,721	1,721	1,721	1,721
Tangible Assets		2,007	2,612	2,784	2,713	2,997
Other		616	638	638	638	638
Current Assets		12,610	8,558	6,001	17,366	3,596
Stocks		0	0	0	0	0
Debtors		1,548	3,241	3,241	3,241	3,241
Cash		11,062	5,317	2,760	14,125	355
Other		0	0	0	0	0
Current Liabilities		(2,647)	(3,750)	(3,750)	(3,750)	(3,750)
Creditors		(1,642)	(2,496)	(2,496)	(2,496)	(2,496)
Short term borrowings		0	0	0	0	0
Short term leases		0	0	0	0	0
Other		(1,005)	(1,254)	(1,254)	(1,254)	(1,254)
Long Term Liabilities		0	0	0	(16,000)	(16,000)
Long term borrowings		0	0	0	(16,000)	(16,000)
Long term leases		0	0	0	0	0
Other long term liabilities		0	0	0	0	0
Net Assets		14,311	9,779	7,394	2,688	(10,798)
CASH FLOW						
Operating Cash Flow		(12,958)	(14,496)	(20,328)	(11,534)	(12,873)
Net Interest		(35)	(2)	(40)	(14)	(71)
Tax		35	1	0	0	0
Capex		(336)	(1,389)	(695)	(486)	(826)
Acquisitions/disposals		0	0	0	0	0
Financing		0	10,010	18,505	7,400	0
Dividends		0	0	0	0	0
Other		(16)	27	0	0	0
Net Cash Flow		(13,310)	(5,849)	(2,557)	(4,635)	(13,770)
Opening net debt/(cash)		(23,777)	(11,062)	(5,317)	(2,760)	1,875
HP finance leases initiated		0	0	0	0	0
Other		595	104	0	0	0
Closing net debt/(cash)		(11,062)	(5,317)	(2,760)	1,875	15,645

Source: Edison Investment Research and CollPlant

Contact details		Revenue by geography	
CollPlant 3 Sapir St, Weizmann Science Park, P.o.B 4132 Ness-Ziona 74140 Israel +972 (0) 73 232 5600 www.collplant.com		N/A	
Management team			
CEO: Yehiel Tal		CFO: Eran Rotem	
Mr Tal has been CEO since January 2010. He has extensive management experience in both Israeli and American high-tech and biotech industries. Prior to joining CollPlant, Mr Tal served as CEO and co-founder of Regentis Biomaterials, VP of Business Development at ProChon BioTech, VP of Marketing and Business Development at OrthoScan Technologies and director of business development and business unit manager at Kulicke and Soffa Industries.		Mr Rotem has been CFO since January 2012. He has broad financial experience in the biotech and industrial sectors. Prior to joining CollPlant, he served as the CFO of Tefron, Healthcare Technologies and Gamida. The latter two are a group of companies specialising in the development, manufacturing and marketing of clinical diagnostic test kits and medical equipment and services to the biotech and high-tech industries. Prior to joining Healthcare Technologies he was a senior manager at Ernst & Young.	
CSO: Professor Oded Shoseyov		COO: Dr Ilana Belzar	
Professor Shoseyov founded CollPlant in 2004 and has served as the chief scientific officer since August 2008. He was a member of CollPlant's board of directors from May 2010 until October 2016. Professor Shoseyov has extensive experience with plant transformation systems and protein engineering and has authored or co-authored over 160 scientific publications and is the inventor or co-inventor of 45 patents. He is the scientific founder of nine companies, including CBD-Technologies/FuturaGene, SP Nano, Melodea, Valentis Nanotech and Paulee CleanTec.		Dr Belzer has served as COO since October 2015. Prior to joining CollPlant, he served as the chief operating officer of BioHarvest, a biotechnology company, from October 2012 to September 2015, and prior to that as VP of Research & Development and operations at Procognia. Previously, Dr Belzer held executive positions in Omrix Biopharmaceuticals, now part of the Johnson & Johnson family of companies, and InterPharm Laboratories, now a subsidiary of Merck Serono.	
Principal shareholders			(%)
Meitav DS Investments			15.80
Docor Levi			6.88
Sagi Ame			5.49
Oded Shoseyov			2.13
Yehiel Tal			1.17
Companies named in this report			
Arthrex, Medtronic, Smith and Nephew, Orthofix, Nuvasive, Wright Medical, DMS, Bioventus, Stryker, J&J, Zimmer, Integra, Royal DSM			

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