# Trendlines Report: 10 Companies to Watch

## January 2019 Update

*Note: To align with our quarterly reporting, Trendlines will cease to release this report and will instead incorporate updates on companies that have reached significant milestones through alternate communications such as our monthly investor update, investor presentation and annual report.*

MISGAV, Israel, 23 January 2019 -- The Trendlines Group Ltd. ("Trendlines" and together with its subsidiaries and associated companies, "The Trendlines Group") (SGX: 42T; OTCQX: TRNLY), a leading Israeli investment and innovation commercialization company focused on early-stage innovation-based medical and agricultural technologies, first issued its quarterly update of the "10 Companies to Watch" report in July 2017. The report is published as an aid to understanding the assets of The Trendlines Group.

Trendlines' growing portfolio of 53 companies range from "just started" through companies selling products and growing internationally. These companies all started in the Trendlines' incubators.

This report highlights companies that have achieved significant developmental milestones, which may include investment rounds, patent approvals, clinical or field trials, CE mark or FDA clearance, or sales of their products in global markets. Reaching these milestones brings the companies reported here closer to achieving their commercial goals.

The 10 companies reviewed in this report, listed alphabetically, are:

ApiFix Ltd.
Arcuro Medical Ltd.
BioFishency Ltd.
Fidmi Medical Ltd.
Gordian Surgical Ltd.
Leviticus Cardio Ltd.
OrthoSpin Ltd.
Saturas Ltd.
STS Medical Ltd.
ViAqua Therapeutics Ltd.

In addition, at the end of the report we include an update on the status of our most valuable portfolio company, Stimatix GI Ltd.

## ApiFix Ltd.

### Minimally invasive scoliosis treatment device

ApiFix Ltd. **("ApiFix")** (http://trendlines.com/portfolio/apifix/) aims to disrupt the scoliosis device market with its minimally invasive, non-fusion spinal implant system for the correction of Adolescent Idiopathic Scoliosis (AIS). Worldwide, there are approximately 126,000 scoliosis procedures per year, of which 40,000 are AIS, representing a US$2.4 billion implant market. ApiFix believes its total addressable market currently reaches US$1.15 billion.[1]

[1] U.S. National Center for Health Statistics; OECD Health Data 2015; Statistique annuelle des établissements de santé and CNAMTS (Evolution des actes techniques en secteur liberal); Statistisches Bundesamt; Conjunto Mínimo Básico de Datos – Hospitalización and Ambulatorio; UK Hospital Episode Statistics databases for Admitted Patient Care and Outpatients; Life Science Intelligence Surgical Procedure Volume database.

**Recent Developments**

- Increased the number of surgical procedures to >275
- Earliest treated patients have now achieved six-year follow-up

**Status**

- Offices in Boston, Massachusetts (U.S.), and Misgav, Israel
- CE mark approval
- Targeted sales in Europe, Canada, Israel and Asia
- 7 active patent families (issued and pending patents)

## Arcuro Medical Ltd.

### All-suture meniscus repair system

Arcuro Medical Ltd.'s **("Arcuro")** (http://trendlines.com/portfolio/arcuro-medical/) SuperBall™ all-suture, knotless, meniscus repair system is based on a technique in which the entire procedure is performed inside the joint space using suture material only and requiring just one entry into the joint. Arcuro's technology enables simple, effective, reliable meniscus repair addressing an unsolved problem affecting over two million meniscal surgeries of the knee annually. The global market (excluding China) is valued at US$300 million, with a compound annual growth rate ("CAGR") of 13%.[2]

**Recent Developments**

Completed nine successful first-in-human ("FIH") procedures in the U.S. and Chile

**Status**

- FDA 510(k) cleared
- EN/ISO 13485:2016 certified
- Raised capital from Chinese medical company and from private investors
- Approved patent in U.S. and China; pending in Europe and Israel

## BioFishency Ltd.

### Advanced water treatment systems for land-based aquaculture

BioFishency Ltd.'s **("BioFishency")** (http://trendlines.com/portfolio/biofishency/) cost-effective, plug-and-play water treatment system enhances water quality, making it possible to double production in ponds and to reduce water use by up to 95% in tanks. Aquaculture is the fastest-growing sector in animal protein production with a market value of US$135 billion in 2015[3]; 62% of food fish will come from aquaculture by 2030.[4]

**Recent Developments**

- Closing US$2.3 million investment round
- Closing agreement with the Technion Research & Development Foundation Ltd. to license a new technology that will enable growing fish in any temperature (cold, warm) and water type (fresh, sea); beginning R&D of the project, together with the Technion

[2] MedDevice Tracker, March 2017

[3] The State of World Fisheries and Aquaculture, https://issuu.com/asgcapbiz/docs/a-i3720e

[4] The World Bank, FISH TO 2030: Prospects for Fisheries and Aquaculture, http://www.fao.org/docrep/019/i3640e/i3640e.pdf.

**Status**

- 2018 sales of ~US$1,350,000 (2.4 times 2017 sales)
- BioFishency units continuing to operate effectively with increased sales around the world in countries including Israel, China, Bangladesh, India, Congo, Nigeria and Indonesia
- Completed large project in China in June 2018 (several systems for over 40 fish tanks); completed installation for additional units in Nigeria
- IP: patent in National phase (Israel, China, Europe, India, Brazil)

## Fidmi Medical Ltd.

### Novel feeding device for improved nutrition delivery

Fidmi Medical Ltd. **("Fidmi")** (www.fidmimedical.com) has developed a uniquely designed, low-profile, enteral feeding device that offers a secure, reliable, and discreet solution immediately post-surgery, and when needed, pain-free removal. Annually, there are approximately 1.3 million enteral device insertions worldwide, and an additional 3 million replacement procedures performed for blocked or dislodged tubes, representing sales of US$540 million. The worldwide market for Enteral Feeding Tube is expected to grow at a CAGR of roughly 7.2% over the next five years, reachingUS$960 million in 2023, from US$630 million in 2017.[5]

**Status**

- Performed 11 First in Human (FIH) procedures in Israel
- Developing a low-profile percutaneous endoscopic gastronomy (PEG) device for children
- Preparing CE mark submission
- Submitted FDA 510(k)
- 3 patents pending (all in National phase; U.S. EU, China), one patent granted in China
- Raised US$2 million investment from B. Braun Melsungen AG (2017); funds to be used to complete clinical trials and prepare for market entry

## Gordian Surgical Ltd.

### Integrated port closure system

Gordian Surgical Ltd. **("Gordian")** (http://trendlines.com/portfolio/gordian-surgical-2/) has developed and is currently marketing the TroClose1200™, the only integrated port closure system available worldwide. The product enables the surgeon to insert surgical instruments into the abdominal cavity, and then close the port site in a simple, secure, and safe manner when the procedure is completed. The global trocar and closure markets are estimated at a combined US$1.45 billion yearly revenue.[6]

**Recent Developments**

- Continuing next investment round
- Increased usage of the Gordian TroClose™ 1200 to >500 in >100 hospitals (including surgical procedures in urology robotics, general surgery robotics, bariatric, gynecology, hernia repair)

**Status**

[5] https://www.decisiondatabases.com/ip/25522-enteral-feeding-tube-market-analysis-report

[6] Endoscopic Access Site Closure Devices Market, General and Pelvic Endoscopic Surgery Devices Market, Ch. 8, Medical Market and Technology Reports, MeddeviceTracker.

- Direct sales began in the U.S. Q2 2018
- Raised >US$7 million to date, including grants
- FDA regulatory clearance and CE mark certification
- Portfolio of 3 U.S. patents; two provisional and one in National phase
- Regulatory clearance in Israel; performed surgeries
- Regulatory clearance in Mexico; initiated distribution
- 6 distribution agreements (U.K., France, Turkey, Greece, Mexico, Panama)

## Leviticus Cardio Ltd.

### Wireless energy system for LVADs

Leviticus Cardio Ltd. **("Leviticus")** (http://trendlines.com/portfolio/leviticus-cardio/) is developing a wireless solution to provide the energy needs of left ventricular assist devices (LVADs), eliminating the need for a driveline, a potential entry point for infection. According to Grand View Research, the global LVAD market was valued at US$763 million in 2014 and is set to grow to US$1.98 billion by 2022, driven by increased prevalence of cardiovascular disease, advances in technology, and favorable reimbursement, among other factors.[7]

**Recent Developments**

- Awarded US$950,000 grant from Israel-US Binational Industrial Research and Development (BIRD) Foundation together with Jarvik Heart, global #3 in the LVAD market
- Successful completion of chronic animal study in conjunction with a Jarvik heart pump (180-day follow-up)
- Ongoing animal trials with successful follow-up

**Status**

- Fully operational system
- Raised US$9.2 million to date
- 12 issued patents and several pending (U.S.)
- High visibility among LVAD players
- ISO 13485

## OrthoSpin Ltd.

### Smart, external, robotic orthopedic fixation system

OrthoSpin Ltd. **("OrthoSpin")** (http://trendlines.com/orthospin/) offers a new robotic treatment system for use in orthopedics, specifically external fixation. OrthoSpin's innovative system has the potential to change the outcomes of various orthopedic treatments, such as bone lengthening, setting complex fractures, and correcting deformities. According to the OrthoSpin's estimates, OrthoSpin addresses the US$450 million market for circular and hexapod fixation frame and other external fixation devices that use adjustable struts.[8]

[7] Congestive Heart Failure (CHF) Treatment Devices Market Analysis by Product (Ventricular Assist Devices, Counter Pulsation Devices, Implantable Cardioverter Defibrillators, Pacemakers, Cardiac Resynchronization Therapy) And Segment Forecasts to 2024. Grand View Research, October 2016.

[8] Trauma Fixation Devices - Global Pipeline Analysis, Competitive Landscape and Market Forecasts to 2017, Global Data

**Recent Developments**

Completed US$3 million investment round led by Johnson & Johnson Innovation – JJDC, Inc.

**Status**

- Completed successful FIH clinical trial
- Alpha-version ready
- IP National phase (U.S., E.U., China); 1 provisional patent
- Chairman Dr. Assi Dekel, practicing orthopedic surgeon with more than 13 years' experience in medical device industry; founded OrthoSpace and NeatStitch

## Saturas Ltd.

### Advanced decision support system for optimal irrigation

Saturas Ltd.'s **("Saturas")** DSS (Decision Support System) (http://www.saturas-ag.com/) for precision irrigation is based on its miniature Stem Water Potential (SWP) sensor. Embedded in the trunks of trees, vines, and plants, Saturas' sensors receive direct feedback/input from the tree or vine to provide online, accurate information for optimized irrigation. Current solutions for measuring water status lack accuracy and are labor-intensive or costly.

**Recent Developments**

- Completed successful field trials in California (May-October 2018) in vineyards, almond, and walnut trees
- New field trials in South Africa in vineyards, almond, apple and citrus
- Based on successful trials, received request from growers in Israel and in California to acquire sensors for next irrigation season
- Based on successful trials, received interest from leading companies for distribution opportunities
- Finalizing assembling procedure of the sensors for industrial stage

**Status**

- Updated user interface model – developed and in use
- Completed an investment round of US$4 million in Q1 2018
- Proven technology with Saturas' sensors successfully operating in lemon, clementine, almond, and apple trees for more than a year
- ~600 sensors installed in 3 experimental farms and 20 commercials farms in Israel, California Spain and South Africa
- Established strategic cooperation in 2017 with Netafim Ltd. and NaanDanJain Ltd. (the leading drip irrigation companies in the world) in Israel, Spain, and California for field trials; these industry leaders are also potential distributors of the system. Received additional interest from more leading companies in the field

## STS Medical Ltd.

Removable sinus stent for use after Functional Endoscopic Sinus Surgery (FESS)

STS Medical Ltd. (**"STStent"**) (www.ststent.com) has developed a removable stent for use after FESS to keep the sinus cavity open for almost a month, long enough for the sinus tissue to recover post-surgery. The stent improves patient outcomes and prevents post-surgical complications, thus reducing the probability of revision surgery. Today, about 30% of sinus surgeries fail due to scarring and recurring inflammation that closes the nasal openings and requires revision surgery.[9] According to Intersect ENT, the estimated sinus stent market opportunity exceeds $3 billion in the United States.[10]

**Recent Developments**

- Post marketing surveillance: 20 stents successfully implanted and removed (California, Illinois, Indiana, NY, Texas)
- Began development of larger stent for ethmoid sinus
- Neal Ballius (ex-marketing manager at Acclarent, Spyrox) named Marketing Director
- Preparing manufacturing capabilities for first approved product for United States and Israeli markets

**Status**

- Performed clinical trials (30 patients); including stent removal after four weeks, with three-month follow-up; excellent therapeutic results
- Mike Berman, a serial medical device entrepreneur and investor, was named Chairman of the Board of Directors
- Raised >US$1.3 million
- Issued patents (U.S., China, Australia); two pending (U.S., Canada, Europe, Japan)
- Received FDA clearance (2017)

## ViAqua Therapeutics Ltd.

Orally-administered health management delivery platform for aquaculture

ViAqua Therapeutics Ltd. **("ViAqua")** (https://www.viaqua-t.com/) is developing the first orally-administered health management delivery platform for shrimp that provides resistance to viral diseases, including White Spot Syndrome Virus (WSSV), and prevents viral epidemics. ViAqua's first product is for shrimp, the most important aquaculture commodity, which accounts for 20% of the total international trade value of fish products. According to the USDA, diseases cause 10% to 20% losses in shrimp aquaculture. Delivery presents a major challenge for effective, economical treatment.[11]

**Recent Developments**

- Proof-of-concept for oral delivery of first product
- Nutreco NuFrontiers and VisVires New Protein invested in seed funding, round closed

[9] RSNA RadioGraphics, Failed Endoscopic Sinus Surgery: Spectrum of CT Findings in the Frontal Recess, 2009, http://pubs.rsna.org/doi/full/10.1148/rg.291085118

[10] Centers for Disease Control and Prevention, National Center for Health Statistics, Chronic Sinusitis, 2015, https://www.cdc.gov/nchs/fastats/sinuses.htm.

[11] F.-F. A. A. O. O. T. U. Nations, *GLOBEFISH – Update on world seafood markets*, Rome, Italy, 2016

- Signed a joint development agreement with Skretting SA (Nutreco's aquaculture division) for first product, including distribution and marketing by Skretting
- Preparing for high-volume manufacturing, including pursuing collaboration opportunities

**Status**

- Preparing for round A investment during 2019
- Expanded the team and activity to complete product development and plan for production
- Joined development team with Skretting SA for 1st product development; project management is set up and active
- Promising results in recent challenge test
- Product pipeline is in place, utilizing the Ribonucleic Acid Interference (RNAi) and delivery platform developed

## Stimatix GI Ltd. (previously known as Most Valuable Portfolio Company) status update

### Low-profile solutions for colostomy management

In November 2014, Stimatix GI Ltd. ("Stimatix") sold its assets to a subsidiary company of the B. Braun Group, B. Braun Medical SAS ("B. Braun"). Stimatix's low-profile innovative solutions for colostomy management were developed to improve the quality of life for stoma patients. B. Braun have advised Trendlines that their product launch has begun and is on schedule for worldwide rollout.

The worldwide stoma/ostomy care market is estimated to reach US$2.99 billion by 2022.[12] Stimatix represents a very significant achievement for Trendlines as it fulfils Trendlines' mission of creating and developing companies to improve the human condition while creating considerable value for our shareholders. Read more here.

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[12] Markets and Markets, https://www.marketsandmarkets.com/PressReleases/ostomy-care-accessories.asp

## About Trendlines

Trendlines is an innovation commercialization company that invents, discovers, invests in, and incubates innovation-based medical and agricultural technologies to fulfil its mission to improve the human condition. As intensely hands-on investors, Trendlines is involved in all aspects of its portfolio companies from technology development to business building. Trendlines' shares are traded on the Singapore Stock Exchange (SGX: 42T) and in the United States as an American Depositary Receipt (ADR) on the OTCQX International (OTCQX: TRNLY).

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The contact person for the Sponsor is Ms. Jennifer Tan, Senior Manager, Continuing Sponsorship (Mailing Address: 16 Collyer Quay, #10-00 Income at Raffles, Singapore 049318 and E-mail: sponsorship@ppcf.com.sg).