





# Finnish biotech year 2018

KOLSTER



BIOVIAN











# HEALTH L TURKU

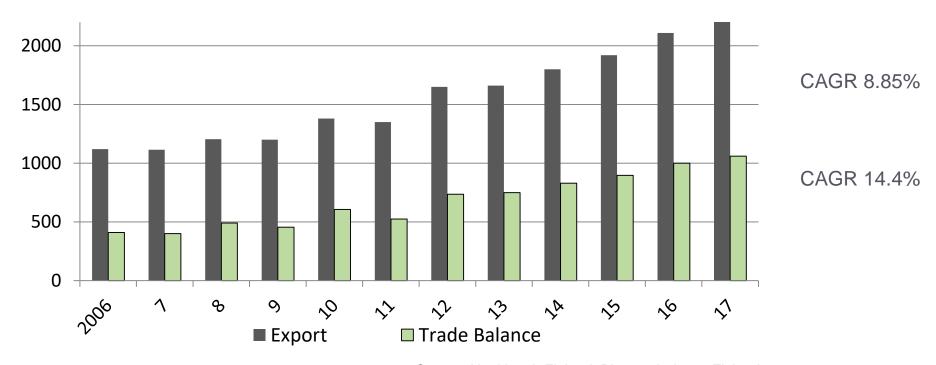
# **Industry statistics**







# Finnish health technology industry



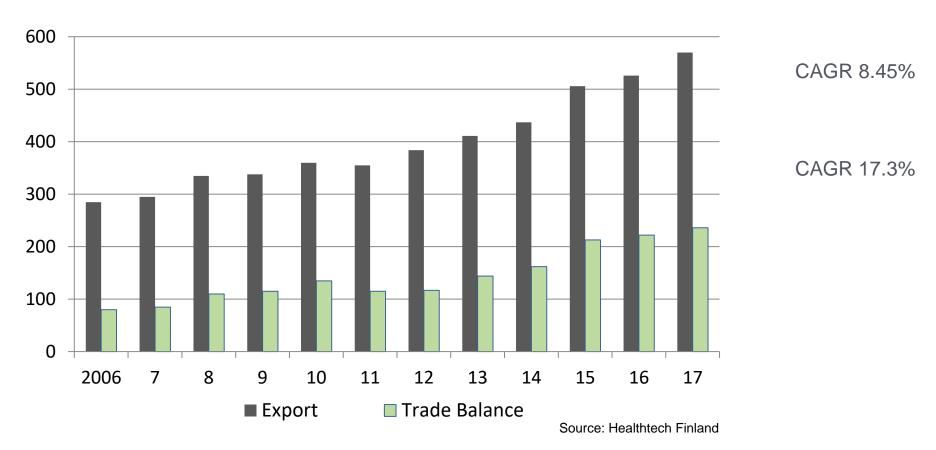
Source: Healthtech Finland, Pharma Industry Finland

- > Finnish health tech export, total: 2,220 M€
- Finnish pharmaceutical export: 1,637 M€





# Finnish in vitro diagnostics industry

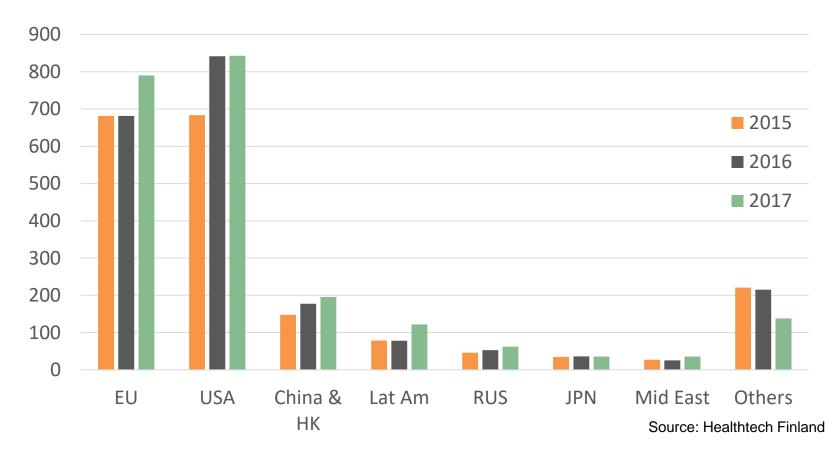


- China largest export market thanks to strong demand of diagnostic equipment
- > export of diagnostic devices 288 M€ (+14,7%) or 50,5% of exports





# Finnish health technology exports



Germany 147 M€ (+6%), France 85 M€, UK 75 M€ (+18%), Sweden 66 M€, Russia 63 M€ (+15%)





# **Professional startups**







# 12 New companies created since autumn 2017

#### **Capital region**

- GlucoModicum blood sugar levels measurement
- **TerveDx** preventive healthcare
- MvisionAl Oy Al in medical imaging
- Osgenic Oy VR simulation, surgery

#### Turku

- BioCad Oy drug development and manufacturing
- Aceman Pharma Oy drug development
- **Aldogen Oy** diagnostic kits, oncology
- Bluezone Oy health monitoring systems
- **Qvalidi Oy** digitalisation in healthcare

#### **Tampere**

- Adaptos Oy tailorable bone graft substitute for surgical operations
- Lean Entries digital service for medical device regulations

#### Oulu

Kipuwex Oy – IoT device for pain assessment





# Good results in all categories







#### **Pharma**

#### Orion

- > H1/2018 net sales of continuing operations 493 M€, operating profit 140 M€, equity ratio 67%
- > sold Orion Diagnostica to Axcel Management A/S for 163 M€
- > Fermion's new plant operational in Hanko (30 M€ investment)
- started a Phase III against ALS with orally administered levosimendan (ODM-109)
- started Ph I against prostate cancer (ODM-208)
- launched its 2<sup>nd</sup> biosimilar Ritemvian® (lymphoma), and agreed to distribute 3<sup>rd</sup> biosimilar (Trastutsumab)
- expands its drug development competence to include also biological drugs
- building a national public-private ecosystem for new modalities and rare diseases





#### **Pharma**

#### **Bayer**

- Mirena product family sales 1126 M€ in 2017 (+9,2%)
  - → Mirena was Bayer's 3rd biggest drug
- > signs agreement to sell Crop Science businesses to BASF for up to 1,7 billion €
- closes Monsanto acquisition
- LEO Pharma to buy Bayer's global prescription dermatology unit. Annual turnover in 2017 more than 280 M€.

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### **Deals and Milestones: Drug Development**

#### **Forendo Pharma Oy**

➤ lead program FOR-6219, a novel, oral, tissue-specific HSD17B1 inhibitor for the treatment of endometriosis, has commenced a Phase Ia study. The first women participating in the study have been dosed.

#### **DelSiTech Oy**

- agrees with KOSDAQ listed C-Tri Co. Ltd, to develop long-acting controlled release formulations, starting with a peptide drug for oncology
- > second consecutive positive fiscal year 2017, turnover 1,4 M€

#### **Biovian Oy**

- > turnover in 2017 raised to 13 M€, profit 4,4 M€ (41,8%)
- Knut Ringbom awarded for the best CEO in Finland 2017 (Kauppalehti Magazine)





### **Deals and Milestones: Drug Development**

#### **Herantis Pharma Oy**

- initiated the Phase 2 study to evaluate Lymfactin® gene therapy in the treatment of secondary lymphedema
- received the Nordic Stars Award at the Nordic Life Sciences Days
- the Innovation prize 2018 of Finland's Chemical Industry Federation was awarded to CDNF protein therapy for Parkinson's disease

#### **Pharmatory Oy and Fermion Oy**

have signed collaboration agreement to provide CDMO services for customers' API development projects from preclinical to commercial stages

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### **Deals and Milestones: Drug Development**

#### **Aplagon Oy**

> announced a development and commercialization agreement with and Cadila Pharmaceuticals Sweden for Aplagon's lead APAC product. APACs are locally acting, potent antithrombotic products, which target blood vessel wall injury.

#### **FIT Biotech Oy**

- has initiated a research collaboration with Avacta Group Plc, UK
- ➤ UK medical authorities have granted the European HIV Vaccine Alliance (EHVA) the permission to start a Phase I/II clinical trial. FIT Biotech's HIV vaccine candidate FIT-06 is a part of a regimen whose safety and efficacy are tested in the UK.





### **Deals and Milestones: Diagnostics & Medtech**

#### **Nightingale Health Oy**

- announced strategic collaboration with PerkinElmer to develop novel precision medicine solutions to address the global burden of diseases
- awarded as one of the Most Innovative Biotech SMEs in Europe by EuropaBio

#### **BC Platforms Oy**

- provides Big Data driven research solutions to Amgen Finland (CV & oncology)
- > provides Real World Evidence solutions to Pfizer Finland in cardiovascular diseases
- co-operation agreement with Abomics Oy to promote a novel pharmacogenetics technology to Healthcare and Life Science customers
- > partnered with Negen Oy for early risk assessment of common diseases





### **Deals and Milestones: Diagnostics & Medtech**

#### **HyTest Oy**

- > H1/2018 Revenue 14,4 M€, operating profit 7,5 M€ (52%)
- high growth in China, becoming the #1 market (China 40%, US 33%)

#### **Labrox Oy**

production agreement with a major international partner; instruments now marketed in more than 150 countries. Strong growth in sales and personnel (+10).

#### **Labmaster Oy**

received CE clearance for its Lucia POC system

#### **Nexstim Plc**

> launched NBT® system for depression





### **Deals and Milestones: Diagnostics & Medtech**

#### **Combinostics Oy**

- received 510(k) from the FDA for its image quantification software cNeuro cMRI
- received start-up award at Future X Healthcare organized by Roche

#### **Ginolis Oy**

distribution agreement with Darwin Microfluidics for dispensing pumps

#### **Medicortex Oy**

- > started the Phase II clinical trial of ProbTBI™ diagnostic kit for (TBI) detection
- agreed with Pro-Lab Diagnostics Inc. (CAN) for registration and sales in CAN and UK

#### **Abomics**

- has partnered with European laboratory network LADR (370 hospitals)
- > first pharmacogenetic samples have already been delivered





### **Deals and Milestones: Diagnostics & Medtech**

#### **Bittium Oy**

- Iaunched the new waterproof Bittium Faros™ ECG device and Bittium FastFix™ patch electrode for ECG measurement
- > Bittium Cardiac Navigator™ has received medical device approval in Europe

#### Finnsusp Oy

> opens a new 1 M€ production line for contact lens solutions and OTC eye drops

#### Revenio Group Oyj

was granted a sales permit in China and MEX for the next-gen tonometer, Icare ic100

#### Planmeca Oy and MetGen Oy

> CTO's Vesa Varjonen and Matti Heikkilä awarded for the CTO's of the year





# Money found!







#### **Evondos Oy**

> raised 21,2 M€ from Serendipity Partners (N) to grow internationally its automatic medicine dispensing service

#### Fimmic Oy

> raised 5 M€ from Ascend Capital and existing investors

#### Kaiku Health Oy

raises 4,4 M€ series A financing from Debiopharm and TeSi to accelerate its digital therapeutics/patient monitoring software pipeline

#### **BBS-Bioactive Bone Substitutes Oy**

raised 3,5 M€ and listed in First North (HEL & STO)

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### Crowdfunding in Finland in 2017 totaled to 56 M€ (+100%)

#### **Mobidiag Oy**

- > completed a 4 M€ crowdfunding from Springvest (formerly Kansalaisrahoitus)
- yets 1,5 M€ loan from Business Finland to develop a new sepsis assay.

#### **ArcDia International Oy**

> completed a 2 M€ crowdfunding from Springvest in a few hours!

#### **Desentum Oy**

raised 2,3 M€ in crowd financing from Springvest to develop allergy vaccine

#### **Askel Healthcare Oy**

> raised 0,65 M€ in crowd financing from Invesdor





#### **Faron Pharmaceuticals Oy**

> raised 11,3 M€ in a private placement (Traumakine & Clevegen)

#### **FIT Biotech Oy**

> secured min 3 M€ and max 10 M€ convertible loan from Alpha Blue Ocean Group

#### Forendo Pharma Oy

- > received 3 M€ loan from Business Finland to progress the DUAL HSD Inhibitor program, targeting broader gynaecological conditions, into preclinical development
- Raised 4 M€ from Vesalius BioCapital Partners (press release Sept 5th)

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#### **Oura Health Oy**

> received 5 M€ funding from Bold Capital Partners (US) and TeSi to scale US market operations of the wellness IOT ring manufacturer

#### **Surgify Medical Oy**

raised 1 M€ from Butterfly Ventures, Cascara Ventures (BE), Merkatura AB and FRIIH GmbH

#### **Disior Oy**

> raised 0,6 M€ in seed funding from Maki.vc and others to boost sales of the image analysis software for diagnostics, pre-operative planning and treatment optimization





#### **Nexstim Plc**

> raised 0,96 M€ via a directed issue of new shares to Capricorn Health-tech Fund

#### **Neuro Event Labs Oy**

raised 0,6 M€ from Maki.vc and OmaMedical +1,3 M€ loan from Business Finland

#### **Olfactomics Oy**

- received EU's SME Ph I grant
- raised 1 M€ risk funding (undisclosed source)





# **M&A** activity







### Selected M&A's

### Venture capitalists on the move...

#### **Orion Diagnostica Oy**

> was acquired by Axcel Management A/S for 163 M€

#### **Biovian Oy**

> majority of shares acquired by Keensight Capital. Biovian receives also a significant investment increase capacities, and to expand internationally.

#### **Medix Biochemica Oy**

> majority of shares acquired by DevCo Partners Oy. Aim is to develop Medix Biochemica into a significantly larger player in the In Vitro Diagnostics sector.





## Selected M&A's

#### **Bittium Oy**

- acquires 17,4 % share of Evismo AG (CH) to expand remote diagnostics service
- acquire's RemoteA Oy's remote diagnostics service platform

#### **KIDE Systems Oy**

was acquired by Topcon Corporation (JPN)

#### 2M-IT Oy

was formed in the merger of Medi-IT Oy and MedBit Oy

#### **Optomed Oy**

> has acquired Commit Oy, a healthcare software solutions company





## Selected M&A's

#### Mehiläinen Oy

> buyout fund CVC Capital acquired majority in Mehiläinen for 1800 M€

#### **Lojer Oy**

- acquired the Nordics' largest supplier of acupuncture needles Hegu Svenska Ab
- > acquired **Teoteam Oy**'s hospital furniture service unit

#### Revenio Group Oyj

acquired the remaining 46,5% of Oscare Medical Oy





# Fast growth vs profitability

Companies	4-Y Growth	Turnover, 1000€	Profitability
Blueprint Genetics	519 %	8069	
Medisapiens	428 %	2063	
Delsitech	328 %	1364	+
Biovian	293 %	13400	+ +
Labrox	219 %	1865	+ +
BonAlive Biomaterials	128 %	2907	-
Reagena	113 %	2500	+
BCB Medical	96 %	4241	
Kaivogen	77 %	2294	+ +
HyTest	59 %	24100	+ +





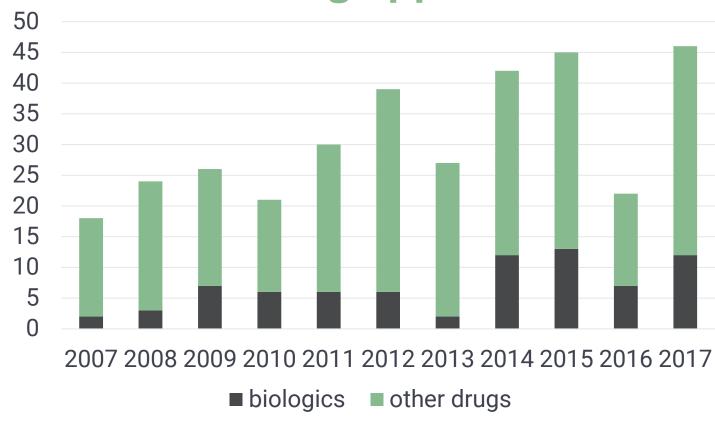
# Technologies collide







# FDA drug approvals 2017



More than 50% increase ingeneric drug approvals, with a high of 92 generics approved in October 2017.





# FDA: New technologies approved, finally

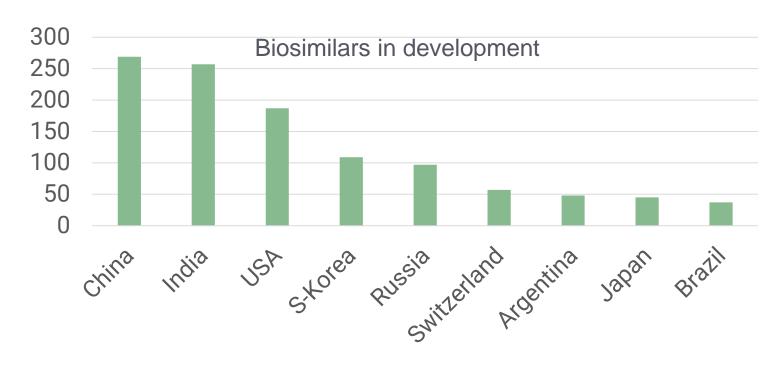
- > FDA, through the Center for Biologics Evaluation and Research, has approved gene therapies for the first time in 2017
  - the 1st, Kymriah from Novartis, is a chimeric antigen receptor (CAR) T-cell immuno-therapy for the treatment of acute lymphoblastic leukemia.
  - the 2nd, Yescarta is also a CAR T-cell therapy, but for the treatment of adult patients with certain B-cell lymphoma (Kite Pharma/Gilead,12 billion \$)
- in 2017 CDER approved a tablet with an electronic sensor that allows the patient to track via smartphone or cloud whether he or she has taken the medication. Abilify (aripiprazole) was first approved for schizophrenia in 2002.

"The use of more expensive and personalized medicine means that hospitals need to evaluate more thoroughly the benefits of them" Petri Virolainen, Turku Univ Central Hospital in Turun Sanomat Sept 5 2018





## **Biosimilars: China rules**

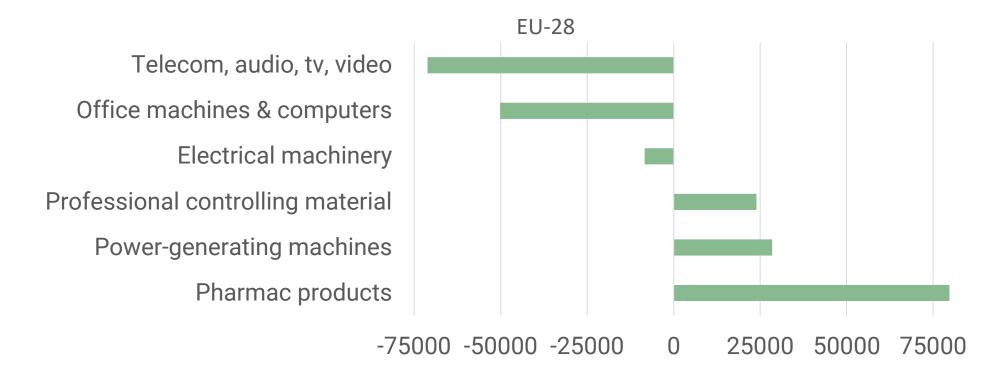


- Biologics are predicted to comprise more than 25% of the pharmaceutical market in 2020.
- China and Asia-Pacific region becoming the frontier market for biosimilars?





### Trade balance of EU's industries



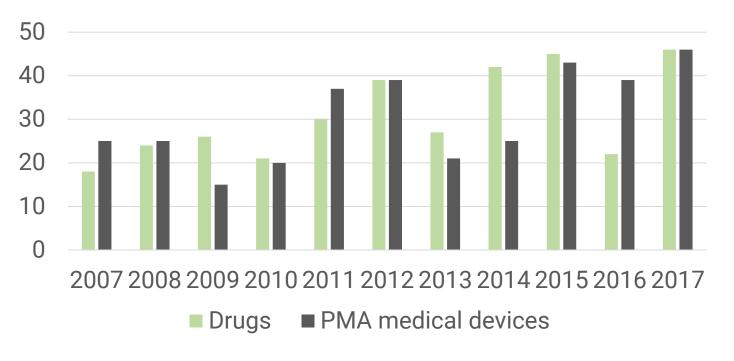
#### **Pharmaceutical industry in Europe**

- > employees 745 000
- > investments in R&D 35 000 M€





# Medical device approval challenging



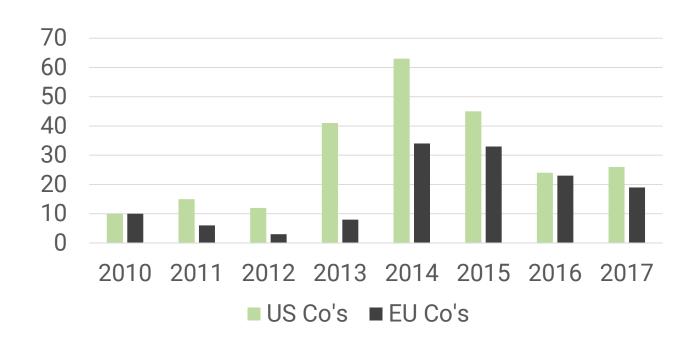
Class III devices present a potential for serious risk to the health, safety or welfare of the patient.

- average cost to bring a medical device onto the market through PMA is 94 M\$ compared to 31 M\$ for the 510(k) process
- > 98% 100% of products are approved, if the FDA files the applications





### Number of biotech IPOs 2017

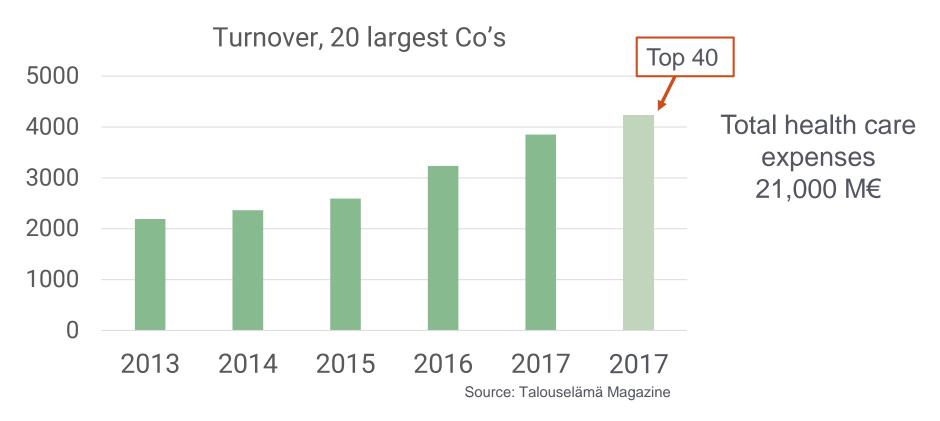


- > 19 European biotechs made an IPO, raising totally 815 M€
- > 4 out of 19 European biotechs listed in Nasdaq, raising 324 M€





### Finnish healthcare business

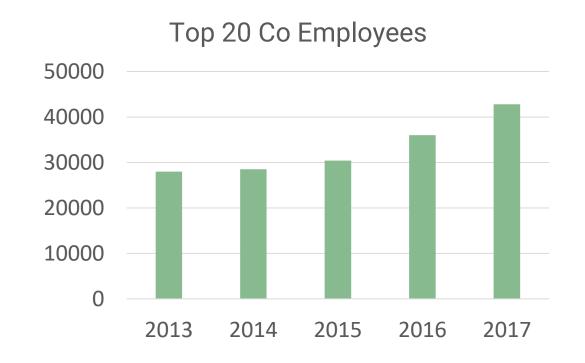


- Mehiläinen, Terveystalo, Attendo and Pihlajalinna alone almost 2400 M€ turnover
- ➤ Fimlab Laboratoriot Oy 102,6 M€





### Finnish healthcare business



Healthcare Co's investments during past 5 years more than 1400 M€





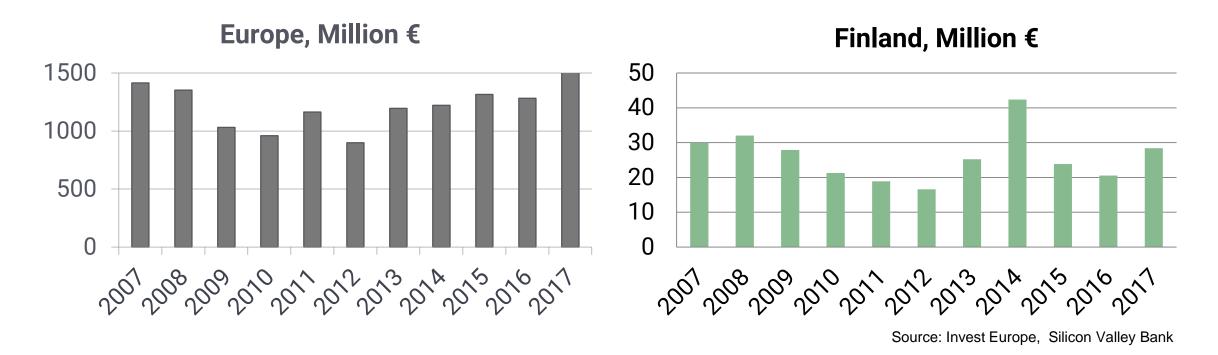
# Watch your neighbors







# Life sciences venture investments: EU vs Finland

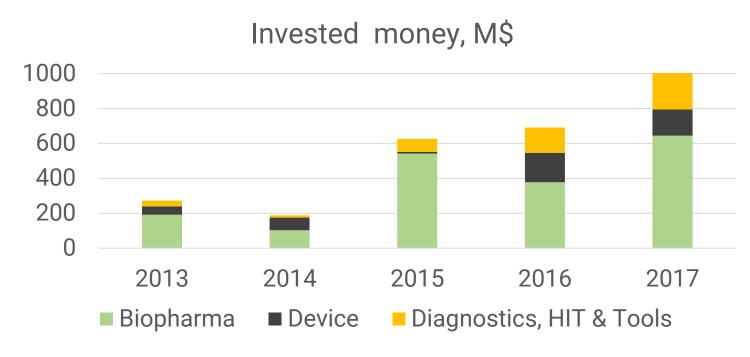


- Finland represents 1,88% of EU VC investments in Life Sciences
- US Series A venture financings to biotech 2259 M\$ and to medtech 333 M\$





# Series A funding in Europe



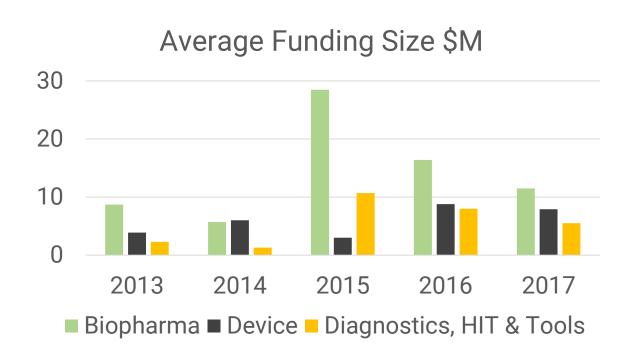
Source: Silicon Valley Bank

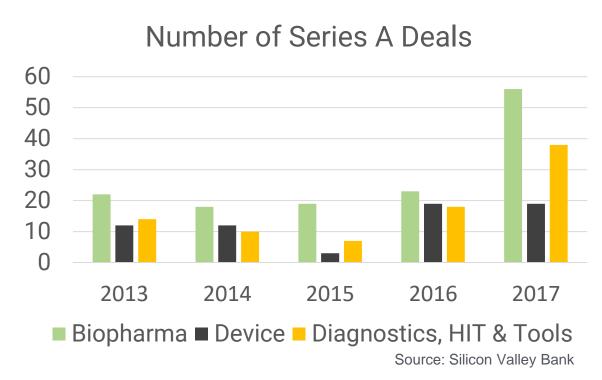
In the USA, H1/2018 sees a surge in Series A: biotech 2632 M\$ and medtech 232 M\$





# Series A funding in Europe



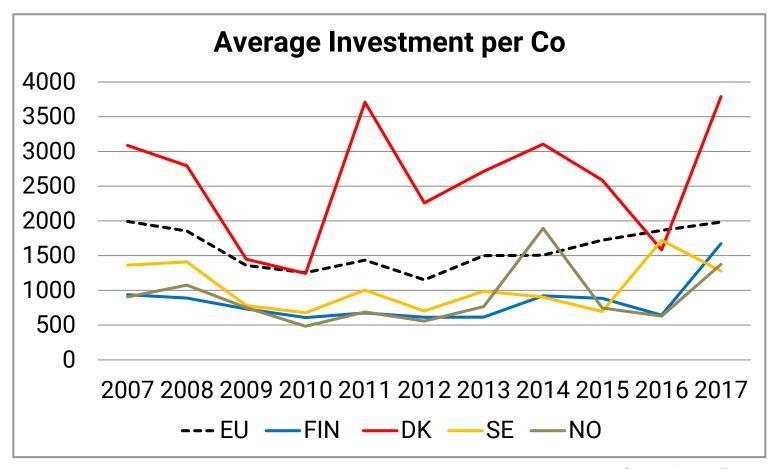


More money, but even more deals → average deals size low





# Average investment per company in the Nordics



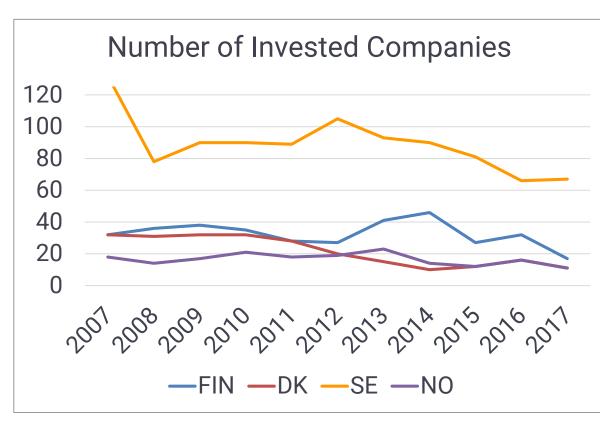
Source: Invest Europe

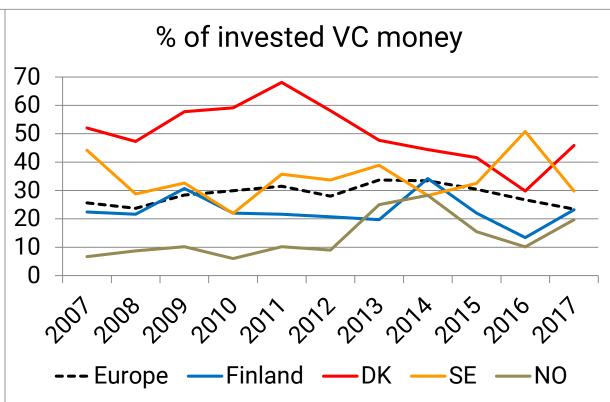
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# What is happening in Denmark?





Source: Invest Europe





# Sweden - life science stock market superpower?

Swedish IPOs	Value, M\$
Handicare Group	114,6
BioArctic Neuroscience	81,6
Oncopetides	81,0
BoneSupport	58,3
Isofol Medical	50,1
Xspray Pharma	15,4
IRLAB Therapeutics	13,5
Sedana Medical	11,7
SenzaGen AB	10,5

Swedish IPOs	Value, M\$
Promore Pharma	8,9
Surgical science Sweden	8,0
BiServo Technologies	7,5
Biovica International	7,0
Annexin Pharmaceuticals	5,8
Paxman Ab	3,6
hemCheck Sweden	3,5
Integrum	2,0
AcuCort	2,0

Source: EY, Medwatch

In the USA, average IPO size was 81 M€, in Europe 32,7 M€

Medtech Biotech





# See you next year



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13.9.2018





# Thank you for your attention

