

#### **Microfluidic business**

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### Four parents of microfluidics

**Molecular analysis:** simultaneously achieve high sensitivity and high resolution using very small amounts of sample.

**Biodefence:** field-deployable microfluidic systems designed to serve as detectors for chemical and biological threats.

**Molecular biology:** required analytical methods with much greater throughput, and higher sensitivity and resolution.

**Microelectronics:** photolithography and associated technologies.

## **Microfluidic segmentation**

#### By Device Type

- Chips
- Sensors
- Others

#### By Material

- Glass
- Silicon
- Polymer
- Others

#### **By Applications**

- Pharmaceutical & Life Science Research
- Diagnosis & Treatment
- Others

#### **By End User**

- Pharmaceutical and Biotechnology Companies
- Research Institutes
- Diagnostic Centers
- Healthcare Facilities and Others

All chips are application specific – no general purpose chips exist

> https://www.fortunebusinessinsights.co m/industry-reports/microfluidicdevices-market-101098

#### Another view

- By Device Type Global Microfluidic Devices Market and Forecast
- The chips segment accounted for maximum share of the microfluidic devices market in 2019.
- Sensors is the second leading segment for microfluidic devices market, responsible for around 20% share in 2019.
- Micro needle system plays an important role in pharmaceutical, biotechnology and medical industries.
- Globally, the market for microfluidic pumps is gaining significant importance due to growing R&D investment in life sciences, pharmaceuticals, and increasing point of care testing demand.
- By Application Global Microfluidic Devices Market and Forecast
- Pharmaceutical and life sciences research
- Clinical and veterinary diagnostics
- Point-of-care diagnostic devices founded in microfluidic technologies will lead the change to personalized medicine, thereby, having a great effect in the diagnosis and treatment of diseases.
- By Industry Global Microfluidic Devices Market and Forecast
- In-vitro diagnostics remained the largest segment type by industry, accounting for around 50% share of the microfluidic devices market in 2019.
- Microfluidic technologies are emerging for drug discovery and development processes.
- The technological advancements in medical devices such as miniaturization, automation and enhanced functionality with help of complex electrical control, mechanical properties are major factors driving growth of the global microfluidics medical devices market.

#### The players

10X Genomics, Abbott, Bionano Genomics, Bio-Rad, BioSurfit, Boehringer Ingelheim, Bosch Vivalytic, PerkinElmer, EVG (EV Group), Fluidigm, IBM, Illumina, Little Things Factory (Plan Optik), L'Oréal, Luminex Corporation, LumiraDx, MBio Diagnostics, MedSpray, Mesa Biotech, MGI (BGI), Micralyne (Teledyne), Microfluidic ChipShop, NeuMoDx (Qiagen), Nypro (Jabil), Omniome, Oxford Nanopore Technologies, Pacific Biosciences, Philips Innovation Services, Samsung, Sanwa Biotech, Sartorius, Schott, Siemens Healthineers, Silex Microsystems, STMicroelectronics, Truvian Sciences, TSMC, Two Pore Guys (Ontera), Varioptic (Invenios, Corning), Veredus Laboratories, X-FAB, z-microsystems, and many more ...

#### Lots of small start-up companies Divisions of large companies

https://www.ventureradar.com/keyword/Microfluidic https://www.fluidicmems.org/microfluidic-companies

#### Different types of COVID-19 tests for different purposes – All complementary

(Source: Status of the Microfluidics Industry 2020 report, Yole Développement, 2020)

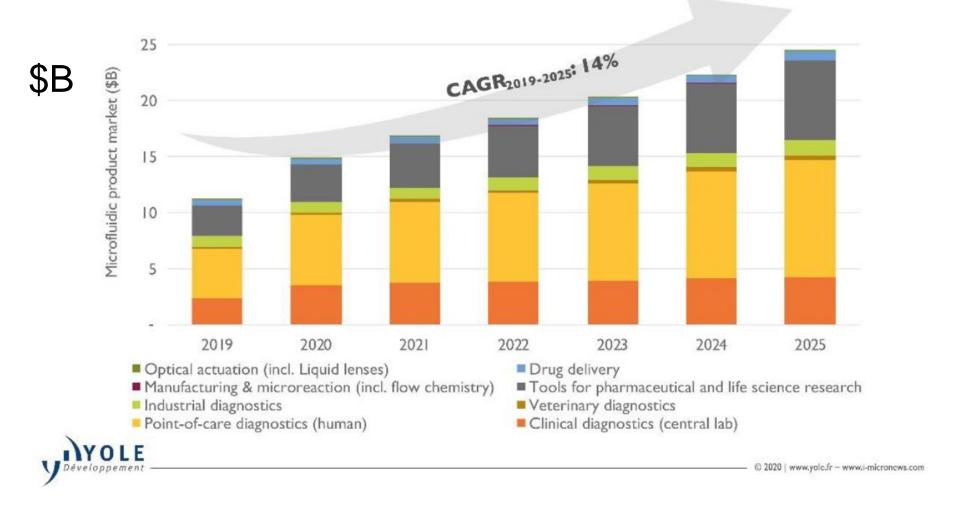


Y Développement

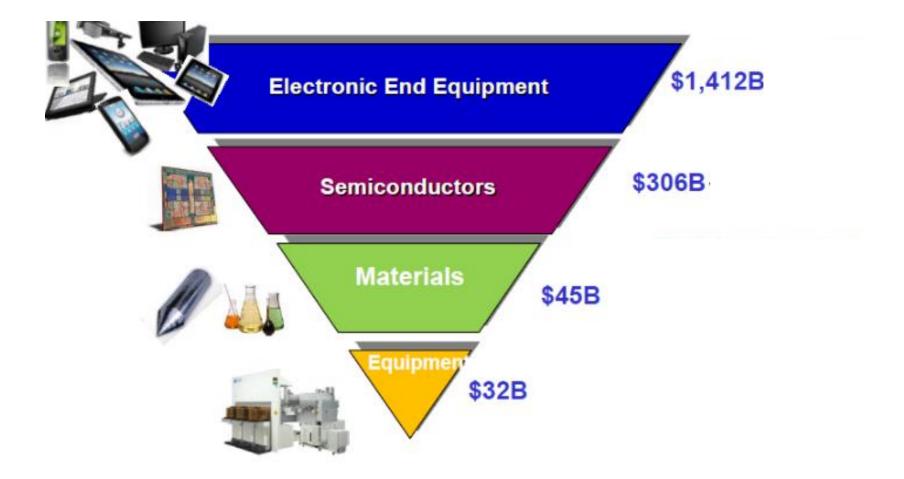
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#### 2019-2025 microfluidic product market forecast in value

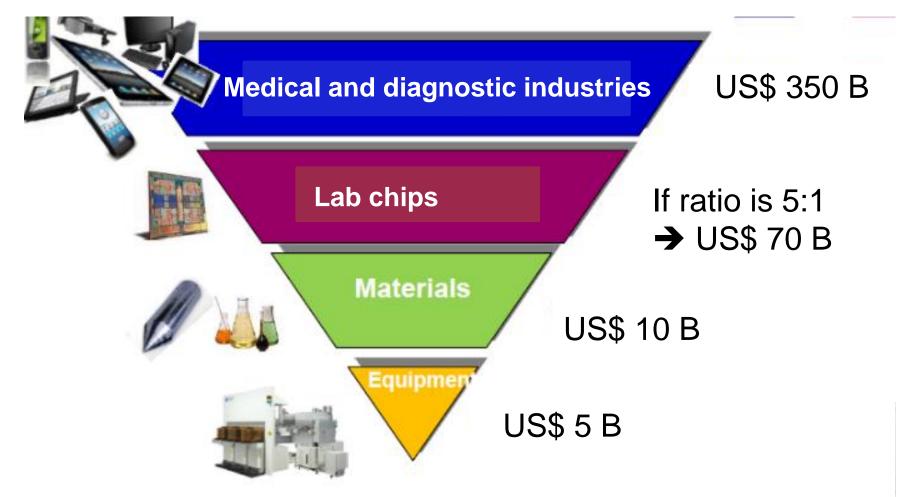
(Source: Status of the Microfluidics Industry 2020 report, Yole Développement, 2020)



#### **Microelectronics industries**



#### By analogy...



## Analogy continued...

IC chip sales were US\$ 15B in 1982. Compound annual growth rate (CAGR) was 17%

→ \$30B in 2025, \$55B in 2030, \$100B 2035...

→ Microfluidics is lagging microelectronics by ~ 40 years,
→ In 1981 IBM PC was introduced...



Yole development: https://www.i-micronews.com/categorylisting/product/status-of-the-microfluidics-industry-2017.html

### Markets for microfluidics

- Chemistry (separation, detection, reactors)
- Biotechnology (R&D tools)
- Information technology (ink jets, displays)
- Industrial (flow, chemical sensing)
- Environmental monitoring (gases, liquids)
- Medical/Diagnostic (blood, urine, saliva)

# Cell biology microfluidics

#### **Single-Cell Analysis**

Direct Analysis of Intact Cells Analysis of Intracellular Contents

#### **Cell Sorting**

Flow Cytometry

**Cell Sorters** 

Sorting Rare Cells

#### Integrated Microfluidic Cell Culture

Improving Cell Culture Microenvironment Directed Cell Growth

#### **Controlling the Cellular Microenvironment**

Chemotaxis

Combining Multiple Environmental Cues Drug Action and Resistance

#### **CellCell Interactions**

Neuronal Cells

Cancer

#### Organs-on-a-Chip

Lung-on-a-Chip

Cardiovascular System

Interorgan Interactions

#### Organisms-on-a-Chip

Roundworms

Zebrafish

Plants

Oocytes, Embryos, and Embryoid Bodies

#### Cost structure

- chip cost: e.g. 5 €/cm<sup>2</sup>
- packaged chip cost: 10 €
- tested, verified chip cost: 20 €
- distribution & sales costs included: 40 €
- sales price with 33% profit margin: 60 €

 Does the chip provide one test, or 100 tests ? Cost of data point !

#### NRE vs. volume-costs

- Non-recurring expenses (NRE): design mask/mould/stamp fabrication salaries (for scientists and bosses) rents
- Volume-based costs

   wafers & chemicals
   wages (for lab technicians and machinists)
   logistics (shipping, storage)

# Technologies

Material

silicon, glass, polymer, metal

Fabrication

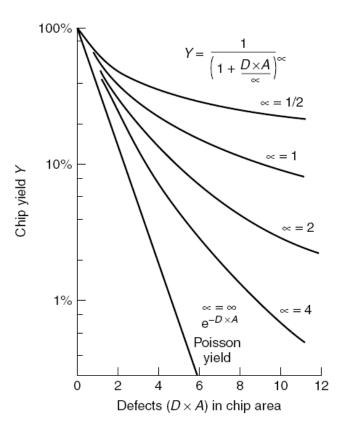
cleanroom or something else

- Packaging & assembly housing, interfacing, shelf-life
- Reliability

disposable vs. reusable testing, documentation, regulatory acceptance

Material cost may not matter: chip cost of \$1 is practically the same as \$5, if final cost is \$60.

## Yield



Different yield models

$$Y = Y_0^n$$

Yield of a total process (Y) is a product of yield of individual process steps  $(Y_o)$ 

$$Y = e^{-DA}$$

Yield depends on chip area (A) and defect density (D)

# Tooling costs

- plastic photomasks 100€
- screen printing sieve
- chrome photomasks
- 100€ 500 €
- injection moulding soft tool 6 000€
- injection moulding hard tool 30 000 €

# **Tooling lifetime**

Copies Technology Cost

500€

6000€

30 000 €

- 100€ plastic masks 100€
  - screen printing
  - chrome masks
  - IM soft tool
  - IM hard tool

thousands 10 000 "infinite" <500 >million

IM = injection moulding

## COP polymer processing

Process	Throughput	Fast prototyping	Feature size
Injection moulding	+++	_	++
Hot embossing	+	+	++
Nanoimprint	+	+	+++
Laser ablation	++	+++	+
Micromilling	_	+++	+

#### Kutter et al: Microfluid Nanofluid (2010) 9:145

## Chip materials

#### TABLE 2. Applications of Microfluidic Systems Made of Different Materials

applications	silicon/glass	elastomers	thermoset
CE electrochemical detection organic synthesis droplets formation <sup>a</sup> PCR protein crystallization bioculture cost of production reusability disposable device use	excellent good excellent excellent excellent poor moderate high yes expensive	moderate limited poor moderate good good good medium no good	good moderate good good good poor moderate high yes expensive
		e.g. PDMS	e.g. SU-8

KANGNING REN, JIANHUA ZHOU, AND HONGKAI WU, 2012 Acc.Chem.Res.

### Start-ups, anybody ?

- •Who are the customers ?
- •What is the benefit they will be paying for ?
- •Who makes the buying decision ?
- •Who pays for the chips in the end ?
- •How much can you charge a customer for a chip that costs 2€ to fabricate ?
- •How do you finance the growth ?

## The big question

•Do you want to own 10% of a 10 M€ company which has great growth prospects, or 100% of a 1M€ company that has little money to burn and dismal future ?

## **Application environments**

- central labs/hospitals
  - professional users and analysts
  - tool size not an issue
- doctors offices:
  - time is money
  - semi-skilled/occasional user
  - tool size matters
- home users:
  - chronic users willing to take training
  - occasional users need very simple systems
  - small, disposable devices (no cross contamination)

#### **Business needs**

- Customer benefit, for example
  - less pain from smaller needle
  - fast analysis while waiting at doctors
  - sensitivity to see biomarker previously unseen
- Supply chain
  - stable technology (e.g. stable yield)
  - materials and component availability
  - distribution channels (e.g. biomolecule shelf life)
- Commercial
  - regulatory issues (esp. biomedical/implantable)
  - final customer (person herself, government, insurance...)

#### **Customer wishes**

Academics/research institutes:

• novelty, performance

Ho many chips for validation ?

Industrial:

• thruput, cost

Phase 1: analytical in the lab

Medical:

Phase 2: in hospital with patient samples

validation, regulatory approval

#### **Business models**

- Tie customers to your instrument, and then sell them disposable tests
- Cheap instrument, expensive disposables (razor blades & ink jet cartridges)
- Make your specialized chips compatible with existing base of readers/instruments
- Sell service of testing instead of selling hardware
- Sell sensitive and fast tests cheaply...

#### Business models (2)

Make your own devices, but sell services

Make your own devices, but only sell systems

Make inspection/measurement equipment for fluidics

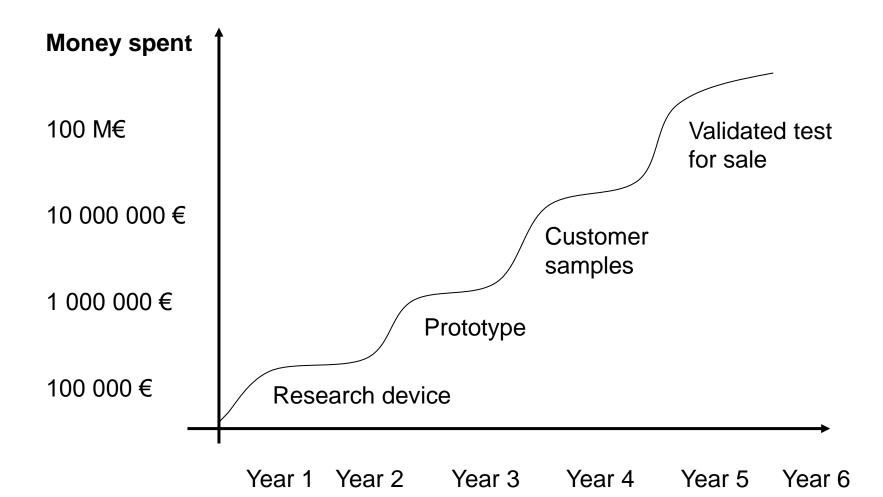
Specialize in materials, packaging, chemicals

Become a distributor to others (to generate cash flow)

Specialize in design/simulation (consultancy, training,...)

Supply tools and machinery for microfluidic companies

#### Time vs. money



#### Steps forward

Bet the farm = money from your own pocket

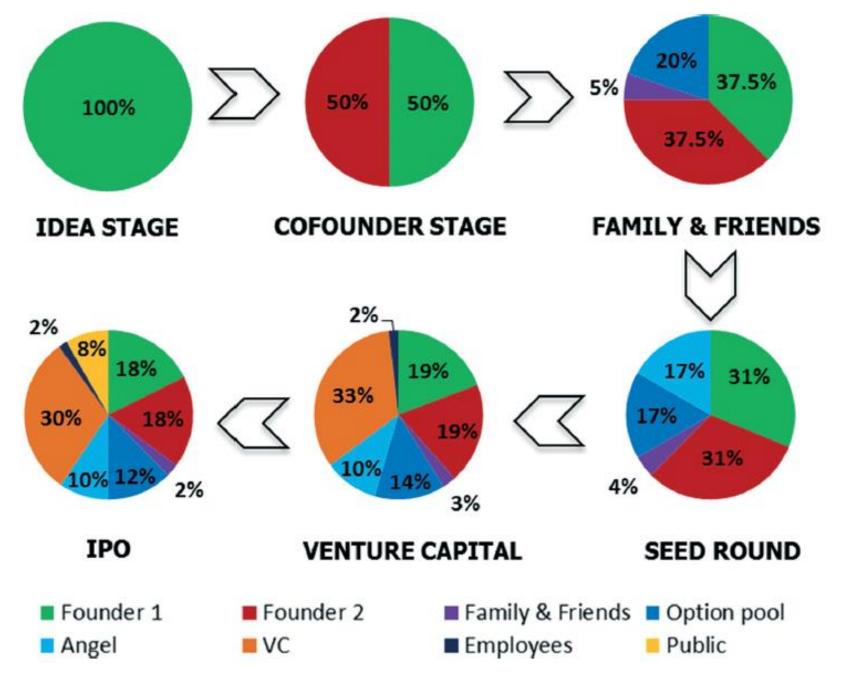
a.k.a. FFF-round: family, friends and fools

**TEKES**/public funding agencies

Business angels (=wealthy individuals)

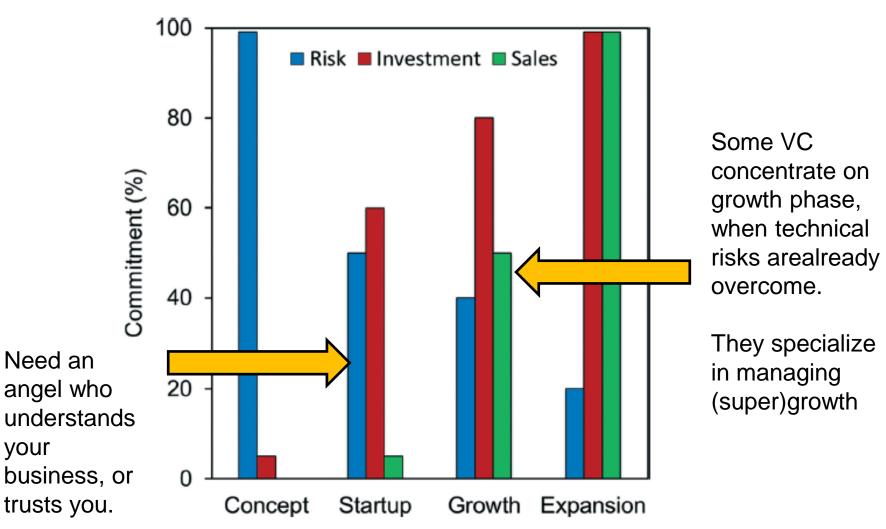
Venture capital in various stages

Markets/IPO

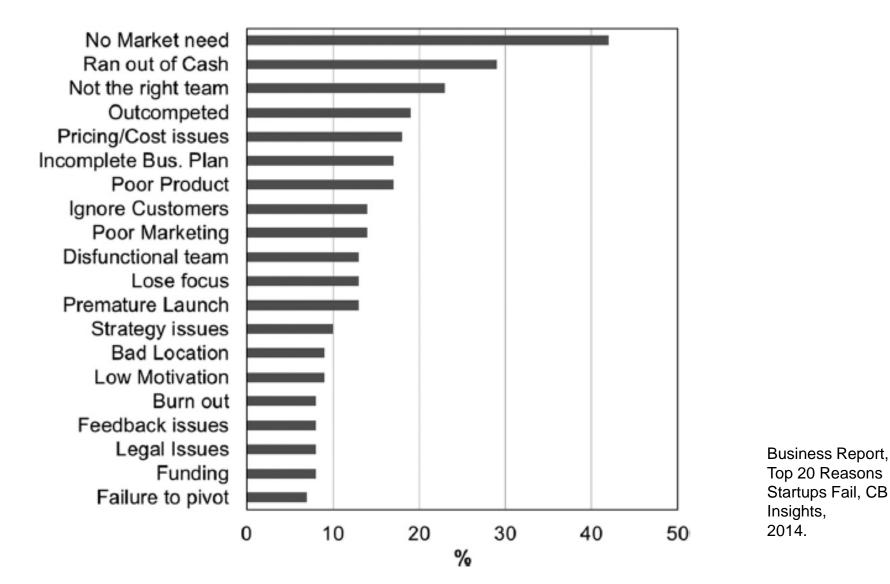


Lab Chip, 2015, 15, 3638

### Profile change upon growth



#### Reasons for start-up failures



#### Theranos

Holmes founded Theranos in 2003 with the goal of revolutionizing blood testing. [It] had invented a machine that could conduct hundreds of laboratory tests with a single finger prick of blood.

Most of the tests Theranos claimed to perform on its Edison machines were actually being performed by traditional blood-testing machines bought from other companies.

Theranos and its chief executive Elizabeth Holmes were charged by the Securities and Exchange Commission (SEC) on Wednesday with "massive fraud" for raising \$700m.

"The alleged Theranos fraudster Elizabeth Holmes is pregnant, according to a new court filing, potentially delaying her trial by several weeks."

(Guardian March 2021)

### Business plan template

**1. Explain your product or service**. What does it do for the customer? Does it have any unique features or facets? How is it produced?

**2. Describe your target customers**. Why have you chosen to market to these customers? Back up your argument with evidence from your experience, reports, white papers, and market research.

**3. Describe any unique selling points or advantages you have**. Why will your customers buy from your business? Are you providing better value, guarantees, superior quality, reduced risk, or better location?

4. Explain how much your customers will pay for each of the products or services you will provide. Describe any up-selling or cross-selling opportunities and how many times a customer will buy from you in a typical year. Again, use any market research or other evidence you can bring to support your argument.

5. Explain how many products you can produce or how much service you can provide in a typical year. Back this up with whatever supporting evidence you have.

6. Examine how much each unit of product costs to produce. If your business is a service business, describe how much it costs to provide the service. Don't forget overhead expenses, such as keeping the lights on or paying somebody to staff the front desk.

7. Detail how much start-up investment the business will require and what you require it for.

8. Explain why your business is viable and what evidence you have to support this claim. This will require some market research to demonstrate that there is a viable market for your product or service.

## 9. Summarize.

On a single page *at the beginning*, list the main points of you plan in bullet point form. This is single most important part of your business plan.

It will be read first by all readers of your business plan and will determine if they will read further and ultimately support your business idea or not.

Write this summary last but put it at the front of your plan.