

5 High-Impact Technology Companies in Healthcare to Watch in 2021-2022

December 2020

www.deep-pharma.tech
info@deep-pharma.tech

Table of Contents

Introduction	3
5 companies	4
Nano-X Imaging	8
What is new in Nanox ARC?	11
Investment rounds in Nano-X Imaging	17
Outset Medical	22
What is Tablo?	25
Investment rounds in Outset Medical	30
Eargo	35
What is Eargo?	38
Investment rounds in Eargo	44
TransMedics	49
What is OCS?	52
Investment round in TransMedics	59
Silk Road Medical	64
Silk Road Medical devices in brief	67
Investment rounds in Silk Road Medical	71
General conclusions	76
Comparative analysis	77
Disclaimer	80

Disclaimer: Our research institute does not have any direct or indirect relations with any of the parties mentioned in this document, any of its employees, affiliates, directors, partners, founders or suppliers. We do not hold any shares of companies mentioned in the document, either directly or indirectly and have no options, warrants, long or short positions in their equities or its derivatives. Our research is an independent review with no financial or other benefits to be derived from its publication. The information and opinions in this report were prepared by us as an independent organization. Though the information herein is believed to be reliable and has been obtained from public sources believed to be reliable, we make no representation as to its accuracy or completeness. Hyperlinks to third-party websites in this report are provided for reader convenience only. We neither endorse the content nor are responsible for the accuracy or security controls of these websites. This report is provided on an independent basis and should not be deemed as a recommendation to buy or sell any stocks.

This report provides an overview and brief assessment of 5 highly impactful and promising medical hardware technologies to be watched in 2020-2021, and companies behind their development and commercialization:

1. **Nano-X Imaging**, a developer of innovative high-powered field-effect cathodes and AI software for X-ray medical imaging.
2. **Outset Medical**, pioneering a first-of-its-kind technology to reduce the cost and complexity of dialysis.
3. **Eargo**, a producer of direct-to-consumer hearing aids, allowing customers to access help for their hearing loss from their homes
4. **TransMedics**, a developer of innovative transplant technology and devices.
5. **Silk Road Medical**, a pioneer of a new approach for the treatment of carotid artery disease

All selected companies went through initial public offerings (IPO) in 2019-2020 and have strong business models, product offerings and value propositions to the healthcare market.

All the selected companies have strong histories of research and development (R&D) work behind them, which in each case resulted in state-of-the-art innovative technologies and medical devices.

The choice for the list of top candidates takes into account factors like the overall potential impact on healthcare, technological novelty and uniqueness, robustness, the company's R&D strength and commercialization prospects, and other relevant considerations.

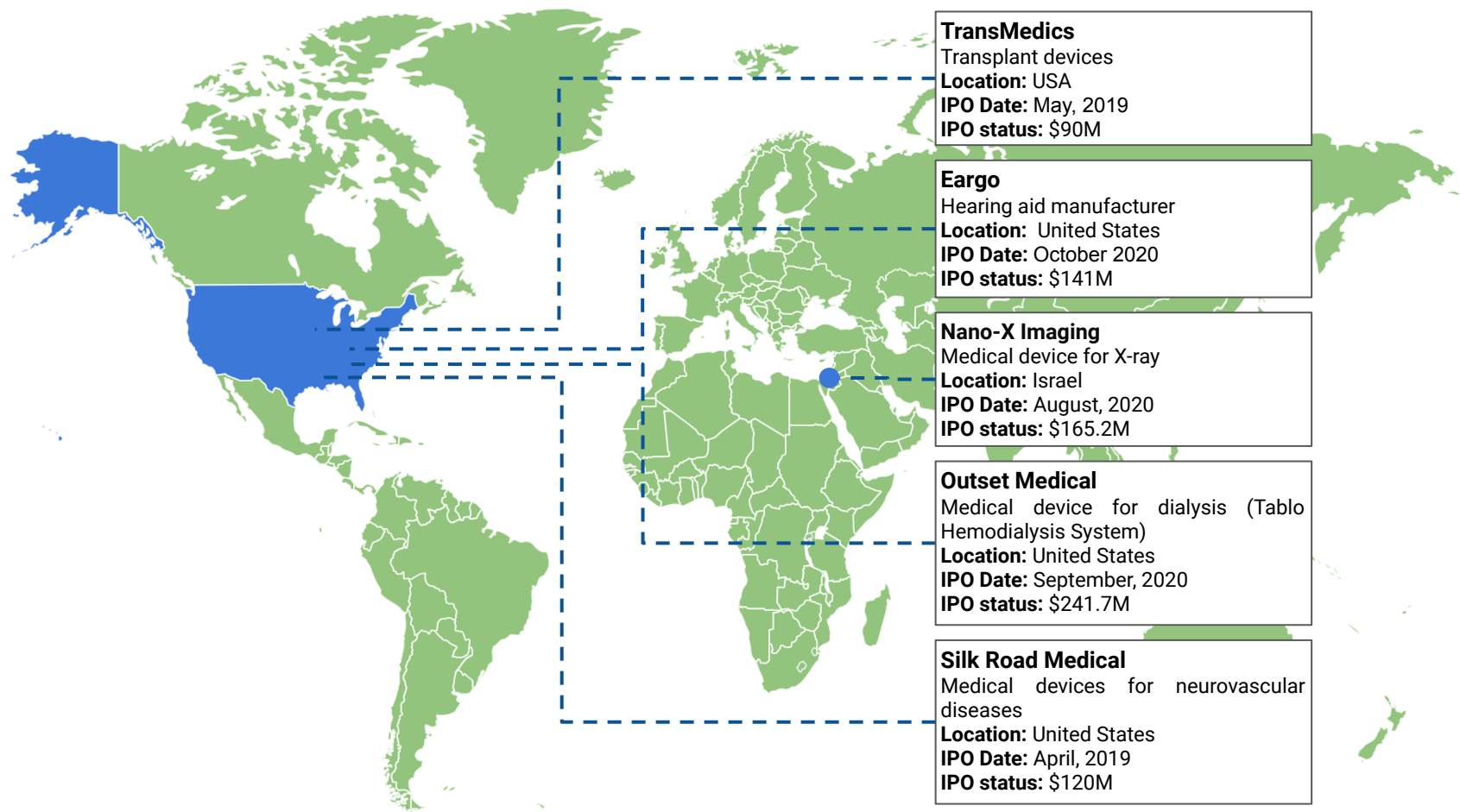
The report features companies' business background, brief history, state of research and development and intellectual property (IP), overview of companies' product and value offerings outlining technological novelty, summary of their major partnerships and customers, the history of funding rounds and IPO-related information, dynamics of R&D spending over years, property analysis, and brief SWOT analysis (strength, weaknesses, opportunities, and threats).

We believe that these 5 promising, advanced and potentially disruptive technologies in healthcare, and 5 companies which are developing them, will provide substantial impact on healthcare industry and will help patients and consumers around the world. Besides, we also consider these 5 companies to be well-balanced, strong, and well-positioned enough to successfully implement product development and commercialization strategies, and achieve prominent growth dynamics.

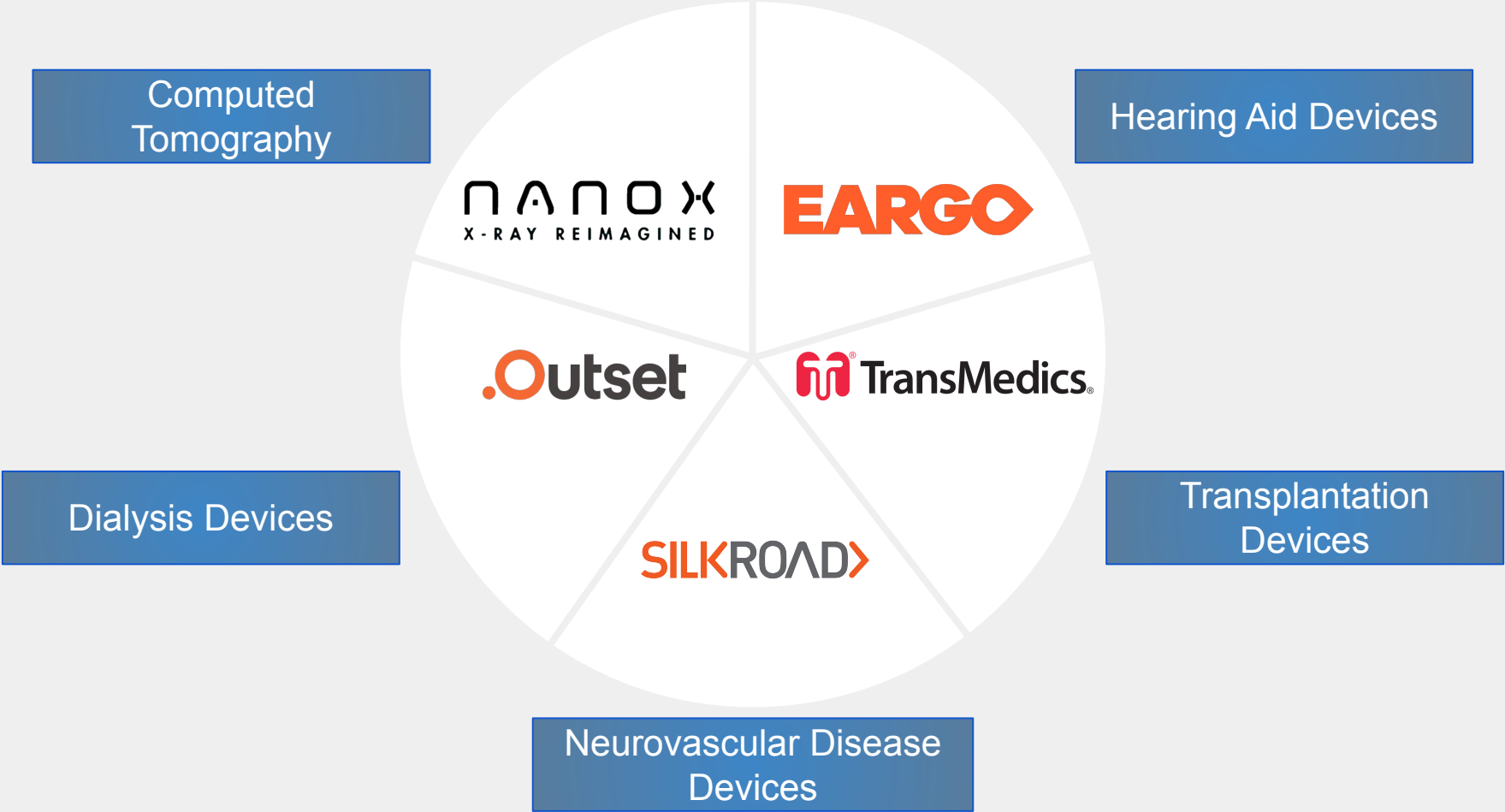
5 High-Impact Technology Companies in Healthcare to Watch in 2021-2022

Company Name	Type	Description	IPO status (million)	Prototype readiness
Nano-X Imaging	Medical device for X-ray	Nano-X Imaging develops a digital X-ray source designed to be used in real-world medical imaging applications.	\$165.2	Presented
Outset Medical	Medical device for dialysis (Tablo Hemodialysis System)	Outset is a pioneering medical technology company reimagining dialysis for patients and health care providers.	\$241.7	Operating
Eargo	Hearing aid manufacturer	Eargo is an American hearing aid manufacturer based in San Jose, California. The company's hearing aids were inspired in their design by a fishing fly. Each unit is also rechargeable.	\$141.3	Operating
TransMedics	Transplant devices	TransMedics is a medical device company that addresses the unmet need for better, more effective organ transplant technologies.	\$90M	Operating
Silk Road Medical	Medical devices for neurovascular diseases	Silk Road Medical is innovating around proven surgical principles and developing breakthrough technology for vascular specialists, trying to improve the lives of people with arterial disease.	\$120M	Operating

Companies Regional Distribution



5 High-Impact Technology Companies in Healthcare to Watch in 2021-2022



5 High-Impact Technology Companies in Healthcare to Watch in 2021-2022

5 - Companies
23 - Partners
60 - Investors



DEEP
PHARMA
INTELLIGENCE

Nano-X Imaging (NNOX)



Nano-X Imaging develops a digital X-ray source designed to be used in real-world medical imaging applications.

Commercial and legal history

After a partnership with Sony, and over \$1B investment in developing an electron field emission technology for production of a new kind of television, the founder of the original company (**Hitoshi Masuya**) **teamed up with Israeli entrepreneur Ran Poliakine** and incorporated Nanox Imaging PLC in Gibraltar (in 2012). The purpose of forming a new company was to provide a tax planning structure allowed by the state in order to enable ongoing spending on research and development.

Several small equity rounds later (in 2018), a new entity (Nanox Co Ltd) was established in Israel which aimed to prepare the whole consortium of companies (from Japan, Gibraltar and Israel) to launch an Initial Public Offering (IPO). An additional factor behind the establishment of the new company was to appropriately reflect the correct ownership structure as management of the Nanox project moved entirely from Japan to Israel. Two years later, on 21st of August, 2020, the company initiated its Initial Public Offering with its digital x-ray source developed on the basis of the Sony electron field emission technology.

The **latest investment round**, executed in **July, 2020**, amounted to **\$59 million**. This brought the **total capital** raised by the startup since December 2019 to **\$110 million**. Investors included global corporations like **SK Telecom**, South Korea's largest wireless carrier, **Industrial Alliance**, **Foxconn**, and **Yozma Korea**.

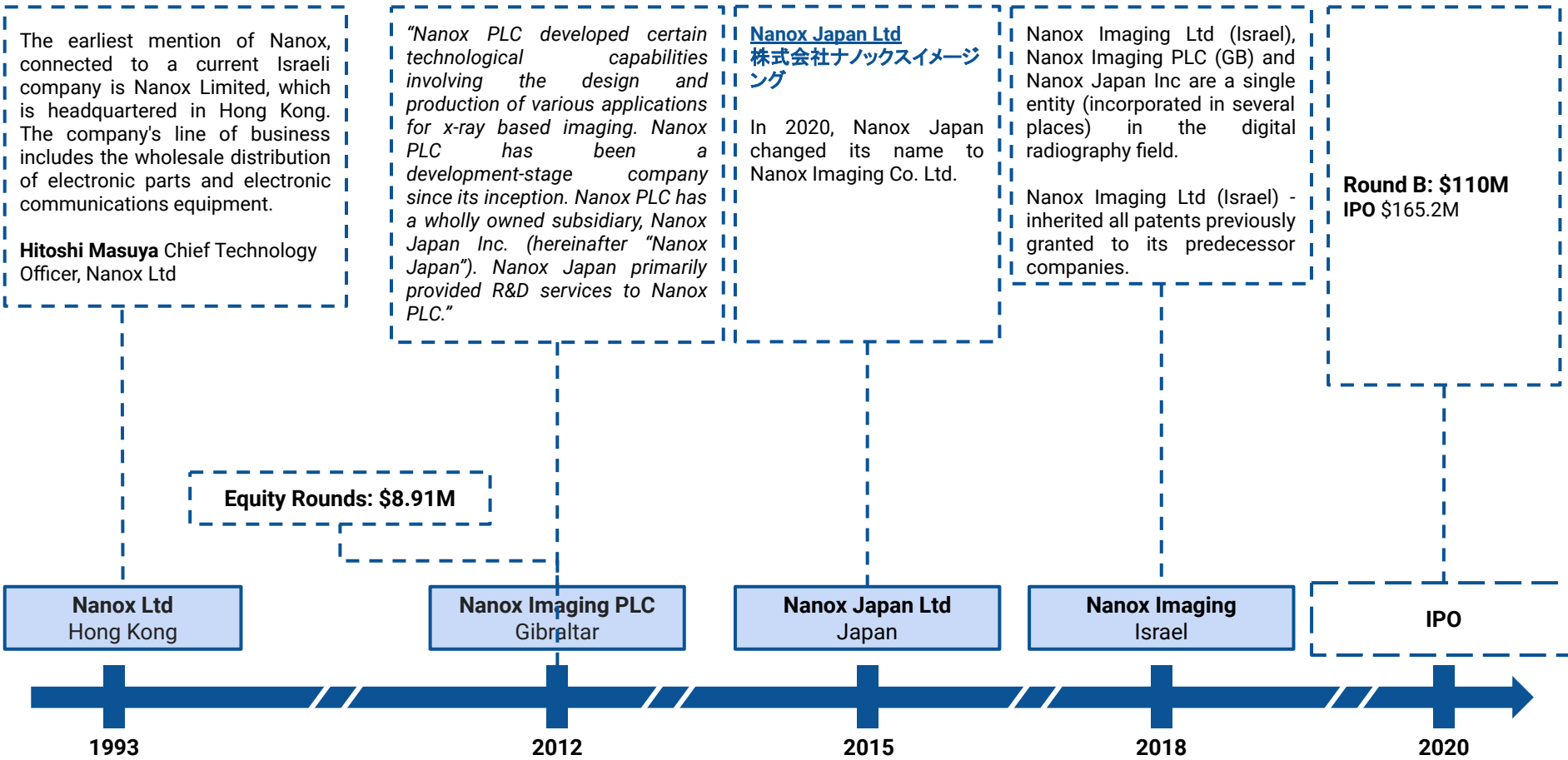
Technology and business model

After more than **20 years of research and development**, with over **\$1B invested**, the company's team of engineers has managed to develop unique intellectual property, patents, and the capacity to design and build **high-powered field-effect cathodes**. Their system combined digital **X-ray device Nanox.ARC** and an **AI cloud-based software** called Nanox.CLOUD.

Nanox Imaging's proprietary **cold cathode technology** greatly improves the cost effectiveness and efficiency of X-ray imaging. At the core of the cold cathode technology is a **"chip" made out of nano-scale structures** developed using proprietary nanofabrication techniques and methods supported by peripheral technologies in order to translate their benefits into real-world applications.

Nanox Imaging has an additional specific feature that differentiates it from other similarly-focused technology providers: their unique **medical screening as a service (MSaaS)** business model, which allows for wide distribution and accessibility, and which charges health providers with a **pay-per-scan service model**.

Nanox Timeline



What is new in Nanox ARC?

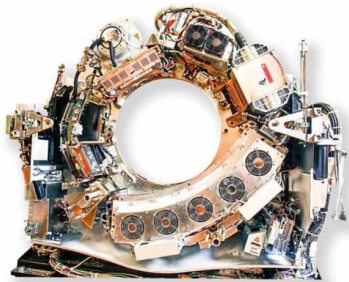
The Nanox.ARC employs the novel digital X-ray source that is designed to be energy-efficient, smaller and can be more precisely controlled compared to existing X-ray sources.

In the medical imaging sector, using a Field-Emission-type X-ray tube has several desirable properties:

- Rapid time switching
- Rapid intensity change
- Colder mechanism
- Lifetime improvement

The Nanox tubes are significantly smaller and require less energy to operate, enabling a new generation of medical imaging devices.

Traditional systems



Nanox.ARC



The Nanox System aims to address the limitations of existing medical imaging systems on three levels:

- Digital X-ray source with the potential to significantly reduce the costs of medical imaging systems
- Technology designed to improve upon the industry standard with integrated radiology diagnostics via a cloud-based MSaaS platform.
- Business model designed to increase the availability of medical imaging

Early detection via medical imaging may potentially save millions of lives annually for cancer patients alone.

Despite the fact that a Nanox.ARC prototype is still not publicly tested, Nanox have presented results with phantom body parts in its official IPO filing on NASDAQ.

Nanox have officially submitted "a 510(k) application for a single-source version of the Nanox.ARC to an accredited Review Organization under the U.S. Food and Drug Administration's (the "FDA") Third Party Review Program" (Source: [Prospectus](#))

Nanox.ARC

Using the Nanox tube's unique features, such as its fast response time, small size, and lower cost, Nanox has built a radiographic system called the Nanox.ARC.

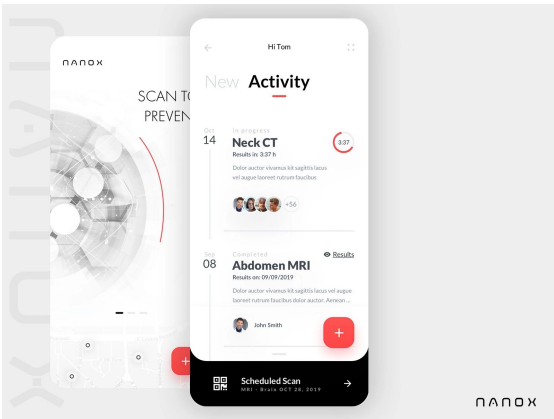
This system uses several Nanox tubes arranged in a curve above a patient's radiographic table. Using advanced image processing techniques such as Tomosynthesis, Nanox can provide advanced imaging where no imaging existed before.



Nanox.CLOUD

The Nanox.CLOUD is designed to provide an end-to-end medical imaging service, including services such as image repository, radiologist matching, online and offline diagnostics review and annotation, connectivity to diagnostic assistive AI systems, billing and reporting.

Source: [Nanox Announces Agreement With CureMetrix For AI-based Assistive Diagnostic Tool to Support Nanox Cloud Platform](#)



Main Partners and Customers

Partner Name	Description of the partnerships	Date	Type of Cooperation
SK Telecom	<ul style="list-style-type: none"> The deployment of 2,500 Nanox Systems in South Korea and Vietnam. Partnership scope includes manufacturing MEMs X-ray chips for the Nanox.ARC. Investor - \$110M 	June, 2020	Collaboration Agreement
USARAD	<ul style="list-style-type: none"> The deployment of 3,000 Nanox Systems Promotion of Nanox.CLOUD services among radiologists to join the Nanox diagnostics services platform. 	February, 2020	Collaboration Agreement
Hadasit	<ul style="list-style-type: none"> Joint research and development projects The provision by Hadasit of services in connection with Products, where no innovative research will be carried out. 	September, 2019	Collaboration Agreement
University of Tokyo	The University of Tokyo is providing clean rooms to manufacture the MEMs X-ray chip.	September, 2020	Cooperative Agreement
Ambra Health	Integration Ambra's enterprise image exchange solution with Nanox.ARC systems as they are deployed via the startup's cloud network.	October, 2020	Collaboration Agreement
Hadassah	Using the Nanox.ARC for developing novel early-detection and screening protocols to promote preventive practices.	September 2019	Collaboration Agreement

Main Partners and Customers

Partner Name	Description of the partnerships	Date	Type of Cooperation
CureMetrix	Integration the CureMetrix advanced AI diagnostics solution into Nanox's planned cloud-based software platform.	March, 2020	Collaboration Agreement
Brainomix Limited	<ul style="list-style-type: none"> Local integrations into health maintenance organizations, electronic health record systems, and insurance companies. To accumulate a significant number of medical images, to be used by collaborators to increase the probability of early disease detection. 	July, 2020	Collaboration Agreement
IMedis AI	Testing of the Nanox.ARC and the Nanox.CLOUD together with proprietary AI algorithms used for the analysis of brain damage caused by stroke, chest and abdominal X-rays.	August, 2020	Collaboration Agreement
Qure.ai Technologies	Offering Qure.ai's AI-powered diagnostics to a large network of radiologists who can benefit from accurate CT scan interpretation.	August, 2020	Collaboration Agreement
Lunit	Joint research with VUNO on digital X-ray and CT technology.	August, 2020	Non-binding Agreement
VUNO	Jointly development with Lunit focused on commercializing medical AI solutions based on digital X-ray and CT technology.	August, 2020	Non-binding Agreement

Customer Regional Distribution

USARAD

USARAD is a radiologist-run and operated full-service subspecialty radiology and teleradiology company that provides teleradiology services.

Location: USA

Date: February, 2020

Number of pcs: 3000

Distribution Partners

JSC Roel Group; Clarity Medical Solution

Location: Russia, Belarus

Date: May-June, 2020

Number of pcs: 600

SK Telecom

SK telecom is a wireless telecommunications operator in South Korea.

Location: South Korea, Vietnam

Date: June, 2020

Number of pcs: 2500

Golden Vine

Golden Vine is led by Ms. Pepi Liao, a second generation of the Liao Wan Lung, family, who is the founder and chairman of CB CERATIZIT – one of the largest global suppliers of Tungsten Carbide to leading medical imaging vendors.

Location: Taiwan, Singapore

Date: June, 2020

Number of pcs: 500

Promedica Bioelectronics

Promedica Bioelectronics S.r.l. is operating in the field of marketing and technical management of high-technology equipment of Diagnostic Imaging and Oncology Therapy.

Location: Italy

Date: June, 2020

Number of pcs: 500

The Gateway Group

Australia's largest independent product distributors including health, wellness, medical supplies and devices.

Location: Australia, New Zealand, Norway

Date: March, 2020

Number of pcs: 1000

SPI Medical

SPI Medical is a distributor of specialty pharma products and medical devices.

Location: Mexico

Date: September, 2020

Number of pcs: 630

LATAM Business Development Group

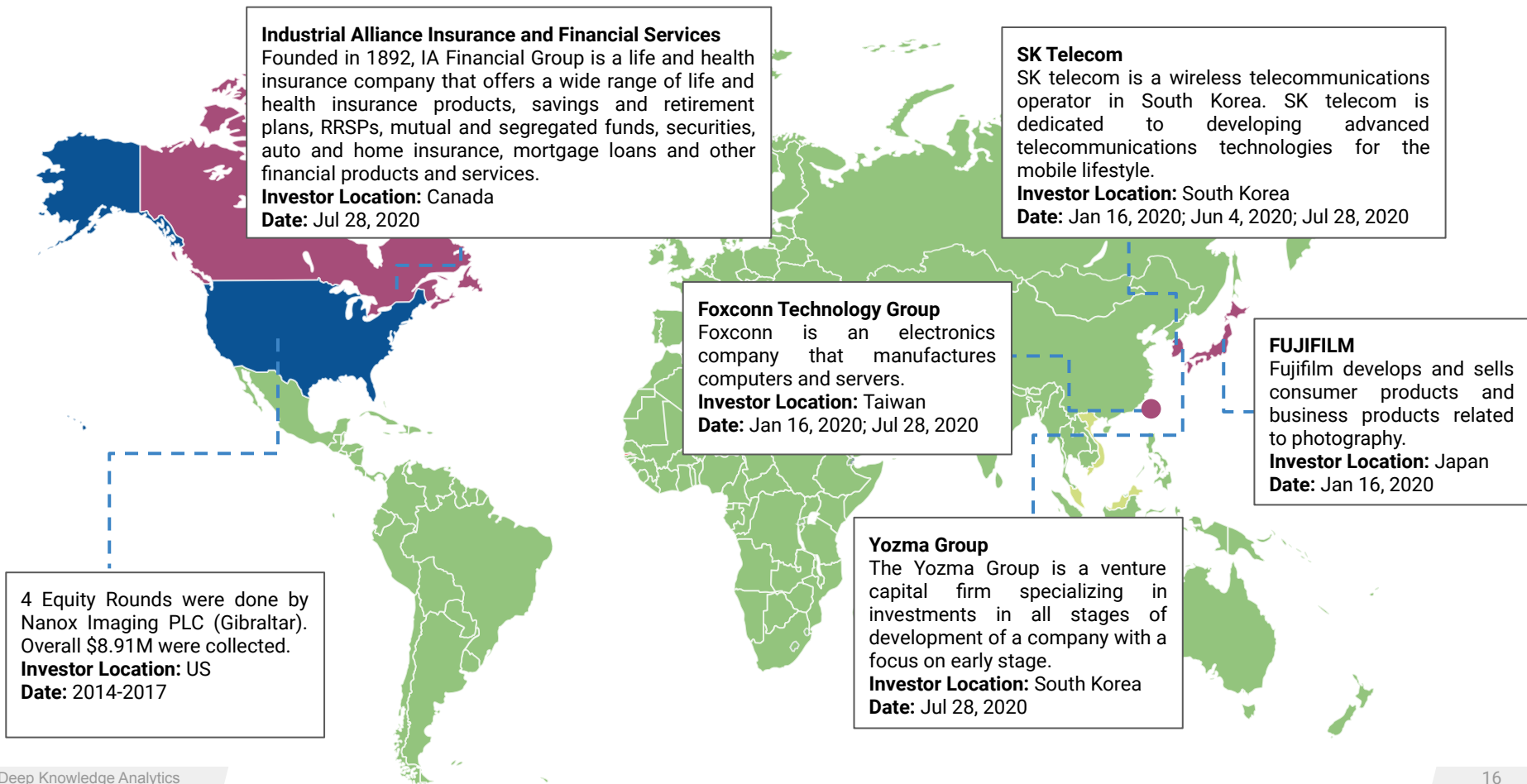
Latam BD Group initiates, develops and promotes business between innovative companies and the Latin American markets, in various technology fields such as life sciences, medical devices, advanced agriculture, Fintech.

Location: Brazil

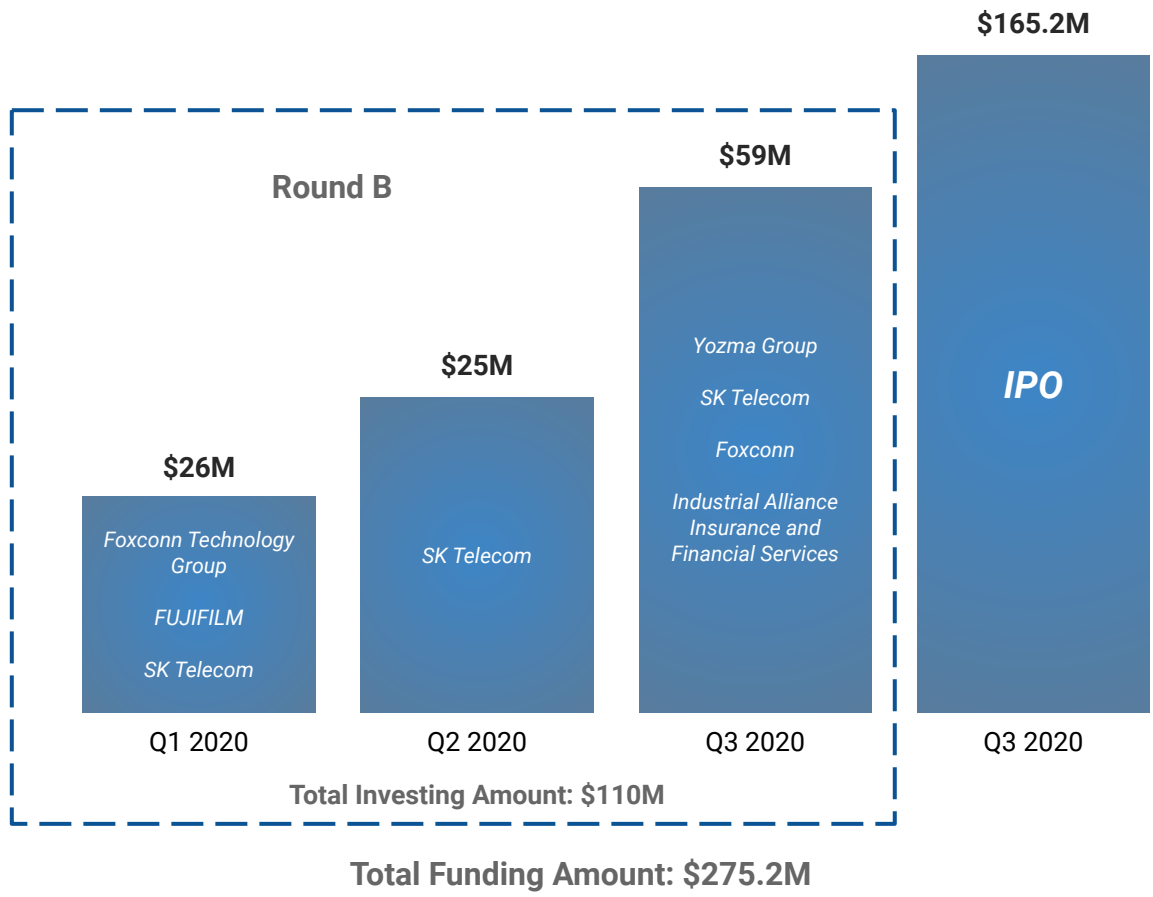
Date: July, 2020

Number of pcs: 1000

Investor Regional Distribution



Investment Rounds in Nano-X Imaging

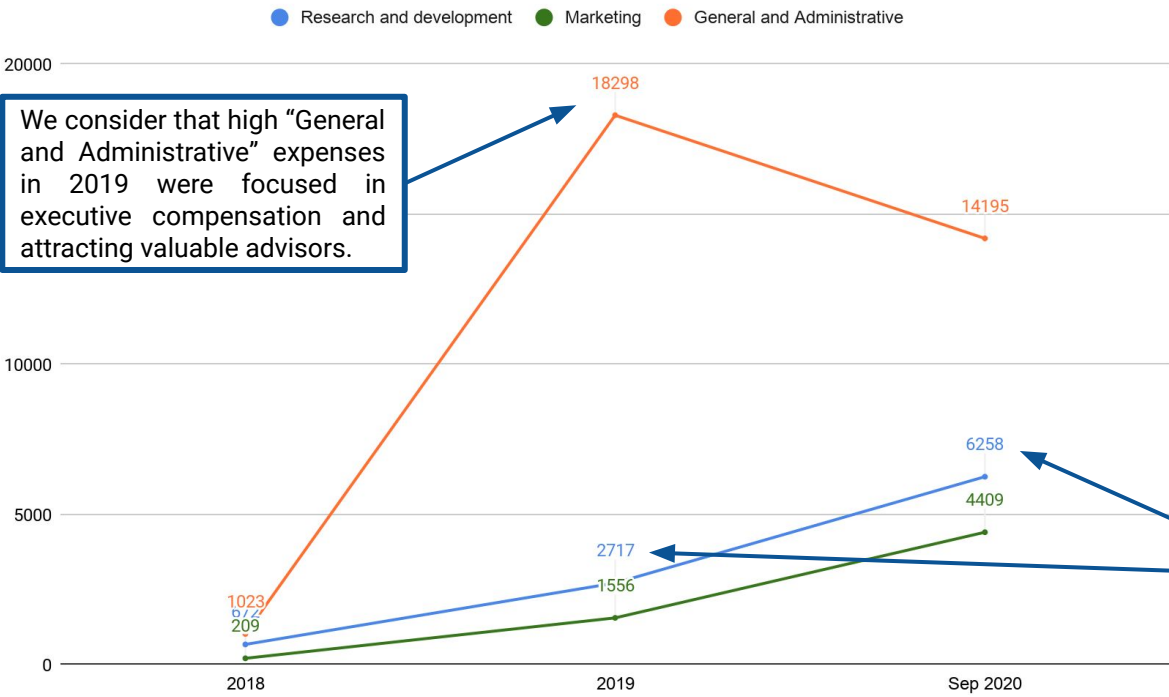


Less than a month after Nanox raised \$59 million in funding, the company announced that it raised \$165.2 million in an initial public offering. And after its shares were priced at \$18 for its debut on the Nasdaq Global Market later under the NNOX ticker, it opened at \$20.34, a moderate increase of 13%, and closed out the day at \$21.70, up 20.6% compared to its offer price.

Overall, in 2020 the company managed to raise money in three funding rounds - in Q1, Q2 and Q3. The participating investors were all large technology corporations operating in the the fields of electronics, telecommunications and medical equipment development. The biggest participant in the funding rounds was **Foxconn Technology Group** - the world's largest electronics contract manufacturer and the fourth-largest information technology company by revenue.

Source: [Nanox Imaging](#)

Consolidated Statement of Operations Data: (\$ in thousands)

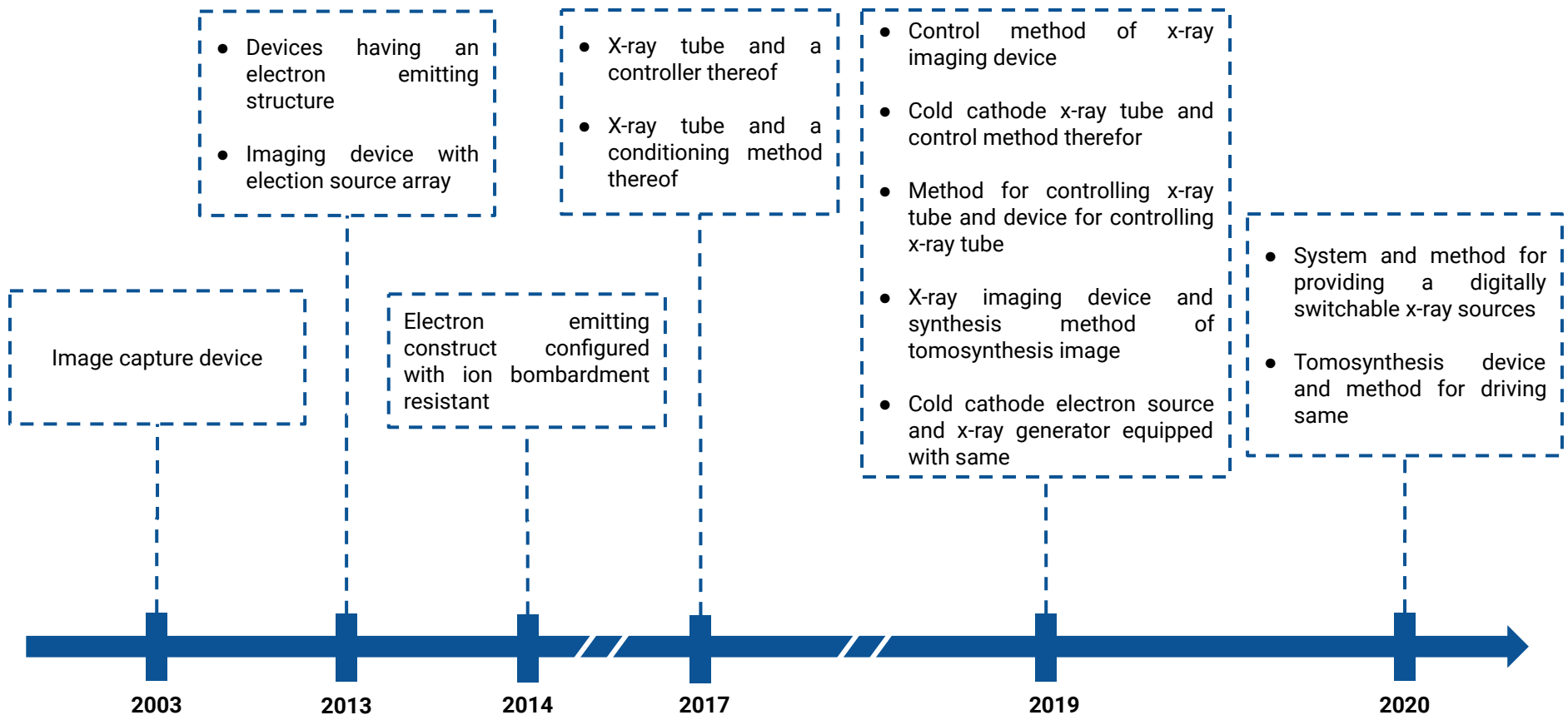


We consider that high "General and Administrative" expenses in 2019 were focused in executive compensation and attracting valuable advisors.

General and Administrative Expenses:	2019 (\$ in thousands)
G&A - salaries and wages	461
Share-based compensation	14,967
Management fee	534
G&A - professional services	1,470
Legal fees	417
Other	449

Because the technology used by Nanox was developed and patented earlier, R&D expenses are not high. Based on the list of the company's technological partners signed by Nanox in 2020, we can assume that the company's main R&D focus is the Nanox.CLOUD system.

Nanox's Patents Timeline



There are 13 patent families assigned to Nanox Imaging LTD, Nanox Imaging PLC (GB) and Nanox Japan Inc, filed from Aug. 2012 to Jan. 2019. Our analysis identified two patents that have been granted and several that have been abandoned, with all others still pending. The majority of the company's IP appear to be inherited from Nanox Inc.

The majority of Nanox patents appear to derive from work performed prior to the incorporation of Nanox, based on research performed at Sony.

Unfortunately, Nanox has not released any data on their device specifications, including current density, power or spot size, precluding the ability of comparing their values to market averages.

According to Nanox Imaging Prospectus: *"We rely upon a combination of patents and trade secrets to protect the intellectual property related to our proprietary technologies. Our success depends significantly on our ability to obtain and maintain intellectual property protection with respect to our technology and products."*

This fact limits the scope of our analysis strictly to publicly-disclosed patents, given that trade secrets are, by nature, undisclosed.

It is notable that among among the company's initial inventors, Hidenori Kenmotsu is the most-featured inventor on the company's patents. However, according to available information on current staff, he is not a current member or employee of the company.

According to information presented in the [Nanox Imaging Prospectus](#), the company is expecting of rise of their expenditure in connection with continuing the research and "hiring additional quality control and scientific personnel".

Nanox's patent portfolio protects the Nanox core x-ray source capabilities for at least 9 additional years. Presently, the company is expecting to increase the size of its R&D department with additional employees to enable technology roadmap development.

We still lack experimental comparison between the Nanox tube and a conventional tube of the same power but we expect to have more information during the upcoming unveiling at the RSNA 2020 conference.

Source: [Taking an X-Ray to Nanox Imaging](#)

Comparative Analysis (SWOT analysis)

The company established in 2018 (Nanox Imaging Ltd) was created with the sole purpose of properly facilitating an IPO and attracting investments. The new entity went public without having a minimum viable product or a prototype at the time. Now the market ambitions of Nanox Imaging are hanging entirely on the success of the prototype demonstration, which will take place at the beginning of December, 2020 which will mark the culmination of 20 years of research and development. With the SWOT analysis below we aim to give a general overview of the organization's market position:

<div>Strengths<ul style="list-style-type: none">• Mobility of product and relatively low price (as was promised by developers);• Large and established R&D partners• Large and stable investors• Two products types: Hardware and Cloud app• Disruptive business model• CSO with a strong scientific background.</div>	<div>Weaknesses<ul style="list-style-type: none">• No commercially available prototype• No FDA approvals• Company demonstrating the prototype 5 months after IPO• No public information on R&D team (which is not entirely necessary as stealth startups tend to operate this way in order to protect their intellectual property)</div>
<div>Opportunities<ul style="list-style-type: none">• Large and ever growing Total Addressable Market• Ties and partnerships in Asia (some Asian regions, such as Japan and China, are anticipated to further the development of advanced medical imaging technology).• Cloud technologies will allow the collection of vast amounts of health data and thus will help healthcare research and early detection in preventive healthcare.</div>	<div>Threats<ul style="list-style-type: none">• Several class action lawsuits which could possibly damage Nanox's brand, investor sentiment and customer loyalty.</div>

Outset Medical (OM)



Outset Medical is a pioneering medical technology company that manufactures medical equipment to reduce the cost and complexity of dialysis.

Outset Medical is a rapidly growing medical technology company pioneering a first-of-its-kind technology to reduce the cost and complexity of dialysis. The company reimagine dialysis for patients and health care providers and believe that the Tablo Hemodialysis System (Tablo) represents a significant technological advancement enabling novel, transformational dialysis care in acute and home settings.

Outset Medical intends to continue building a high growth business that is sustainable, predictable and profitable over time. In order to achieve this goal, they plan to employ the following strategies:

- Further penetrate the acute care market through new customer acquisition and current customer fleet expansion.
- Expand within the home dialysis market with a two-pronged approach to long-term scalable growth.
- Leverage the emergence of transitional care units to expand the market for home dialysis and the demand for Tablo.
- Maintain and widen their technology leadership position.
- Drive to expand gross margins.

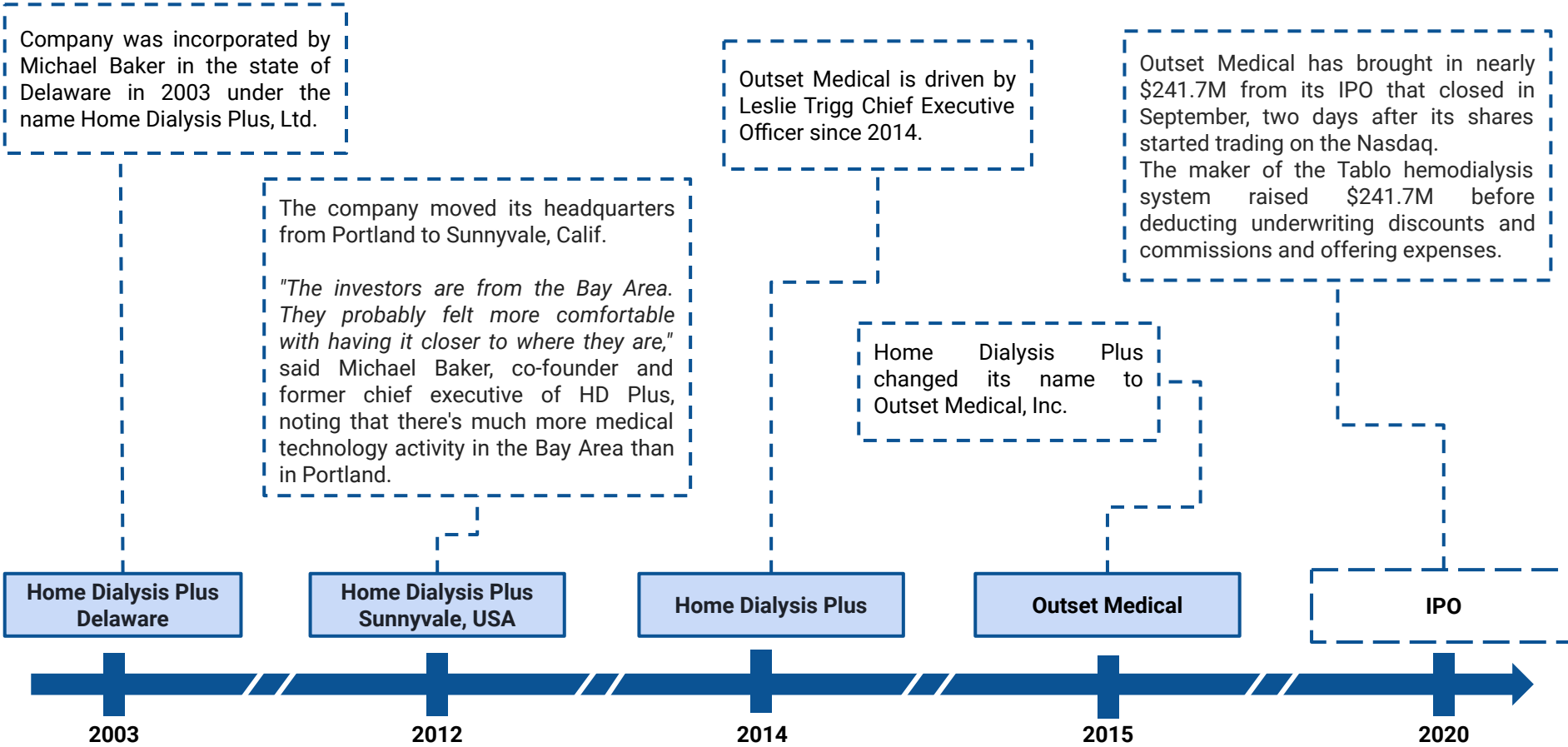
Within Outset, they take a crowdsourcing approach to problem solving in order to leverage their diversity of thinking and collective creativity. This inventive mindset informs us of their core competencies—hardware and software design. Outset's team believes in the power of a single hardware platform with software used to fuel continuous upgrades and improvements.

According to Outset Medical Prospectus: *"Our technology is designed to elevate the dialysis experience for patients, and help providers overcome traditional care delivery challenges. (...) We have generated meaningful evidence to demonstrate that providers can realize significant operational efficiencies, including reducing the cost of their dialysis programs by up to 80% in the intensive care unit (ICU)."*

The company highlights the following strengths which sets them apart:

- First-of-its kind enterprise dialysis solution, offering significant advantages over traditional machines.
- Tablo's unique features offer a compelling value proposition across both acute and home settings.
- Their early and continued investment in software, data science and machine learning.
- Dialysis is a large recession-proof market, supporting their recurring revenue model.
- Company's sales organization advantages us in executing our strategy.
- An invention mindset that permeates their design and execution.

Outset Medical Timeline



What is Tablo?

Tablo is an FDA-cleared enterprise solution for dialysis, designed specifically to reduce the cost and complexity of dialysis across all care settings. Requiring only an electrical outlet and tap water to operate, the mobile Tablo system frees patients and providers from the burdensome infrastructure required to operate conventional dialysis machines. The machine's integrated functionality enables it to serve as a dialysis clinic on wheels and enables providers to standardize to a single platform that can be used across a wide spectrum of care settings.

Tablo's intuitive touchscreen interface combines sensor-based automation designed to enhance the patient experience. It does this by accelerating the training process, reducing treatment set up time, and streamlining the treatment process at home.

The four-wheel system only needs an electrical outlet and tap water connection to automatically produce dialysate required for dialysis. It includes a wireless cloud connection to monitor data. This simplicity contrasts with older systems approved for home use which require separate equipment for purifying water and generating dialysate, plus a number of manual steps to complete treatment.

The Tablo system was confirmed safe and effective for home use in a 2019, prospective, multicenter, home hemodialysis trial with 30 patients. The results were published in [November 2019 in Hemodialysis International](#).

Additional Features:

- Automatic, regular updates that help Tablo get smarter over time;
- Flexible treatment duration – from 30 minutes to 24 hours with no supply changeover;
- Automated self clean;
- Integrated blood pressure cuff;
- Automated saline bolus and tracking;
- One-touch rinseback;
- Compatible with high-flux dialyzers.

Touchscreen Guidance

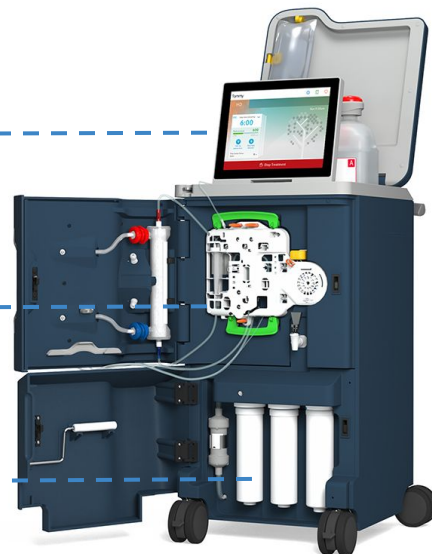
Animations, conversational instructions, wireless connectivity

Tablo Cartridge

Easily snaps into place, reducing setup and takedown time

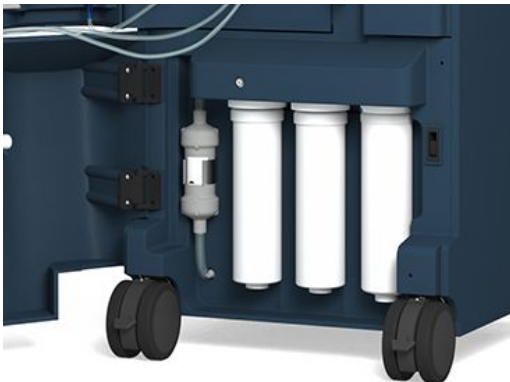
Dialysate on demand

Purifies water and produces dialysate in real-time



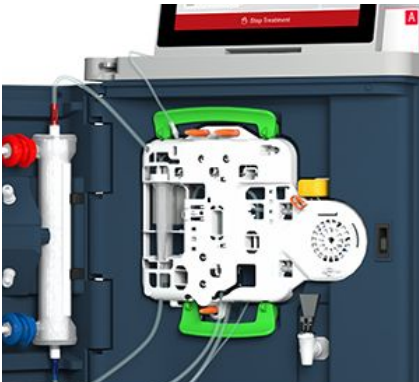
Tablo Console

A single module consisting of multiple fluidic systems that perform the activities of a water purification system (WPS) and a conventional dialysis delivery system (DDS)



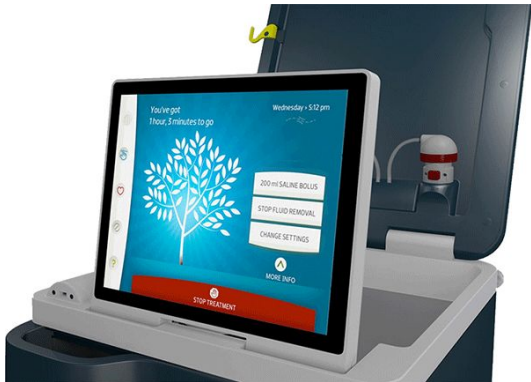
Tablo Cartridge

A single use blood tubing set attached to an organizer tray. The ethylene oxide (EO) sterilized and disposable cartridge is inserted onto the front panel of the console for each dialysis treatment.



Tablo Script

An accessory software to the Tablo Console, is designed for use by medical professionals to a) prepare, update and verify patient dialysis prescriptions b) view and export dialysis treatment information and billing activities and c) set and modify Tablo Console settings.



Main Partners and Customers Regional Distribution

U.S. Department of Health and Human Services

In October 2020 HHS awarded a contract for the use of Tablo in communities hit by natural disasters.

Location: USA

Amazon Web Services

AWS provides information technology infrastructure services to businesses in the form of web services and supports Tablo's cloud connectivity.

Location: USA

Infus Medical

Company specializes in the contract manufacturing of Single-Use Medical Devices. Current Cartridge manufacturer.

Location: Thailand

Providien Medical

A leading contract manufacturer of clinically superior medical devices and advanced manufacturing solutions to the medical device and life sciences industries. Providien will be the second manufacturing source (Q2 2021).

Location: USA

Tacna

Experts at helping companies relocate manufacturing operations from other countries to Mexico. In the Q2 2021 Tacna will provide support services in connection with its manufacturing activities in Mexico.











Location: Mexico

Paramit

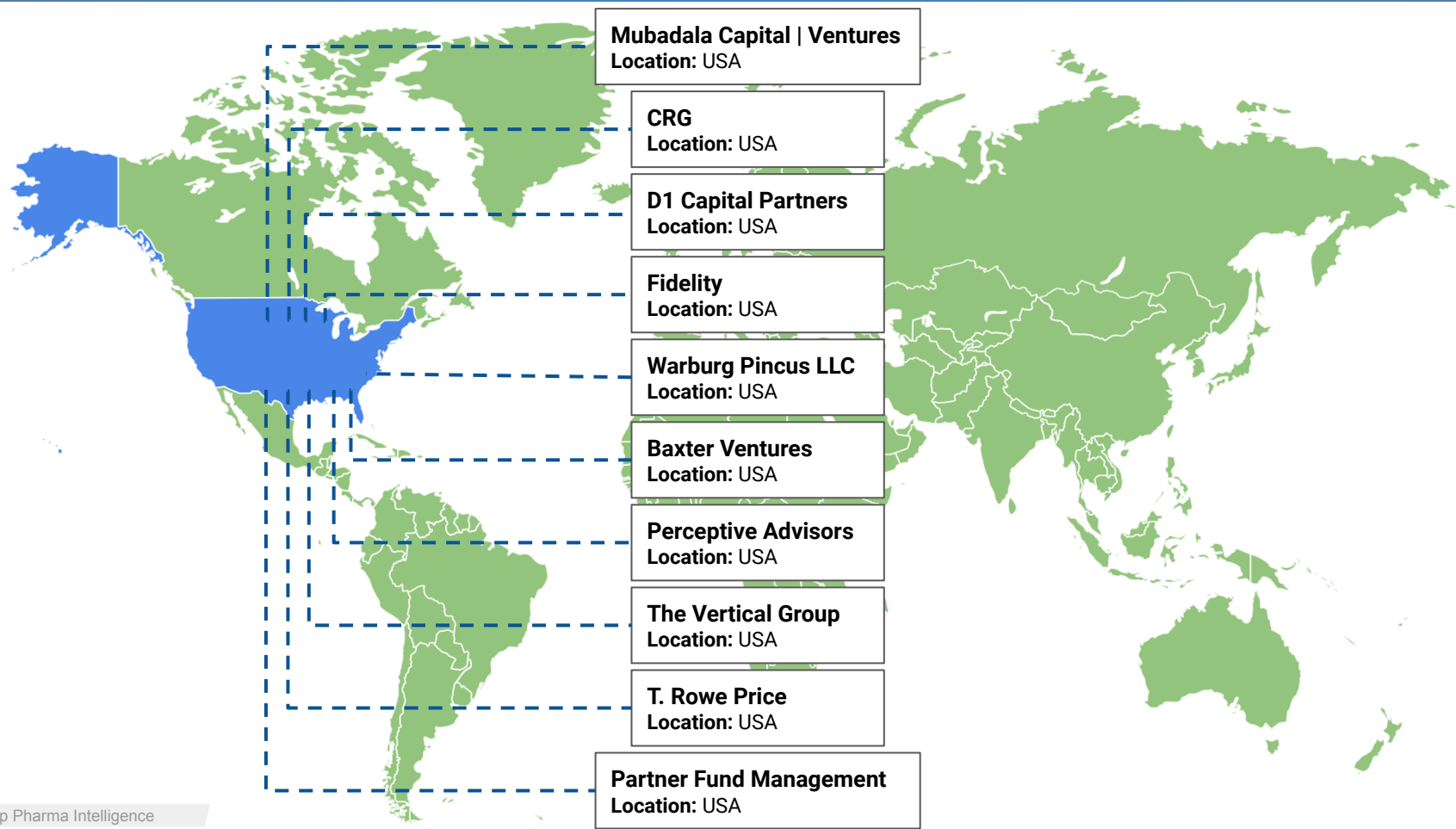
A product development and manufacturing company. Current Console manufacturer (since Jan 2018)

Location: USA

Investors

Investor Name	Description	Location	Investment Date
 Baxter Ventures	Invests in patient care companies with innovative technologies and is an investment firm.	USA	Aug 2018
 CRG	Market pioneer and innovator in healthcare investing that focuses on intellectual property investments in biopharmaceutical assets.	USA	Aug 2018
 D1 Capital Partners	Investment firm.	USA	Feb 2020
 Fidelity	Privately-owned investment manager focusing on a diverse set of customers.	USA	May 2017; Aug 2018; Feb 2020
 Mubadala Capital Ventures	Differentiated and value-added investor.	USA	Aug 2018
 Partner Fund Management	Provides services to pooled investment vehicles.	USA	May 2017; Aug 2018; Feb 2020
 Perceptive Advisors	Privately owned hedge fund sponsor that finances the public equity markets across the globe.	USA	May 2017; Aug 2018
 The Vertical Group	Venture capital firm focused on the fields of medical technology and biotechnology.	USA	May 2015; May 2017
 T. Rowe Price	Investment management firm dedicated to funding technology startups.	USA	May 2017; Aug 2018; Feb 2020
 Warburg Pincus LLC	Private equity firm focused on growth investing.	USA	May 2015; May 2017; Aug 2018

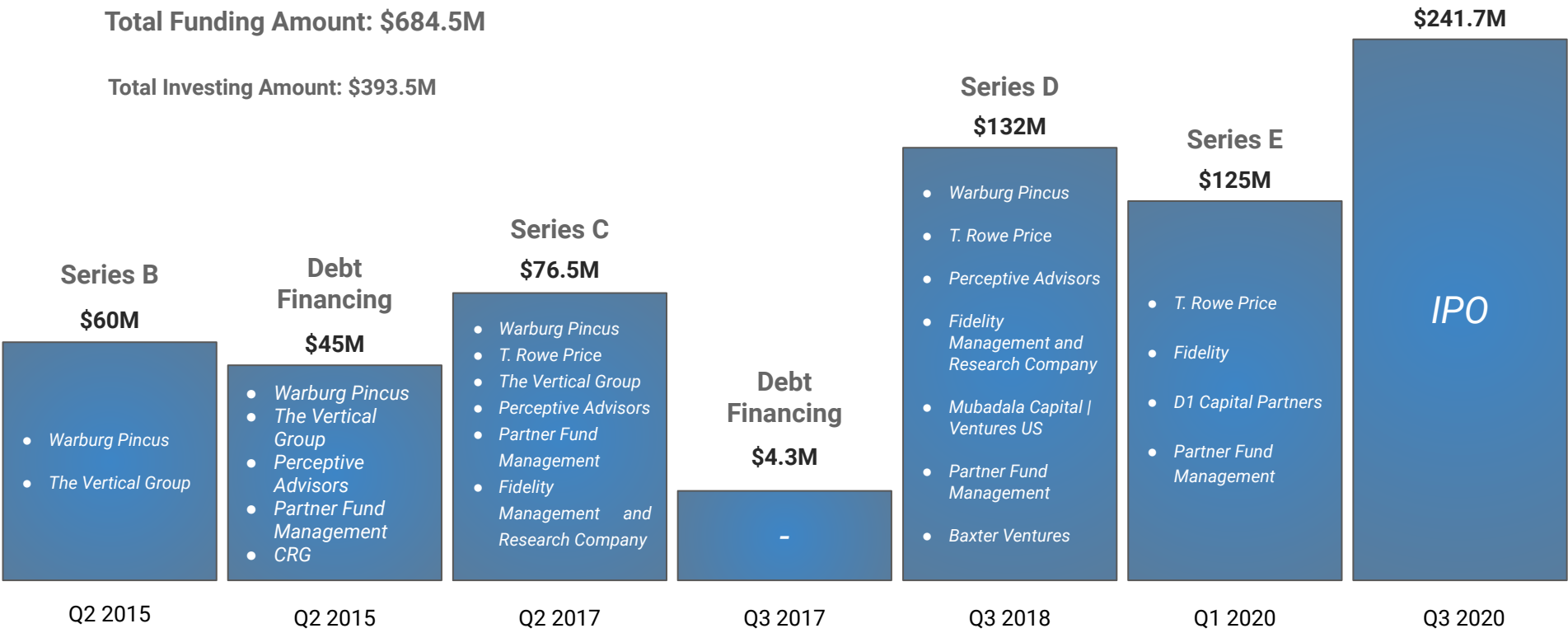
Investor Regional Distribution



Investment Rounds in Outset Medical

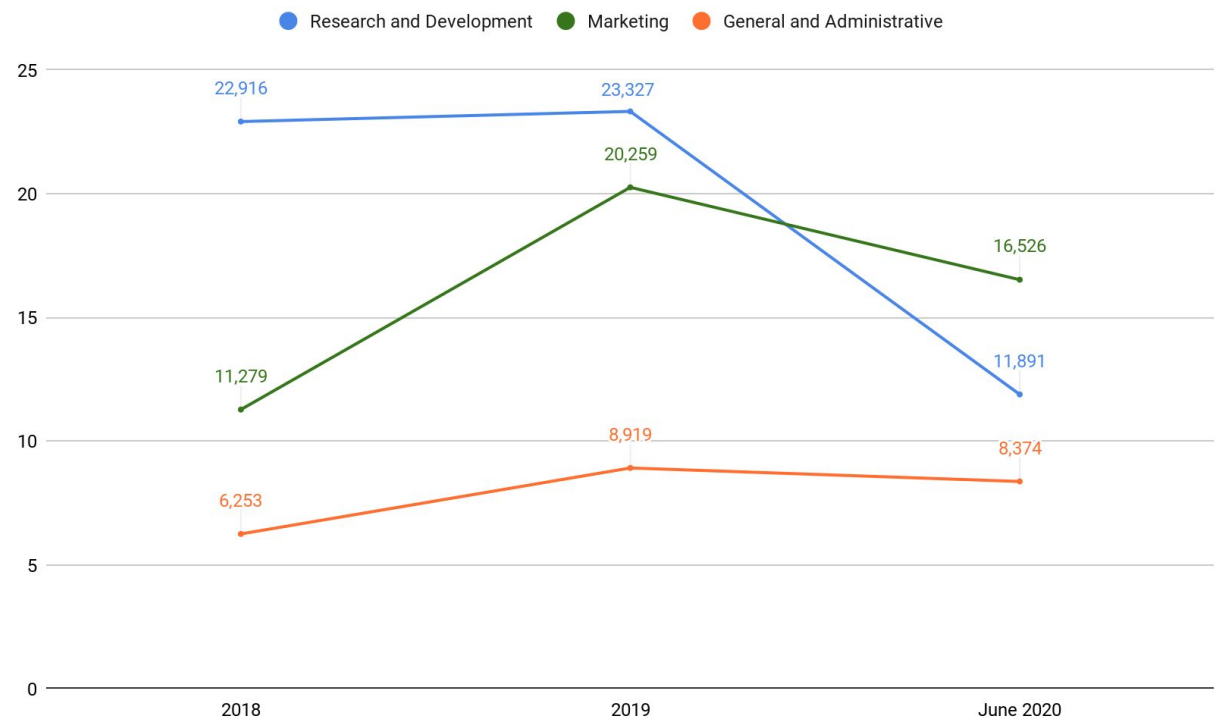
Total Funding Amount: \$684.5M

Total Investing Amount: \$393.5M



Source: [Outset Medical](#)

Consolidated Statement of Operations Data: (\$ in thousands)

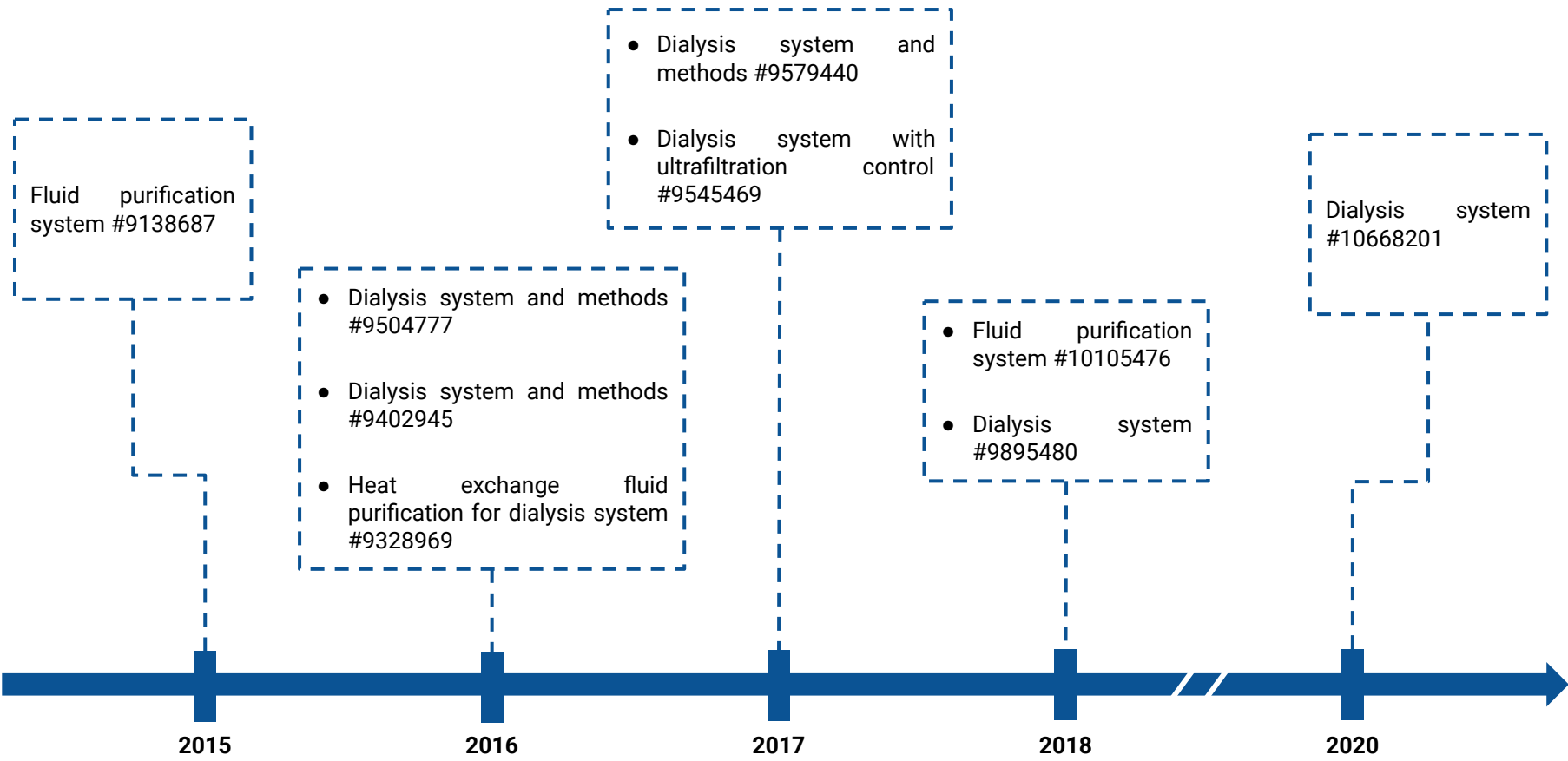


Outset Medical approaches clinical trials of Tablo responsibly. The company commercialized Tablo in the U.S. in mid-2016. And only in October 2019 leading health systems and medical centers across the U.S. have adopted Tablo for hospital and clinic dialysis.

Because of its recent commercial introduction, Tablo has limited product and brand recognition. Its expected that company's sales and marketing, research and development, regulatory and other expenses will continue to increase due to market expanding efforts to increase adoption of Tablo, obtaining regulatory clearances or approvals for future product enhancements to Tablo, and conducting clinical trials on Tablo.

Source: [Outset Medical, Inc.](#)

Outset Medical Patents Timeline



Source: [Patents Assigned to Outset Medical, Inc.](#)

Founded in 2003 as Home Dialysis Plus and securing an option to OSU intellectual property the following year, Outset Medical now makes the Tablo system of hemodialysis – blood pumped out of the body to an artificial kidney machine.

During and after the company's founding, multiple faculty from OSU's colleges of Engineering and Science served as researchers and consultants, including Brian Paul, Goran Jovanovic, Todd Miller, Vince Remcho and the late Richard Peterson, on the core Oregon State IP: microchannel dialyzers and a microchannel heat exchanger.

Oregon State and the company transformed the option deal into a full IP license in 2008, and between 2010 and 2018 the company secured private investments of more than \$300 million.

Outset continues to contract with Oregon State on the refinement of the heat exchanger technology.

"It's essentially a small-scale, efficient, water purification technology that would allow the use of tap water in dialysis as opposed to gallons and gallons of pre-purified water, expanding capabilities in developing countries," said Brian Wall, associate vice president of research, innovation and economic impact at Oregon State.

According to the FORM S-1 REGISTRATION STATEMENT of the Outset Medical: *"As of June 15, 2020, we had seven issued U.S. patents, as well as six pending U.S. patent applications. We had an aggregate of 13 issued patents in Australia, Canada, China, France, Germany, Japan, Spain and the United Kingdom, as well as seven pending patent applications in Japan, Hong Kong, the European Patent Office and under the Patent Cooperation Treaty. We have exclusive licenses from OSU to 12 U.S. patents, nine of which we co-own with OSU, 20 foreign patents, all of which we co-own with OSU, and one pending U.S. patent application, which we co-own with OSU. Some of our patents and other intellectual property cover aspects of Tablo that enable it to be used by anyone, including the patient, through the automation of functions formerly performed by dialysis center technicians using traditional dialysis systems. (...)*

Our patents expire between October 2025 and August 2039 and our patent applications, if granted as patents, are expected to expire between November 2020 and August 2039. The term of individual patents depends upon the legal term for patents in the countries in which they are granted. In most countries, including the United States, the patent term is 20 years from the earliest claimed filing date of a non-provisional patent application in the applicable country."

Strengths <ul style="list-style-type: none">• Company is a pioneer in the field of first-of-its-kind technology reduces the cost and complexity of dialysis.• Company has 7 patents registered in the USA and 13 patents issued worldwide.• Tablo is FDA-approved for use in acute and chronic conditions such as dialysis clinics and hospitals. From 2020, home use is also allowed.	Weaknesses <ul style="list-style-type: none">• The company depends on employees, healthcare facilities and CROs to conduct clinical trials in accordance with clinical clinical practice (GCP) requirements.• So far, Outset Medical has a limited number of large clients.• The manufacture of Tablo components in different parts of the world creates additional expenses for delivery on time and in the right quantity of products.
Opportunities <ul style="list-style-type: none">• Increasing number of chronic diseases and organ failure, growing consumption of alcohol and unhealthy diet, increasing relevance of renal diseases will positively affect market growth.• In April 2020, Outset Medical received FDA approval that significantly expanding the company's sales opportunities.	Threats <ul style="list-style-type: none">• Company's success will partly depend on its ability to develop and implement new products.• Tablo may be revoked in the future.

Eargo
(EAR)



Eargo makes direct-to-consumer hearing aids, allowing customers to access help for their hearing loss from their homes.

Eargo is a medical device company dedicated to improving the quality of life of people with hearing loss. Its innovative product and go-to-market approach address the major challenges of traditional hearing aid adoption, including social stigma, accessibility and cost. Eargo hearing aids are the first and only virtually invisible, rechargeable, completely-in-canal, FDA regulated, exempt Class I device for the treatment of hearing loss. Its differentiated, consumer-first solution empowers consumers to take control of their hearing with personalized, high-quality lifetime support from licensed hearing professionals; all packaged with Eargo devices at less than half the cost of competing hearing aids.

Company's mission is to change the way the world thinks about hearing loss by dramatically improving the consumer experience at every step of the hearing care journey. Its hearing loss solution combines sleek proprietary technology, on demand licensed hearing professionals and an advanced personalized App to offer high-quality performance from a virtually invisible hearing aids.

Eargo products consist of the following:

- Eargo hearing aids,
- Flexi Fibers or Flexi Palms (depending on the hearing aid),
- Portable charger case ,
- Tech-enabled through the Eargo mobile app.

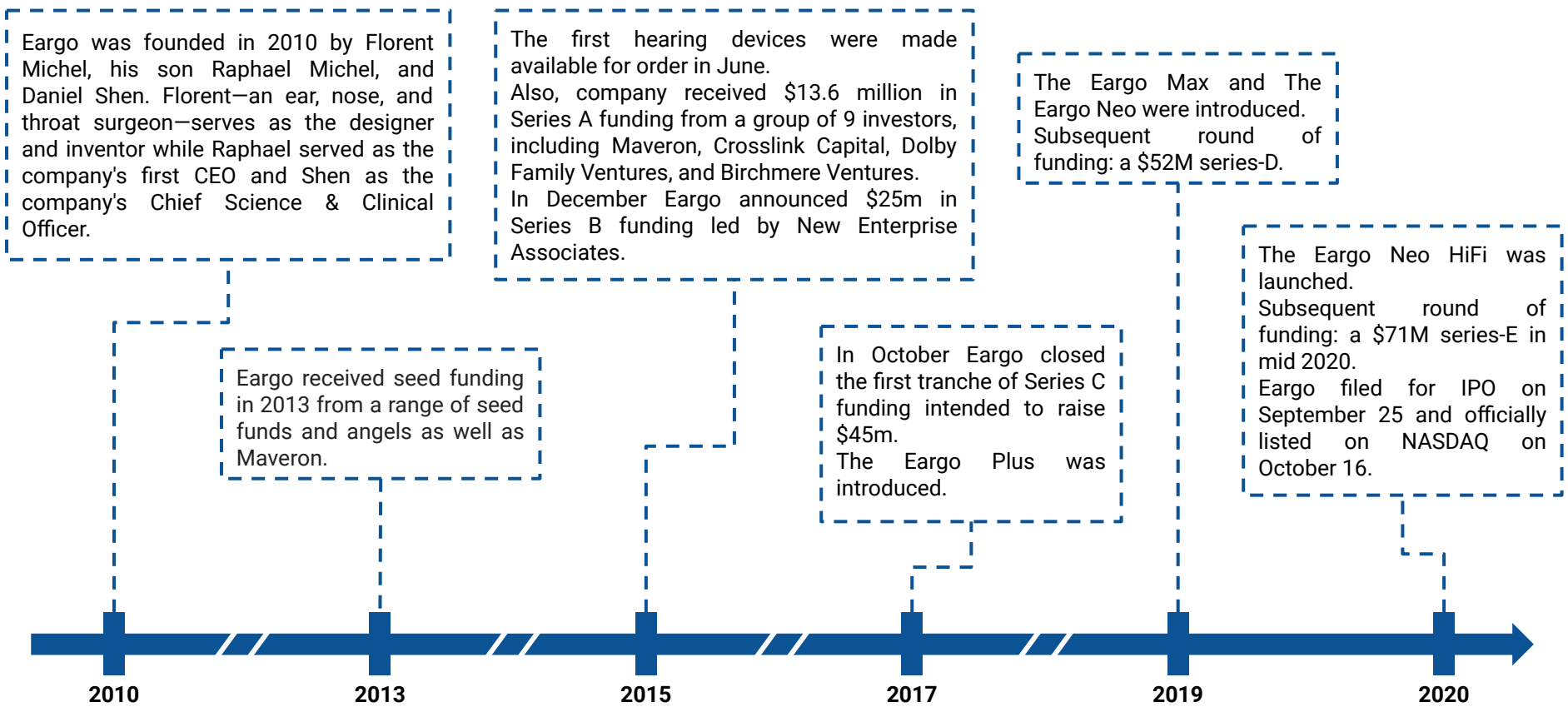
Company believes the following competitive strengths are essential to our mission of empowering consumers to take control of their hearing and will support the goal of penetrating the large population of individuals with untreated hearing loss:

- Highly differentiated product:
- Transformative consumer-centric business model
- Personalized customer experience and support
- Multi-faceted marketing expertise
- Robust technical, engineering and design expertise, supported by our strategic IP portfolio
- Proven management team with deep industry expertise

Company developed the Eargo solution to create a hearing aid that consumers actually want to use. They believe their hearing aids are the first and only rechargeable, completely-in-canal, FDA regulated, exempt Class I device for the treatment of hearing loss. Currently company offers three versions of our Eargo solution, the Eargo Max, the Eargo Neo and the Eargo Neo HiFi, at three different price points to provide customers with choices on cost and functionality.

In designing the Eargo hearing solution, company set out to offer a differentiated product with a compelling value proposition to the consumer centered on the ability to offer high quality audio performance in a virtually invisible and comfortable form factor, which poses significant engineering challenges.

Eargo Timeline



What is Eargo?

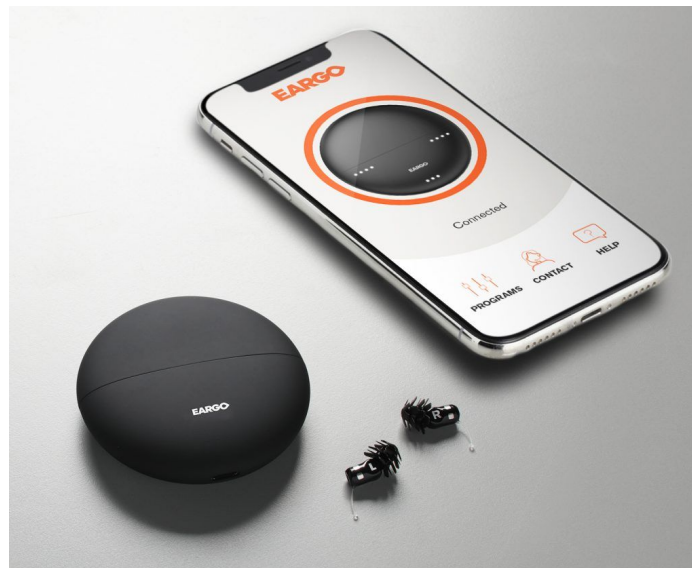
Eargo hearing aids are certified Class 1 medical devices. Their design is modeled after the standard fishing fly, with a small speaker surrounded by medical-grade silicone fibers (for which the company uses the trademark Flexi Fibers) the fibers allow natural bass sounds to flow more freely into the ear canal, so that only treble ranges require amplification.

The devices come in two sizes and are pre-programmed with four standard profiles. To change the setting, wearers double-tap their ear, and an acoustic switch changes the sound profile. The settings for the devices in each ear can be changed independently. Users can also send their personal audiograms to licensed hearing professionals at Eargo who will custom-calibrate the device for that individual's specific needs. The hearing aids can be charged using a portable charging device that is sold with them, and are designed to hold a charge for up to 16 hours. The charging device itself is designed to last up to a week on a single charge.





The company's founders have stated that these devices are designed with younger people in mind to overcome the stigma surrounding standard, bulky hearing aids. The product designer is Ammunition Design Group, which modeled the shape of the charger on a river rock and designed it for ease of use and high visibility of the hearing aids within; the company logo is based on a visualization of a digital recording of Florent Michel saying "Eargo".

As of June 30, 2020, the company sold over 42,000 devices and currently continues to actively expand in the market.

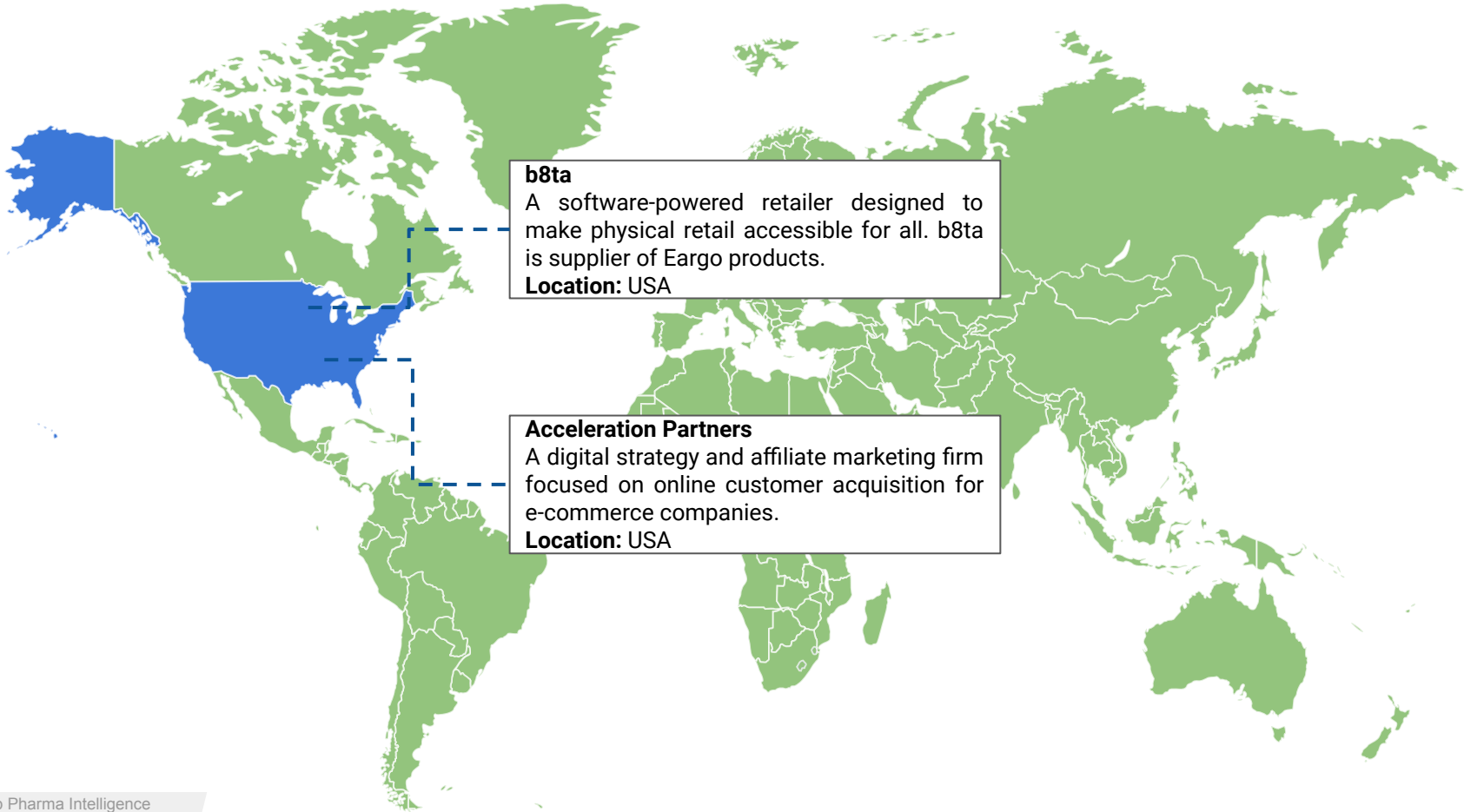
The app allows personalized settings for different listening environments. Eargo offers a several different modes such as a restaurant, the phone-talking, TV-watching or theater. Client can customize a treble and bass settings for each ear and in each program. If a settings could still use a few tweaks, the licensed hearing professionals can make additional programming changes to the Eargos.












Eargo Products in Brief

Name	Description
 Eargo Plus	<p>The Eargo Plus is the first Eargo product. It comes with the flexi fibers and silicone design to optimize comfort and breathability. This model is also equipped with a charging case, hearing aids for each ear, two Flexi Palms, six regular Flexi Palms, USB plug, USB C Cable, wax guard, and a cleaning brush.</p>
 Eargo Max	<p>The Eargo Max is pretty similar to the Eargo Plus. Like Eargo Plus, it comes with the flexi fibers and silicone design to optimize comfort and breathability. This model is totally equipped as predecessor.</p> <p>Eargo Max was developed from the best features found in the Eargo Plus. The biggest difference from its predecessor that the Eargo Max introduces Flexi Domes to increase the amount of ambient bass sounds and eliminate feedback. These domes also deliver richer and fuller sound quality. Eargo Max also has cool features like dynamic noise reduction, profile memory, and voice indicator. Noise reduction will take care of unwanted wind noise and preserve clarity of speech.</p>
 Eargo Neo	<p>Eargo Neo improved upon the core product features Eargo's hearing aids are said to have: comfort, invisibility, rechargeability, and ease-of-use. It has an all-new design, including patented Flexi Palms—which are made from soft, medical-grade silicone—that, according to Eargo, are said to help allow breathability inside the ear, as well as help provide a better in-ear fit. Eargo Neo also has a new design with a new form factor, including stainless steel contacts that are flush with the side of the casing.</p>
 Eargo Neo HiFi	<p>Designed for adults with mild-to-severe, high-frequency hearing loss, the Neo HiFi is the latest in Eargo's product line. The product's new features include increased bandwidth, improved feedback cancellation, and a wind noise reduction algorithm for "enhanced performance processing speech outdoors."</p> <p>Additional features in Neo HiFi include new Flexi TetraPalms, an update to Eargo's patented Flexi Palm design, for improved comfort and a mobile companion app so people can quickly adjust the quality of sounds for specific listening environments such as restaurants or concerts.</p>











Main Partners and Customers Regional Distribution



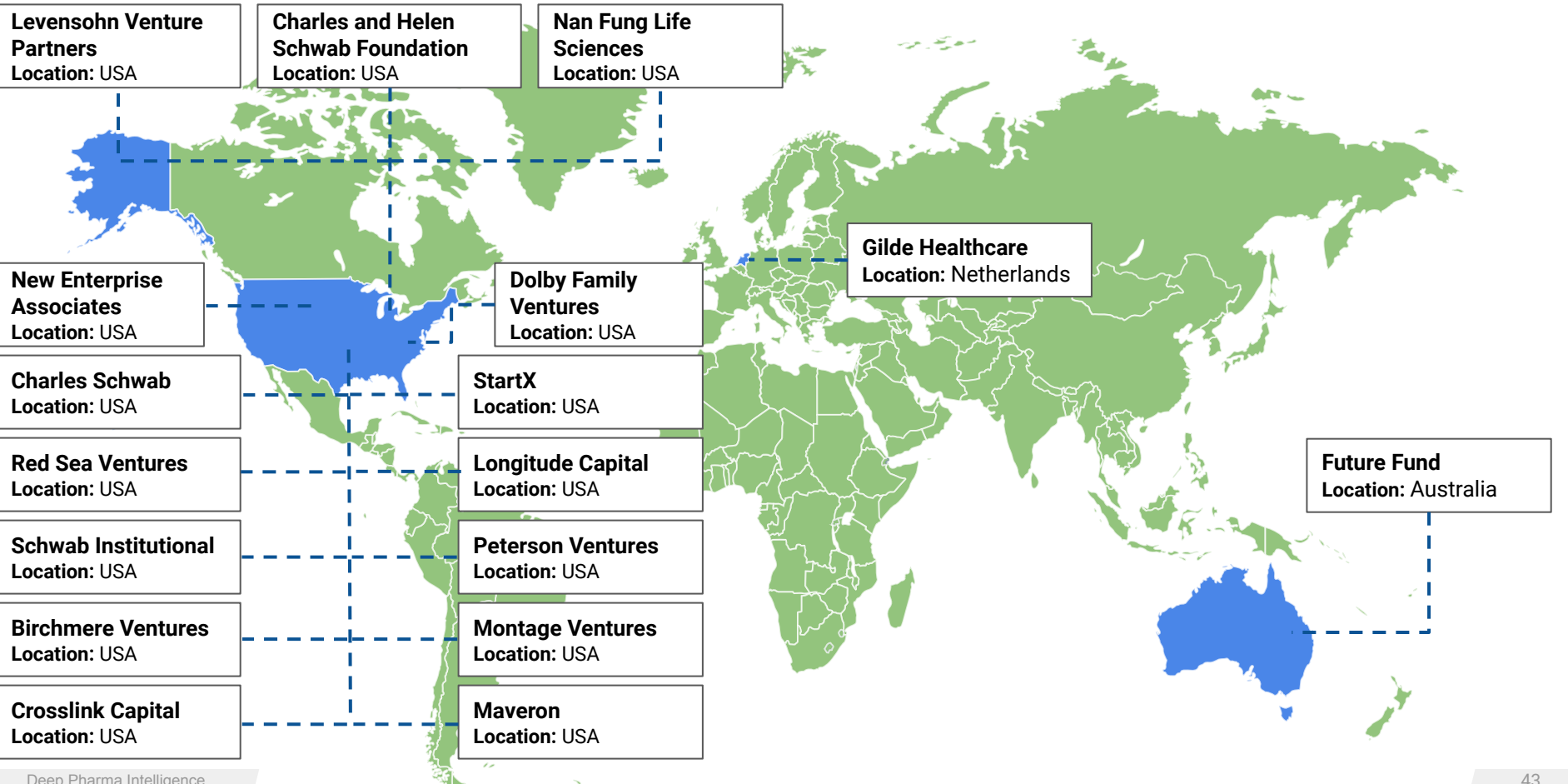
Investors

Investor Name	Description	Location	Investment Date
 Birchmere Ventures	A venture capital firm making investments in early stage and pre-revenue startup companies	USA	Jun 2015
 Charles and Helen Schwab Foundation	A private foundation that collaborates with organizations and individuals that leads in their fields	USA	Jul 2020
 Charles Schwab	A financial institution that provides brokerage and banking services	USA	Oct 2017
 Crosslink Capital	A premier early-stage venture capital firm with over \$1.3B in assets	USA	Jun 2015
 Dolby Family Ventures	An early stage venture firm focused on building great technology companies	USA	Jun 2015, Dec 2015
 Farzad Nazem	Nazem has spent most of his time on investments, philanthropy, and professional mentoring of young entrepreneurs in the technology field	USA	Jun 2015
 Future Fund	An investment fund connected to the Australian Government	Australia	Mar 2019
 Gilde Healthcare	A healthcare investor that does lower mid-market buyouts and later stage venture	Netherlands	Jul 2020
 Levensohn Venture Partners	Manages both biotech and information technology portfolios with an emphasis on breakthrough technologies	USA	Jul 2014, Dec 2015, Oct 2017

Investors

Investor Name	Description	Location	Investment Date
 Longitude Capital	A venture capital firm that invests in biotechnology and medical technology companies	USA	Jul 2020
 Maveron	A consumer-only venture capital firm that empower consumers to live on their terms	USA	Jun 2015, Dec 2015, Oct 2017, Mar 2019
 Montage Ventures	A destination for start-ups looking for investment between Angel and Series A rounds	USA	Jun 2015
 Nan Fung Life Sciences	A global life sciences investment platform with a long-term capital commitment from the Nan Fung Group	USA	Oct 2017, Mar 2019, Jul 2020
 New Enterprise Associates	A global venture capital firm investing in technology and healthcare	USA	Dec 2015, Oct 2017, Mar 2019, Jul 2020
 Peterson Ventures	An early stage venture capital firm that partners with exceptional entrepreneurs	USA	Jun 2015
 Pierre Lamond	Pierre Lamond is a member of the Eclipse investment team	USA	Jun 2015
 Red Sea Ventures	A venture capital firm that specializes in early stage investments based in New York	USA	Jun 2015
 Schwab Institutional	A company that specializes in services for financial advisors	USA	Mar 2019
 StartX	An educational non-profit that helps Stanford's top entrepreneurs	USA	Dec 2015

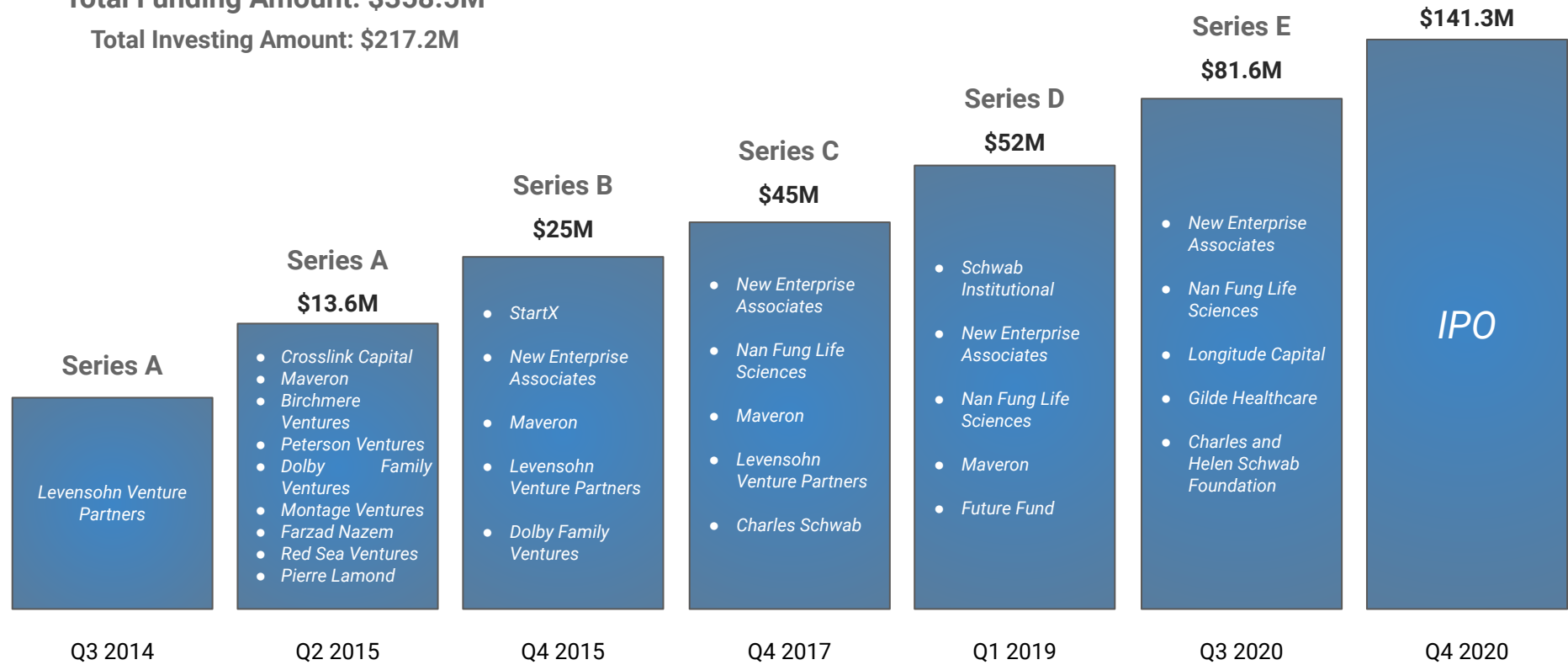
Investor Regional Distribution



Investment Rounds in Eargo

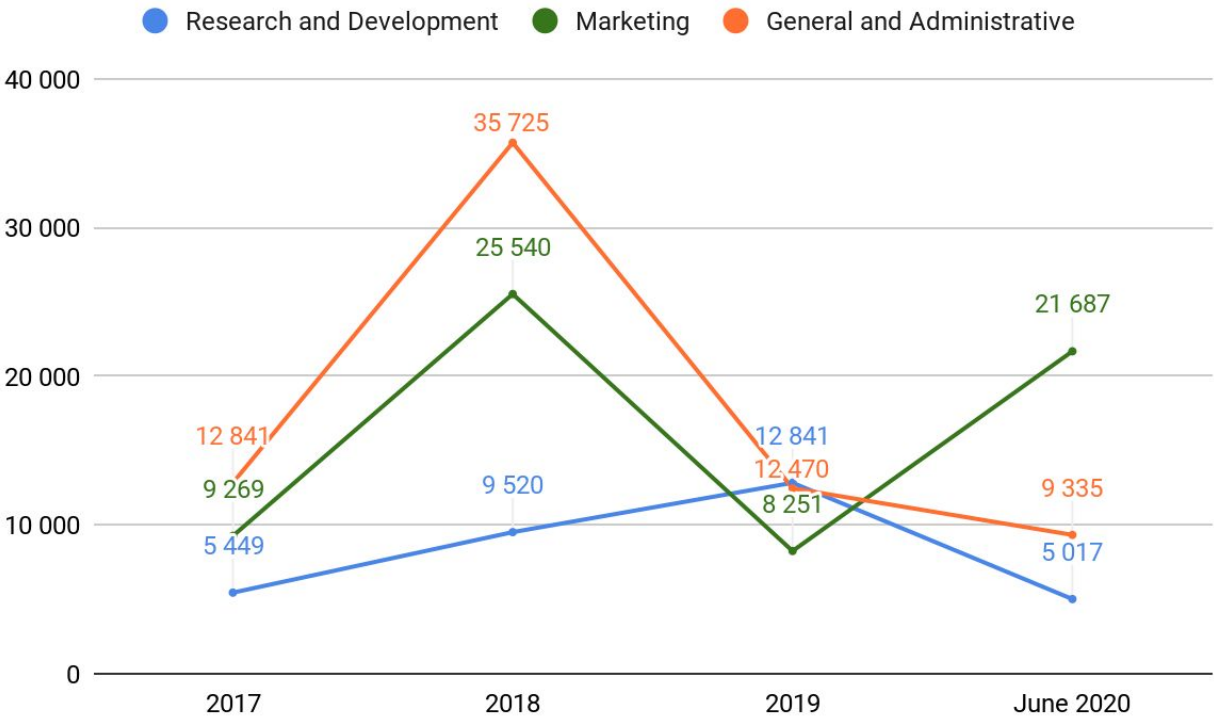
Total Funding Amount: \$358.5M

Total Investing Amount: \$217.2M



Source: [Eargo](#)

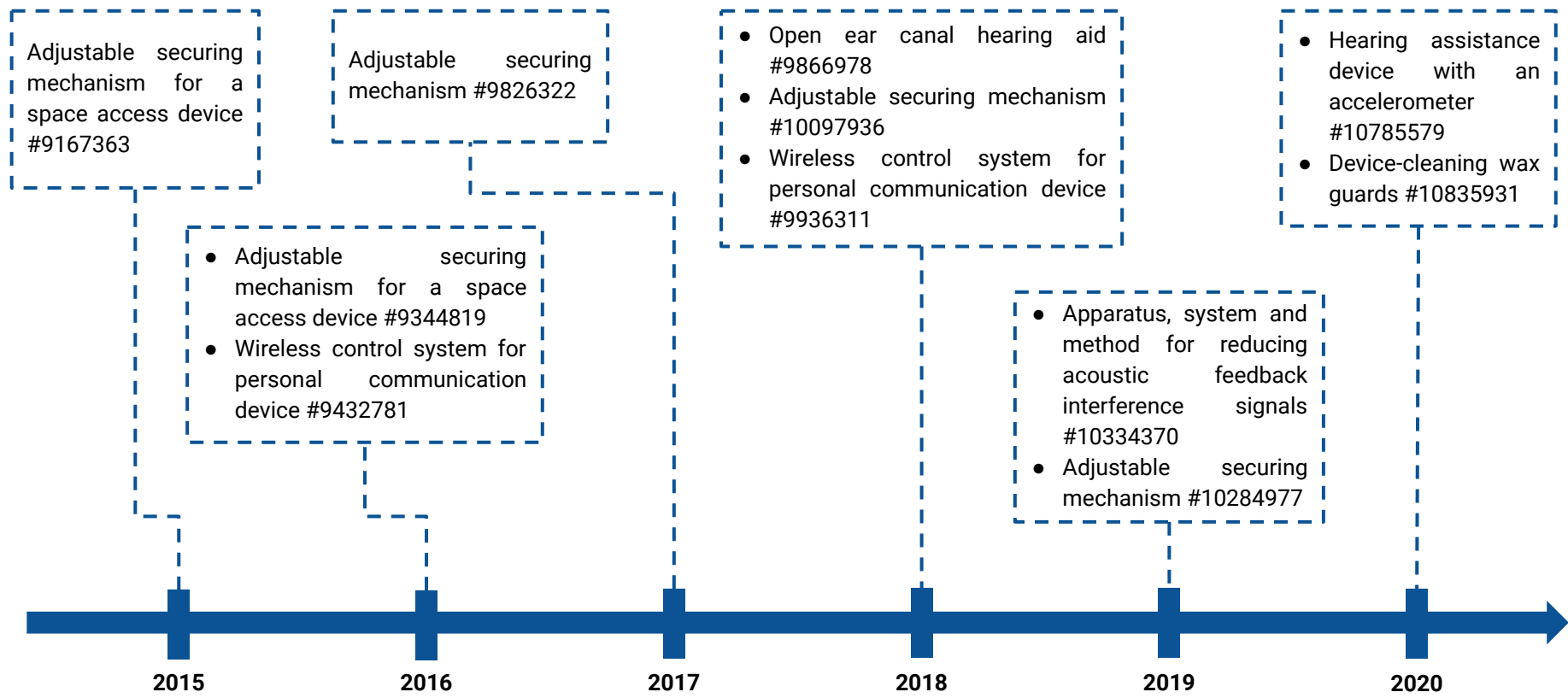
Consolidated Statement of Operations Data: (\$ in thousands)



Eargo has been on the market for 5 years. In fact, they have a ready-made prototype of the device, which is being updated and finalized with each new announced device. As such, R&D expenses are not high and the company focuses on marketing.

Source: [Eargo, Inc.](#)

Eargo Patents Timeline



Source: [Patents Assigned to Eargo](#)

Eargo relies on a combination of patent, copyright, trademark and trade secret laws and confidentiality and invention assignment agreements to protect our intellectual property rights. As of June 30, 2020, company had 17 issued U.S. patents, 16 patents outside the United States, 5 pending U.S. patent applications and 8 pending foreign patent applications. Its patents include utility patents covering technology ranging from remote control of the hearing aids to design patents covering the housing and securing mechanisms for the hearing aids. Eargo has foreign patents in the European Union, Australia, Canada, China, Germany, Japan, Singapore and South Korea. It owns all of the patents and does not rely on any licenses to utilize the technology covered by these patents. The earliest of the patents is expected to expire in 2025.

Eargo issued U.S. patent with claims generally directed to an open ear canal hearing aid comprised of certain electronics and securing portions and its issued U.S. patent with claims generally directed to an adjustable securing mechanism for a space access device are each expected to expire in 2030. As of June 30, 2020, Eargo had 31 trademark registrations and nine pending trademark applications worldwide.

In June 2018, Eargo entered into the 2018 Loan with SVB. Under the terms of the 2018 Loan, Eargo granted SVB first priority liens and security interests in substantially all of their assets as collateral, which included their intellectual property. SVB released its security interest in their intellectual property in September 2020.

The validity, enforceability or scope, as the case may be, of one of Eargo's patents relating to Flexi Palm design is being challenged in Europe. An oral hearing for this challenge is expected to be scheduled in 2021. The preliminary opinion from the European Patent Office's Opposition Division considered the claims to be novel, inventive and sufficient of disclosure, while only making objections regarding added matter.

Eargo's response includes a main request to maintain the claims of the patent as-is and 11 auxiliary requests, each of which will still provide coverage of the Flexi Palms. While any result that narrows or invalidates this patent could harm the ability to prevent third parties from producing competing products similar in design, the result of these proceedings may or may not result in the patent being invalidated and that any result that relies upon one of the auxiliary requests would still provide Eargo coverage regarding Flexi Palms in Europe.

According to Eargo Prospectus: *"Our success and ability to compete depend in part on our ability to maintain and enforce existing intellectual property and to obtain, maintain and enforce further intellectual property protection for our products and services, both in the United States and in other countries. We attempt to protect our intellectual property rights through a combination of patent, trademark, copyright and trade secret laws, as well as licensing agreements and third-party confidentiality and assignment agreements."*

<div>Strengths</div> <div><ul style="list-style-type: none">• A wide range of products.• Hearing aid prices typically range from \$1500 to \$3500 per unit while Eargo prices are various from \$1,850 to \$2,950.</div>	<div>Weaknesses</div> <div><ul style="list-style-type: none">• No Partnerships.• Demand for its hearing aids may not increase as rapidly as it anticipates due to a weakness in general economic conditions or competitive pressures.</div>
<div>Opportunities</div> <div><ul style="list-style-type: none">• To successfully challenge incumbent business models and become profitable, the company will need to continue to refine its product and strategy.</div>	<div>Threats</div> <div><ul style="list-style-type: none">• The demand for its hearing aids may not increase as rapidly as it anticipates due to a variety of factors, including a weakness in general economic conditions or competitive pressures.</div>

TransMedics

(TMDX)



Transmedics is a medical device company involved in the design and production of transplant devices.

TransMedics, Inc., headquartered in Andover, Massachusetts, is a medical device company founded to address the unmet need for more and better organs for transplantation.

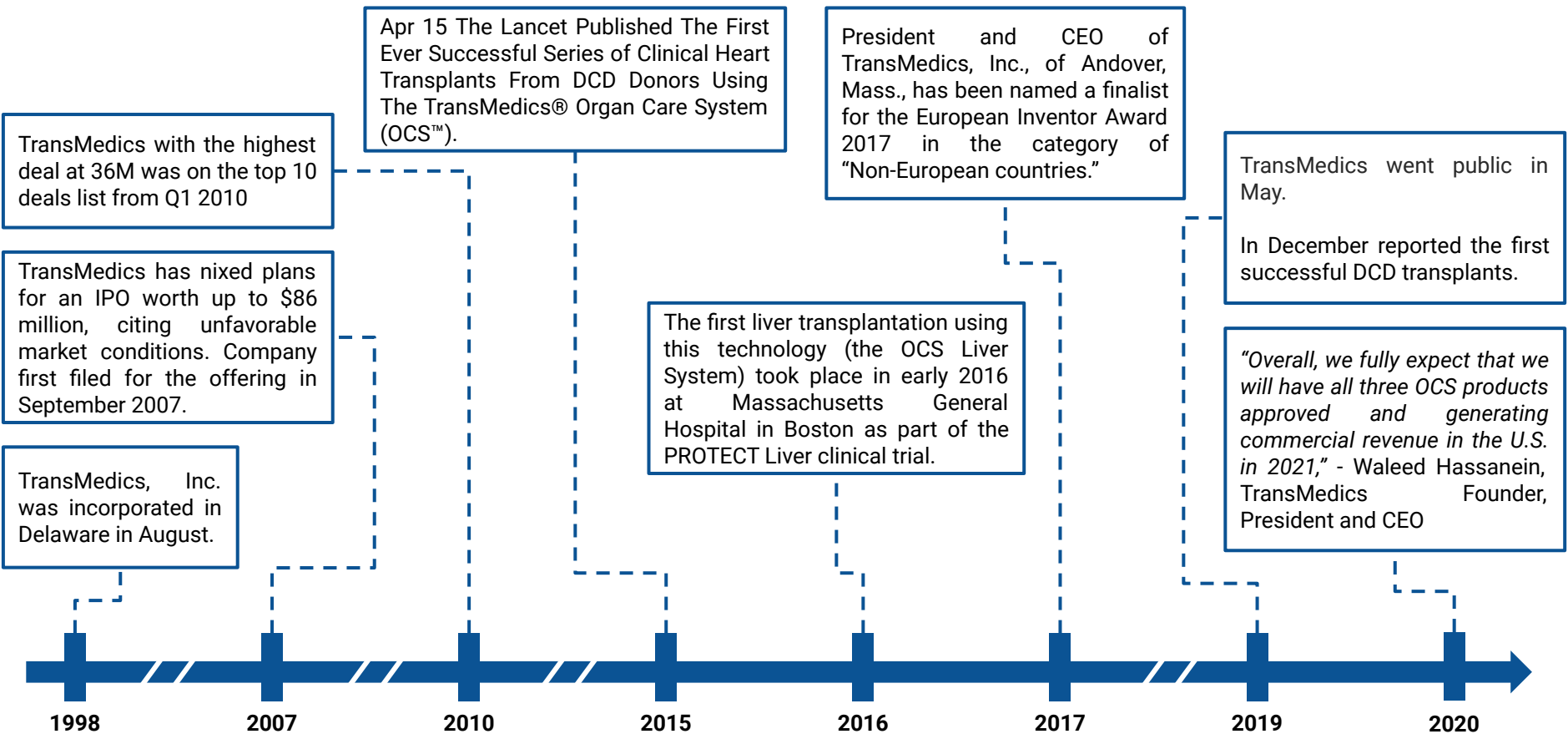


TransMedics is a commercial-stage medical technology company transforming organ transplant therapy for end-stage organ failure patients across multiple disease states. The company developed the OCS, to replace a decades-old standard of care that is significantly limiting access to life-saving transplant therapy for hundreds of thousands of patients worldwide. Its innovative OCS technology replicates many aspects of the organ's natural living and functioning environment outside of the human body. As such, the OCS represents a paradigm shift that transforms organ preservation for transplantation from a static state to a dynamic environment that enables new capabilities, including organ optimization and assessment. TransMedics substantial body of clinical evidence has demonstrated the potential for the OCS to significantly increase the number of organ transplants and improve post-transplant outcomes.

Incidence of end-stage organ failure has been rapidly rising worldwide due to demographic trends that contribute to chronic diseases. Organ transplantation is the treatment of choice for addressing end-stage organ failure due to its positive clinical outcomes and favorable health economics. However, transplant volumes have been significantly restricted by the limitations of cold storage, the standard of care for solid organ transplantation. Cold storage is a rudimentary approach to organ preservation in which a donor organ is flushed with cold pharmaceutical solutions, placed in a plastic bag on top of ice and transported in a cooler. Cold storage subjects organs to significant injury due to a lack of oxygenated blood supply, or ischemia, does not allow physicians to assess organ viability and lacks the ability to optimize an organ's condition once it has been retrieved from the donor.

Time-dependent ischemic injury has been shown to result in short- and long-term post-transplant clinical complications and, together with the inability to assess or optimize organs, contributes to the severe underutilization of donor organs. While there are approximately 67,000 potential donors annually in the United States, Canada, the European Union and Australia, which company refer to as its key geographies, the majority of lungs and hearts donated after brain death, or DBD, go unutilized, and almost no available lungs and hearts donated after circulatory death, or DCD, are utilized.

TransMedics Timeline



What is OCS?

The Company has designed and developed an organ care system (OCS) a portable organ perfusion, optimization and monitoring system that utilizes customized technology to replicate near-physiologic conditions for donor organs outside of the human body. The Company has developed three OCS products, one for each of lung, heart and liver transplantations. Its OCS clinical programs include OCS Lung INSPIRE Trial, OCS Lung Expand Trial, OCs Heart EXPAND and PROCEED II Trials.

Its organ care system (OCS) technology platform to perfuse donor organs with warm, oxygenated, nutrient-enriched blood, while maintaining the organs in a living, functioning state; the lung is breathing, the heart is beating and the liver is producing bile. The Company is also focused on developing additional OCS products for kidney transplantation. Its OCS product consists of three primary components customized for each organ: OCS Console, a portable electromechanical medical device that houses and controls the function of the OCS; OCS Perfusion Set, is a sterile, biocompatible single-use disposable set that stores the organ and circulates blood; and OCS Solutions, a nutrient-enriched solution to replenish depleted nutrients and hormones needed to optimize the organ's condition outside of the human body. OCS products for additional organs, including kidneys, are under development.

The Company competes with OrganOx Limited and XVIVO Perfusion AB.

The OCS technology platform is equipped with the following core technologies that we designed to comprehensively address the limitations of cold storage and improve transplant outcomes:

- proprietary pulsatile blood pump to simulate beating heart perfusion in organs outside of the human body;
- proprietary software-controlled titanium blood warmer to maintain blood at body temperature while maximizing portability;
- gas exchanger to maintain organ oxygenation outside of the human body;
- customized hemodynamics sensors to monitor and assess organ function outside of the human body;
- proprietary software-controlled, miniaturized, electromechanical system with universal power supply and hot-swappable batteries to maximize portability and travel distance for organ retrieval;
- proprietary wireless monitor and control software to provide an intuitive user interface for monitoring critical organ function; and
- customized carbon fiber OCS console structure to reduce the overall weight of the system and maximize portability.

Each OCS product consists of three primary components customized for each organ:

OCS Console

The OCS Console is a highly portable electromechanical medical device that houses and controls the function of the OCS and is designed to fit in the current workflow for organ transplantation.



OCS Perfusion Set

The OCS Perfusion Set is a sterile, biocompatible single-use disposable set that stores the organ and circulates blood. The OCS Perfusion Set includes all accessories needed to put the organ on the system.

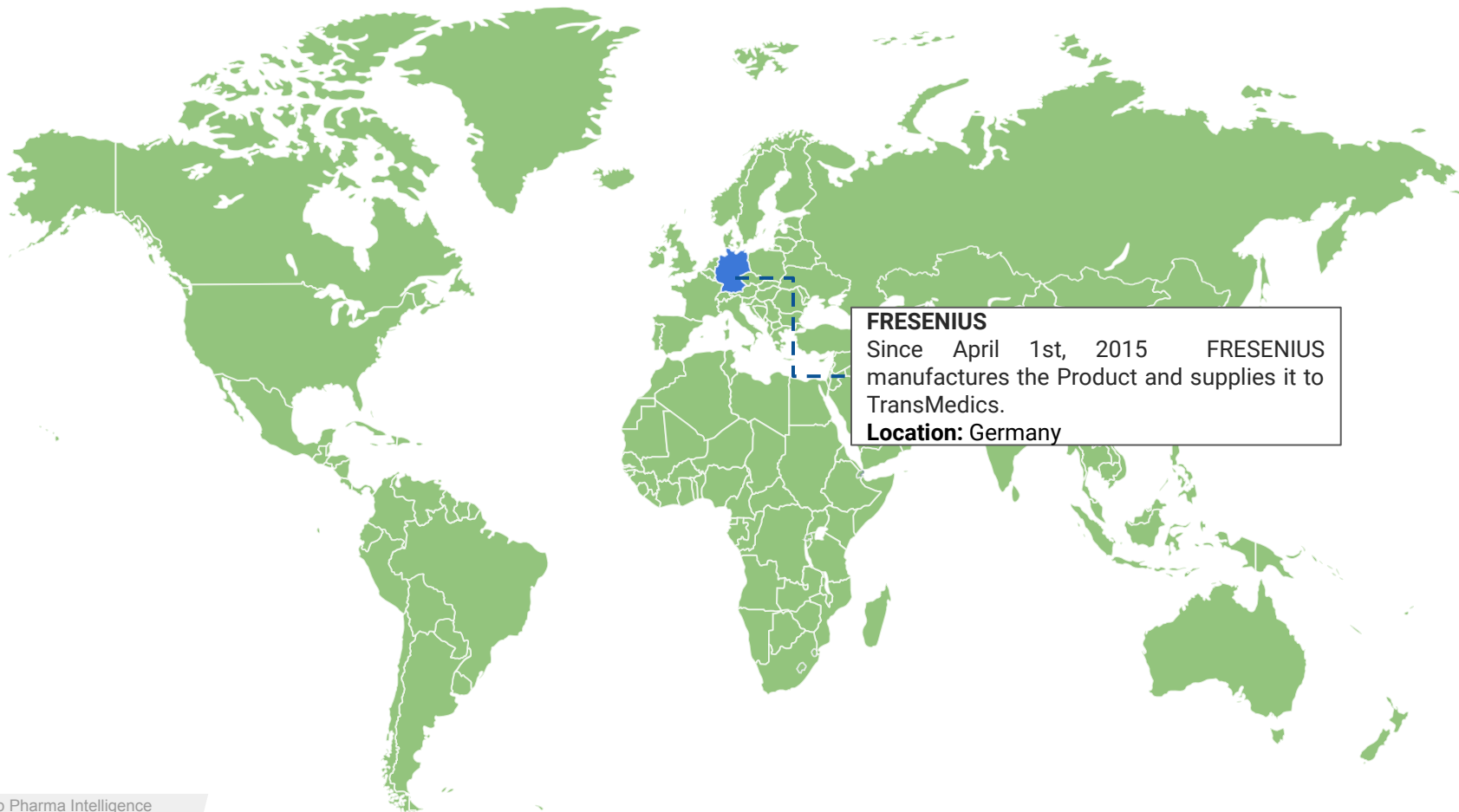


OCS Solutions





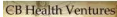


The OCS Solutions are a set of nutrient-enriched solutions used with blood to replenish depleted nutrients and hormones needed to optimize the organ's condition outside of the human body.











Main Partners and Customers Regional Distribution




Investors

Investor Name	Description	Location	Investment Date
 3i Group	An international investment manager focused on mid-market Private Equity, Infrastructure & Debt Management	UK	Jan 2004; Mar 2006; Apr 2007; Mar 2010
 Abrams Capital	A Boston-based investment firm that follows an opportunistic, fundamental and value-oriented approach.	USA	Nov 2012; May 2016; Jul 2016
 Alta Partners	A leading venture capital firm in life sciences, funding over 130 companies in the industry since 1996	USA	Sep 2000; Jan 2004; Mar 2006; Apr 2007; Mar 2010
 BioStar Ventures	A venture capital partnership that focuses on medical device technologies in cardiovascular and orthopaedic medicine	USA	May 2016; Jul 2016
 CB Health Ventures	CB Health Ventures manages \$150 million of private equity funds focused on investment opportunities in healthcare services, medical information technology, biotechnology and genomics	USA	Jan 2004; Mar 2006; Apr 2007; Mar 2010
 CDP Capital Technology Ventures	A Quebec-based investment firm that aims to develop new technology-based companies	Canada	Jan 2004
 Chase Capital Partners	An investment firm and investment bank that used to provide early-stage and later stage investments in the e-commerce, trading and productivity software sectors (out of Business)	USA	Sep 2000

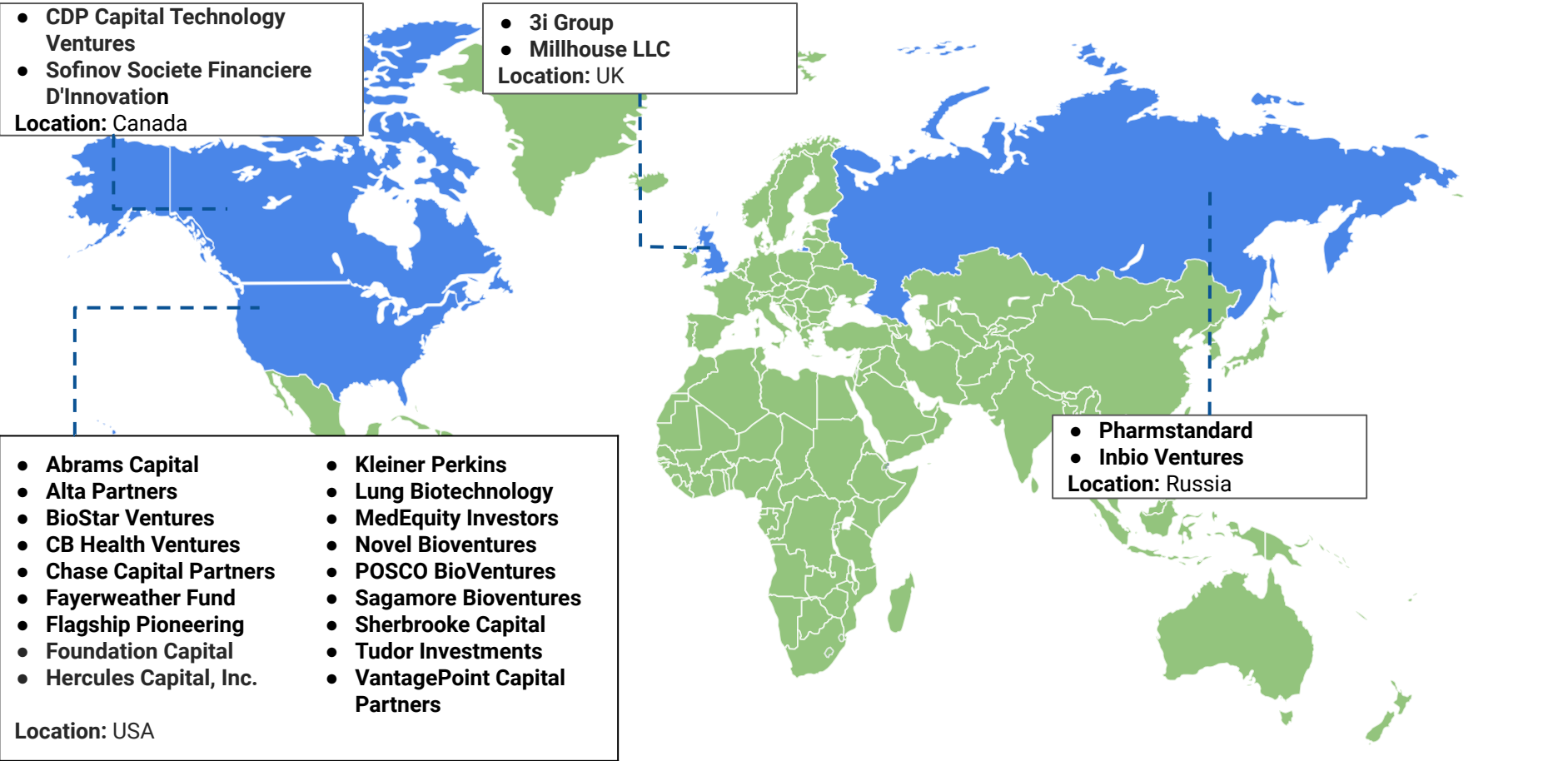
Investors

Investor Name	Description	Location	Investment Date
 Fayerweather Fund	Investors in public securities, private companies, hedge funds, and private equity funds seeking long-term returns.	USA	May 2016; Jul 2016
 Flagship Pioneering	Flagship Pioneering conceives, creates, resources, and grows first-in-category ventures to transform human health and sustainability	USA	Jan 2004; Mar 2006; Apr 2007; Mar 2010; Nov 2012; May 2016; Jul 2016
 Foundation Capital	A venture capital firm made up of former entrepreneurs who set out to create the firm they wanted as founders	USA	Mar 2010
 Hercules Capital, Inc.	A California-based company, lends to technology, life sciences, and sustainable technology companies	USA	Nov 2012
 Inbio Ventures	A venture capital firm that seeks to invest early stage and startups	Russia	May 2016; Jul 2016
 Kleiner Perkins	A venture capital firm specializing in investing in early-stage, incubation, and growth companies	USA	Mar 2010; Nov 2012; May 2016; Jul 2016
 Lung Biotechnology	Lung Biotechnology PBC is engaged in the research and development, and marketing of therapies for pulmonary arterial hypertension (PAH)	USA	May 2016; Jul 2016
 MedEquity Investors	A Massachusetts-based private equity firm that invests in small and lower middle market healthcare businesses	USA	Sep 2000

Investors

Investor Name	Description	Location	Investment Date
 Millhouse LLC <small>MILLHOUSE</small>	A listed international diversified funds management business with its securities quoted on Deutsche Börse	UK	May 2016
 Novel Bioventures	A venture capital fund focused on early stage investments	USA	Jan 2004
 Pharmstandard	A pharmaceutical company that develops and manufactures modern pharmaceutical products	Russia	Jul 2016
 POSCO BioVentures	POSCO BioVentures' primary investment focus is on companies with novel, proprietary bio-molecules.	USA	Jan 2004; Mar 2006; Apr 2007; Mar 2010
 Sagamore Bioventures	Sagamore Bioventures provides later stage venture investments	USA	Mar 2006; Apr 2007; Mar 2010
 Sherbrooke Capital	Invests in the health and wellness industry and is a Massachusetts-based venture capital firm	USA	Jan 2004; Mar 2006; Apr 2007; Mar 2010
 Sofinov Societe Financiere D'Innovation	This investor deals in the range of 10 - 50 millions dollars are most common. The usual method for the fund is to invest in rounds with 4-5 other investors.	Canada	Sep 2000
 Tudor Investments	Tudor Investment Corporation provides investment management services. The Company manages assets across fixed income, currency, equity and commodity asset classes, and related derivative instruments	USA	Apr 2007; Mar 2010
 VantagePoint Capital Partners	A global venture investor supporting companies from start-up to scale-up with a special focus on energy innovation and efficiency	USA	Mar 2006; Apr 2007; Mar 2010

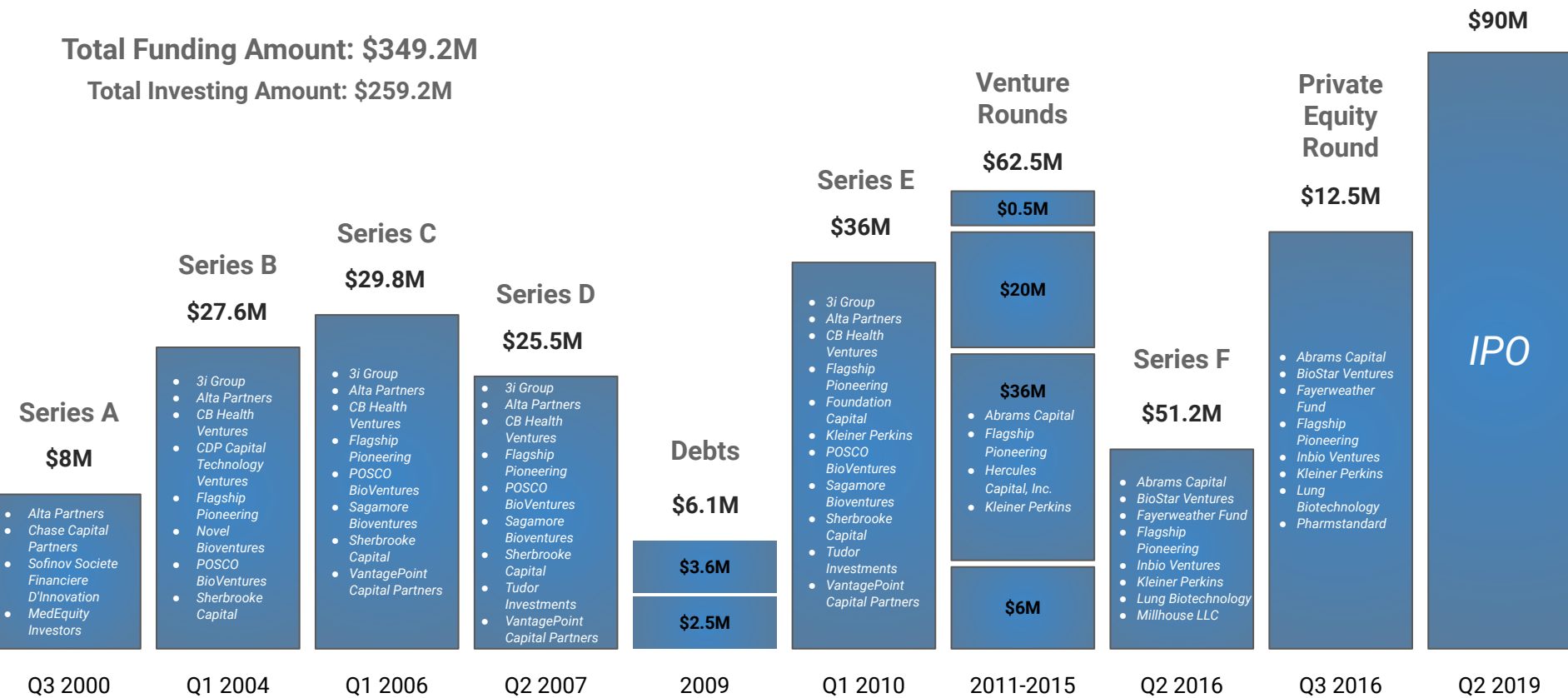
Investor Regional Distribution



Investment Rounds in TransMedics

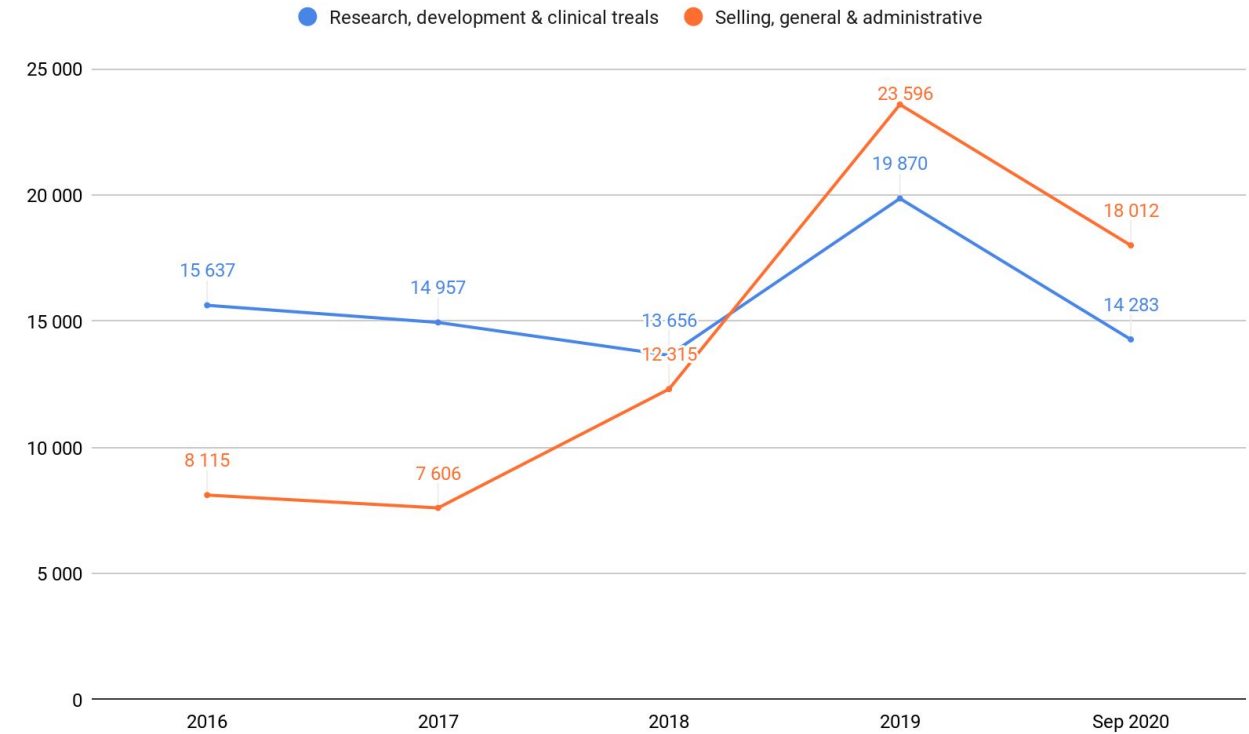
Total Funding Amount: \$349.2M

Total Investing Amount: \$259.2M



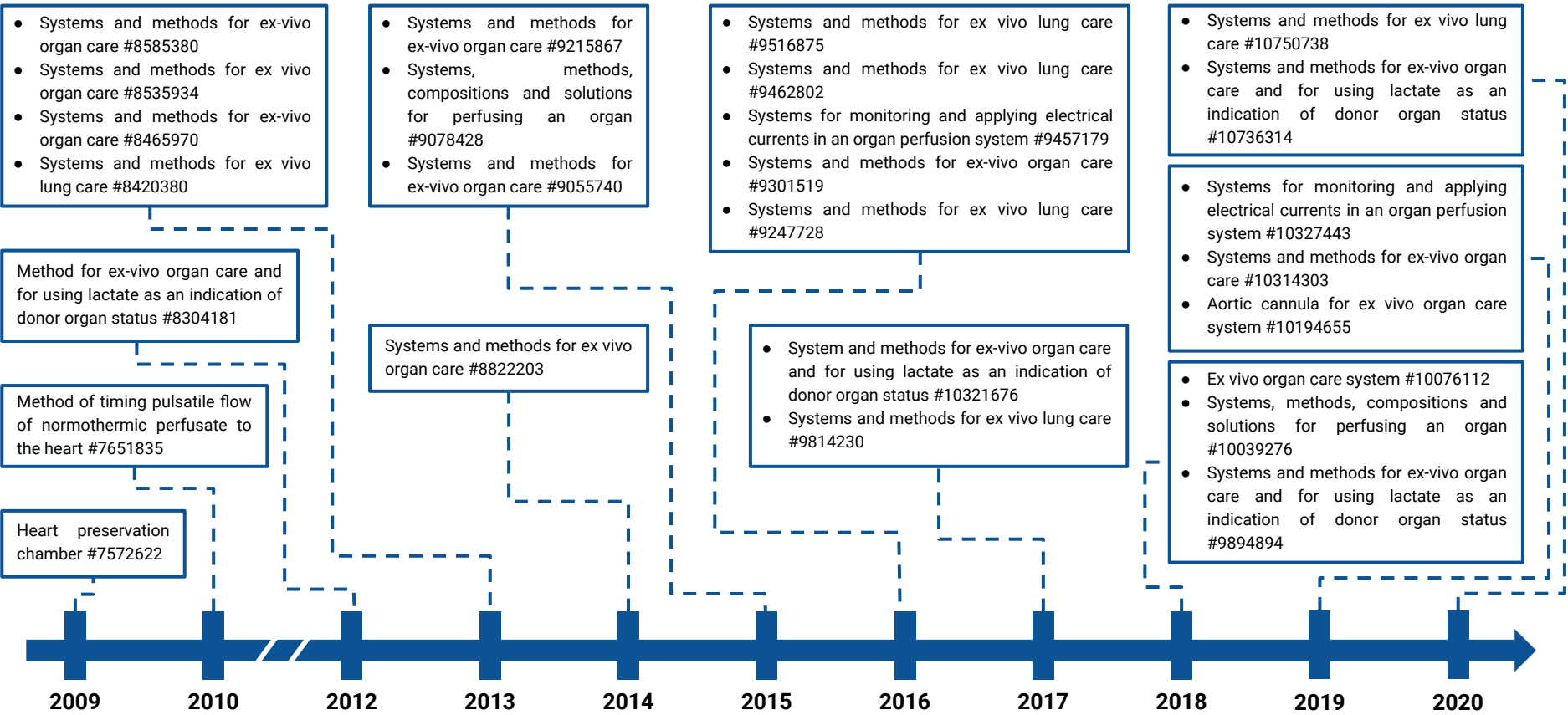
Source: [TransMedics](https://www.transmedics.com/investor-relations)

Consolidated Statement of Operations Data: (\$ in thousands)



In 2019 TransMedics reported the first successful DCD transplants. The company was focused on studies, and remains on track to complete enrollment in 2020 and for a PMA submission in 2021.

TransMedics Patents Timeline



Source: [Patents Assigned to TransMedics, Inc.](#)

TransMedics patent portfolio includes patents and patent applications that company owns or licenses from third parties.

As of March 30, 2019, TransMedics-owned and licensed patent portfolio consisted of approximately 188 issued patents and pending patent applications worldwide, including in Australia, Europe, Canada, China, Israel, New Zealand and Japan. Its licensed portfolio includes one issued unexpired United States patent licensed from the VA. Several other licensed U.S. and international patents expired in 2018. The issued unexpired licensed VA patent includes claims directed to portable perfusion apparatus for preserving a harvested donor heart in a viable state. TransMedics owned portfolio includes patents and applications related to one or more of the OCS Lung, OCS Heart, OCS Liver and solutions.

In the United States, TransMedics owned portfolio includes about 22 issued patents and 9 pending applications (2019). Worldwide, its owned portfolio includes about 99 issued patents and 58 pending applications. Issued patents in its portfolio are expected to expire between 2019 and 2036, excluding any potential additional patent term for patent term adjustments or patent term extensions, if applicable. If granted, the pending U.S. and foreign patent applications in its portfolio are expected to expire between 2023 and 2036, excluding any potential additional patent term for patent term adjustments or patent term extensions, if applicable.

TransMedics' research, development and clinical trial operations function consists of a dedicated clinical trial team that has trial management, data collection and biostatistics expertise. Their product engineering function consists of a multi-disciplinary engineering team that has electrical, mechanical, systems and software engineering expertise. Company's regulatory function includes a team with both U.S. and international medical device regulatory expertise and is supported by senior FDA regulatory advisors and legal counsel. For the fiscal years ended December 30, 2017 and December 29, 2018, their research, development and clinical trials expenses were \$15.0 million and \$13.7 million, respectively.

This team is focused on the following research, development and clinical trial activities:

- expanding the body of clinical evidence supporting the use of the OCS platform through pre-market clinical trials, post-market registries and scientific publications;
- improving incrementally the technology and manufacturing efficiency of our current platform;
- developing the next generation OCS;
- conducting research to investigate new clinical applications and uses for the OCS platform.

<div>Strengths<ul style="list-style-type: none">• A large number of investors.• A large number of patents.</div>	<div>Weaknesses<ul style="list-style-type: none">• The clinical trial process required to obtain regulatory approvals is lengthy and expensive, with uncertain outcomes.• A limited number of clients.</div>
<div>Opportunities<ul style="list-style-type: none">• With the rise of employment numbers, the company growth will develop.• Demand for Organ Transplants -- a highly unmet medical need.• The growth of donors pool stimulates the market expansion.</div>	<div>Threats<ul style="list-style-type: none">• FDA Advisory Committee meeting to review the OCS Heart System was postponed due to the national emergency status relating to the COVID-19 Coronavirus.• TransMedics have incurred substantial losses since its inception, including a net loss of \$23.8 million for the fiscal year ended December 29, 2018 and resulting in an accumulated deficit of \$335.9 million as of December 29, 2018, and its expected that company will continue to incur losses in the future.• Hackers and other third parties may try to circumvent security controls on an OCS.</div>

Silk Road Medical (SILK)



Silk Road Medical provides research and development services of medical devices for neurovascular diseases.

Silk Road Medical, Inc. is a medical device company located in Sunnyvale, California, that is focused on reducing the risk of stroke and its devastating impact. The company has pioneered a new approach for the treatment of carotid artery disease called TransCarotid Artery Revascularization (TCAR).

The TransCarotid Artery Revascularization (TCAR) Procedure is a clinically proven procedure combining surgical principles of neuroprotection with minimally invasive endovascular techniques to treat blockages in the carotid artery at risk of causing a stroke.

The ENROUTE® Transcarotid Neuroprotection and Stent System are the first and only products specifically designed and indicated for TCAR in high surgical risk patients that need carotid intervention.

Silk Road Medical is inspired by the power of the human mind and have dedicated themselves to protect it by developing advanced solutions that reduce the risk of stroke during vascular surgery. The company is inspired by and dedicated to empowering its surgical partners to deliver better patient outcomes, one surgery at a time.

Company presents 4 products:

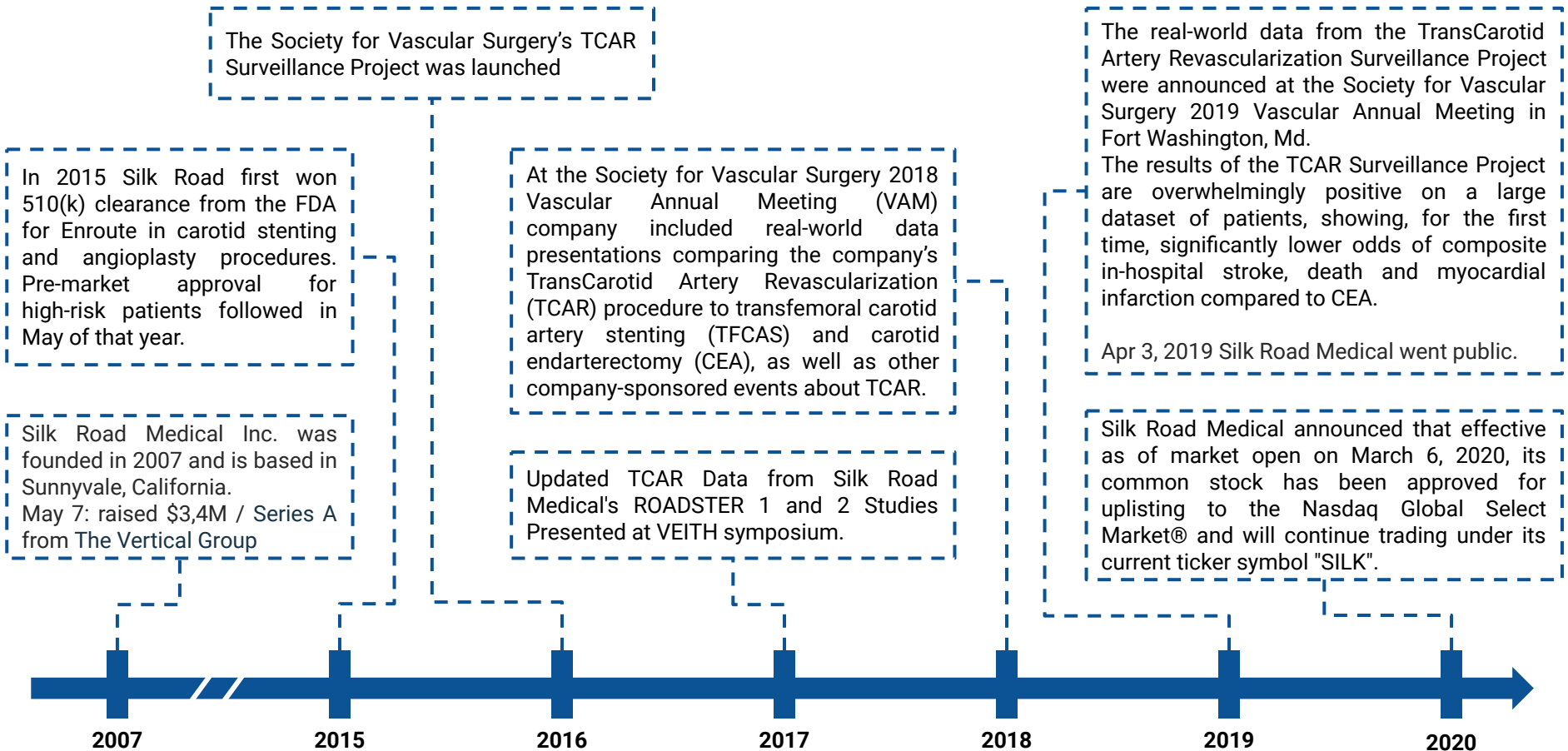
- ENROUTE® Transcarotid Neuroprotection System
- ENROUTE® Transcarotid Stent System
- ENHANCE® Transcarotid Peripheral Access Kit
- ENROUTE® 0.014" Guidewire

There are many efficiencies that can translate to benefits to the patient, physician and hospital. The TCAR procedure significantly reduces clamp time and overall procedure time compared to a more invasive surgical procedure (CEA).

Company has conducted several clinical studies to validate and strengthen TCAR's clinical story as a safe and reproducible alternative to CEA.

- PROOF (First-in-Man validation of concept)
- ROADSTER (Pre-Market Approval of the ENROUTE Neuroprotection System)
- TCAR vs TFCAS (Validation of superior outcomes to TF-CAS)
- ROADSTER 2 (Post Approval registry validating the safety and efficacy of the ENROUTE Stent)
- VQI-TSP (Real world population data validating CEA-like outcomes)

Silk Road Medical Timeline



ENROUTE® Transcarotid Neuroprotection System



Enables the reversal of blood during the TCAR procedure to protect the brain from potential emboli.

ENROUTE® Transcarotid Stent System



The first and only ergonomic and precise carotid stent system designed and indicated for Transcarotid access.

ENROUTE® 0.014" Guidewire



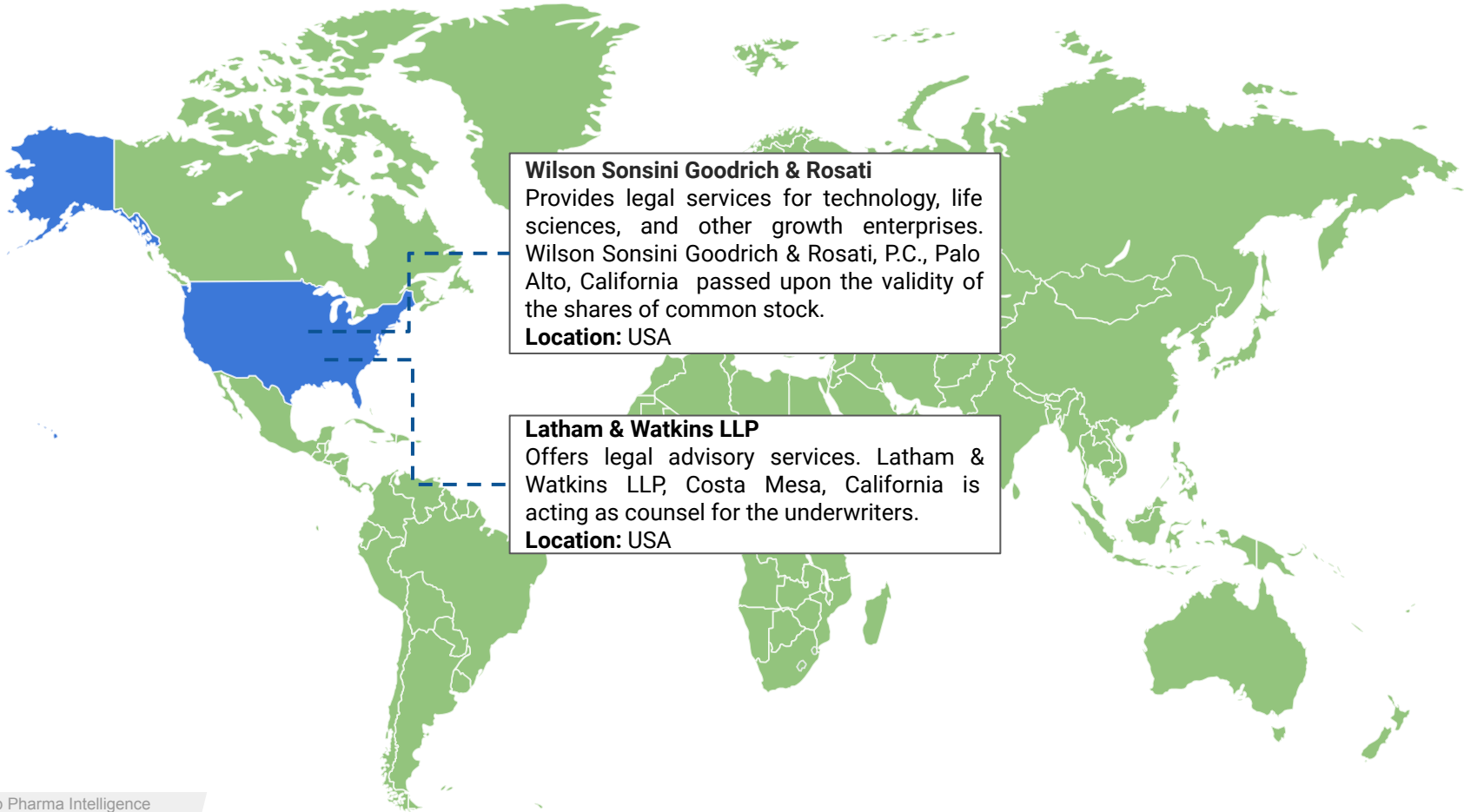
Provides precise lesion navigation in tortuous short vessel segments while performing TCAR.

ENHANCE® Transcarotid Peripheral Access Kit








The only micropuncture access kit developed for the TCAR procedure making it easier, safer, and more efficient.

Main Partners and Customers Regional Distribution

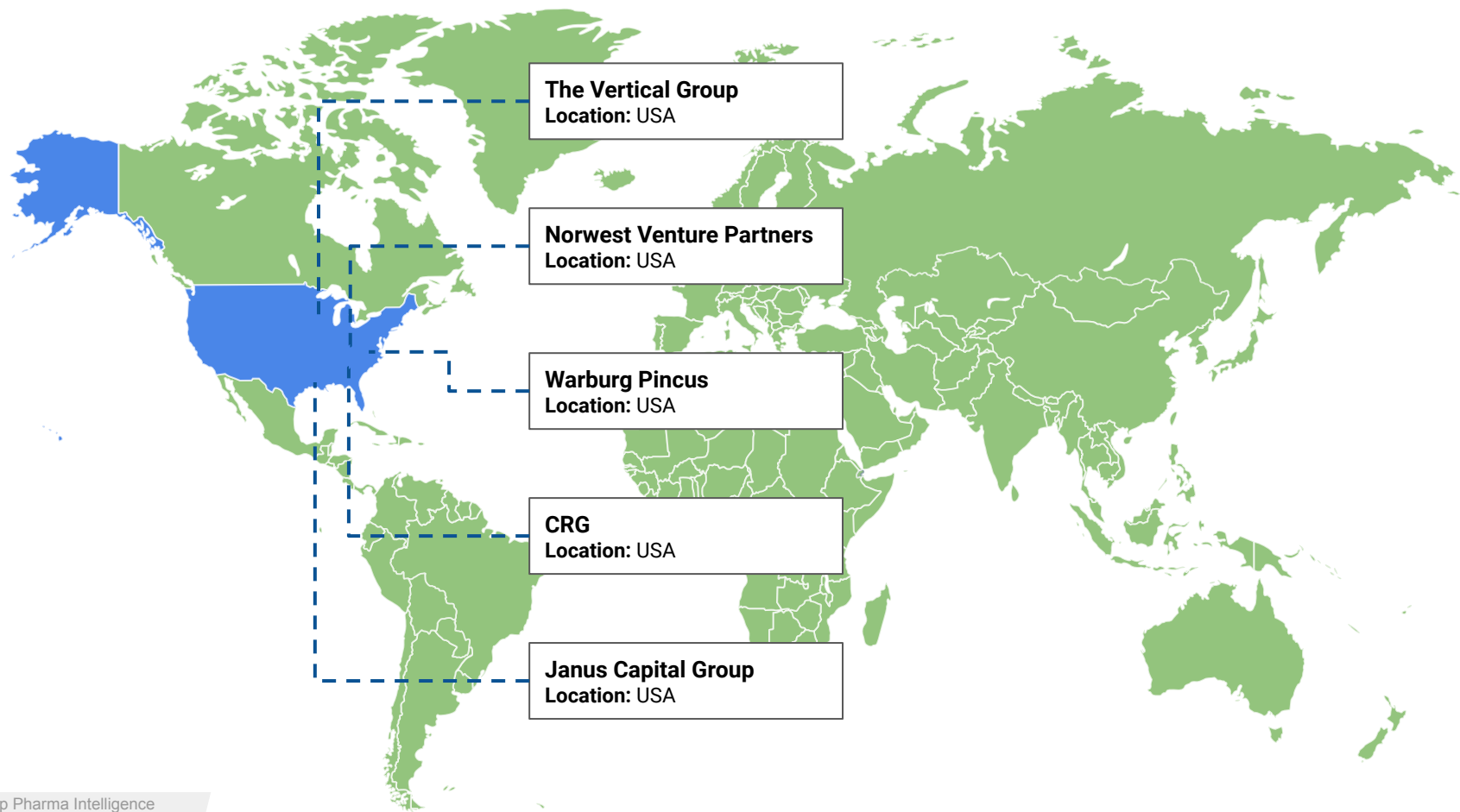


Investors

Investor Name	Description	Location	Investment Date
 The Vertical Group	The Vertical Group is a New Jersey-based venture capital firm focused on the fields of medical technology and biotechnology.	USA	Jul 2017, Oct 2015, Apr 2012, May 2007
 Norwest Venture Partners	Norwest is a global venture capital and growth equity investment firm that manages more than \$7.5B in capital.	USA	Jul 2017
 Warburg Pincus	Warburg Pincus LLC is a private equity firm focused on growth investing.	USA	Jul 2017, Oct 2015
 CRG	CRG is a market pioneer and innovator in healthcare investing that focuses on intellectual property investments in biopharmaceutical assets.	USA	Jul 2017, Oct 2015
 Janus Capital Group	Janus provides growth and risk-managed investment strategies and manages equity, fixed income, money market, and balanced mutual funds.	USA	Jul 2017

Source: [Silk Road Medical](#)

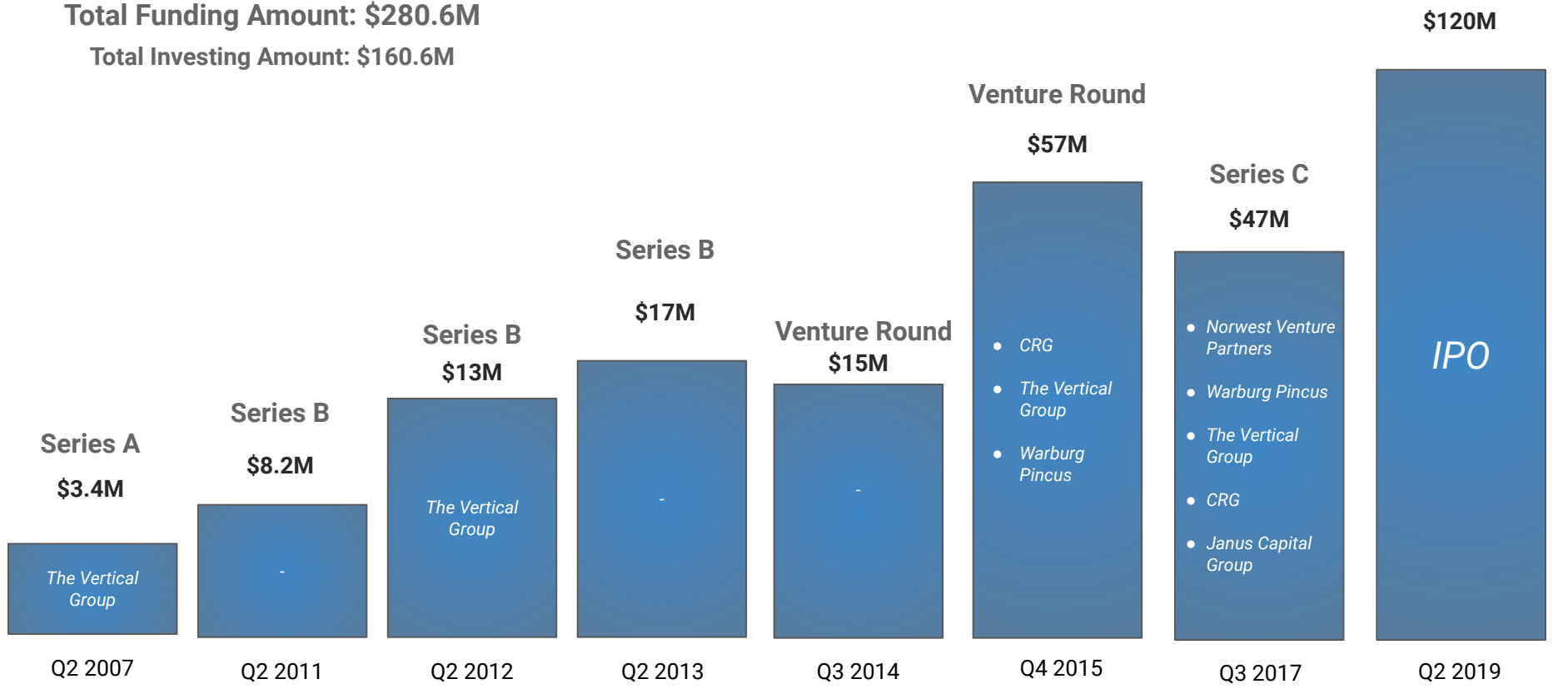
Investor Regional Distribution



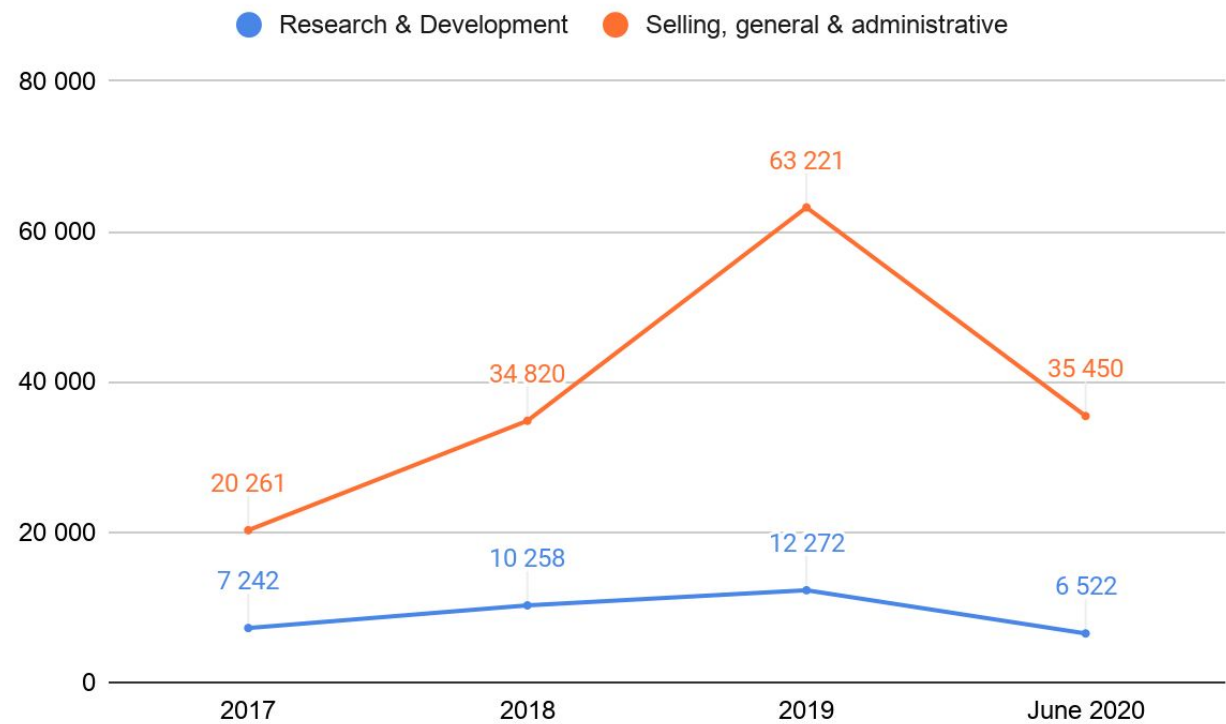
Investment Rounds in Silk Road Medical

Total Funding Amount: \$280.6M

Total Investing Amount: \$160.6M



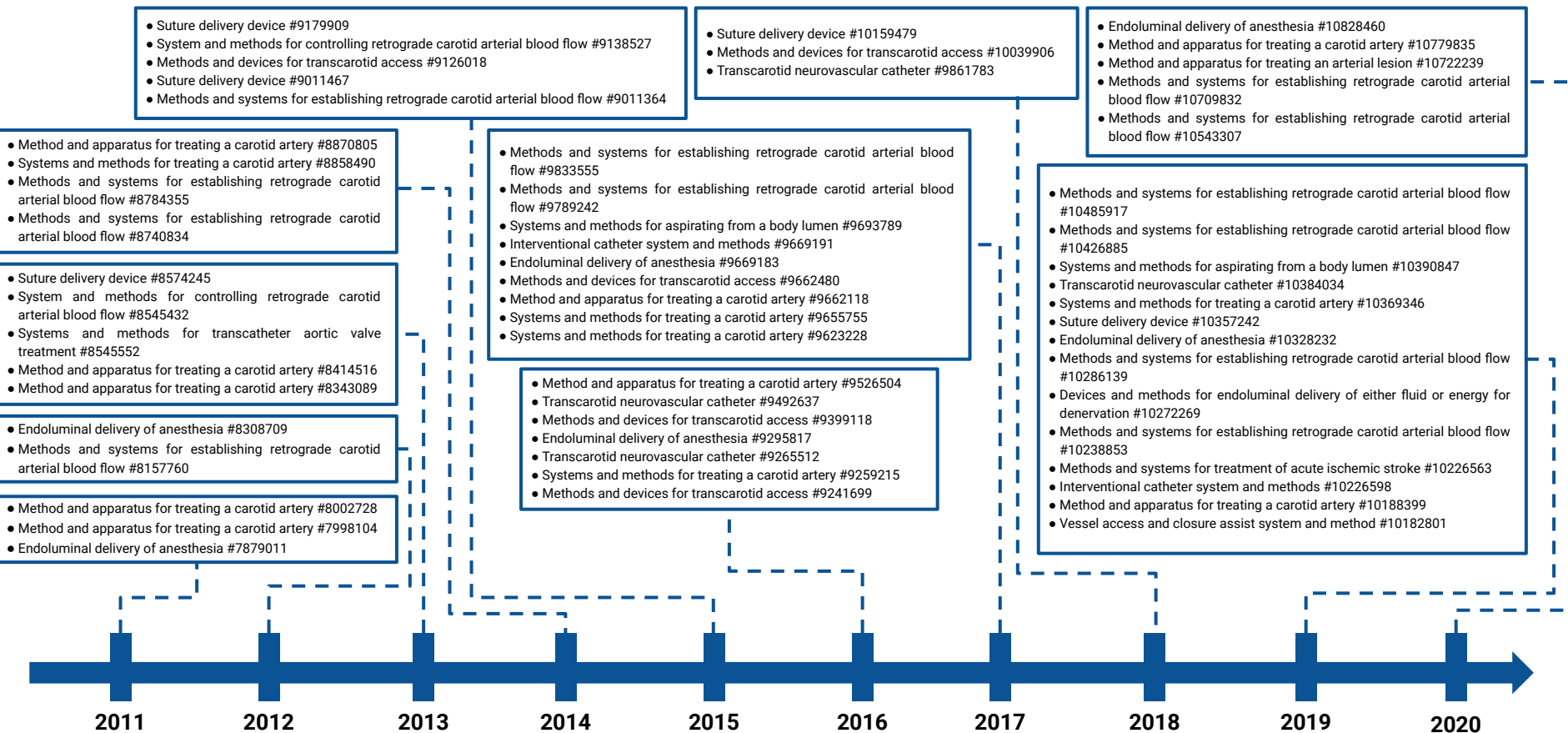
Consolidated Statement of Operations Data: (\$ in thousands)



The company maintains low spending on R&D due to the low cost of product materials.

Most of the total spending goes to participation in important for the company Society for Vascular Surgery (2018/2019) Vascular Annual Meeting and TCAR Surveillance Project.

Silk Road Medical Patents Timeline



Source: [Patents Assigned to Silk Road Medical, Inc.](#)

Silk Road Medical owns a broad intellectual property portfolio. As of December 31, 2018, it held 47 issued patents globally that include device, apparatus and method claims surrounding TCAR and its suite of current and potential future products, as well as for treating other vascular diseases and enabling other transcatheter procedures, primarily directed at acute ischemic stroke, other neurovascular procedures, repair of the aorta and transcatheter aortic valve repair, or TAVR.

According to Silk Road Medical Prospectus: *"The medical device industry has been characterized by extensive litigation regarding patents, trademarks, trade secrets, and other intellectual property rights, and companies in the industry have used intellectual property litigation to gain a competitive advantage. It is possible that U.S. and foreign patents and pending patent applications or trademarks controlled by third parties may be alleged to cover our products, or that we may be accused of misappropriating third parties' trade secrets."*

Silk Road Medical owned 47 patents, of which 34 were issued U.S. patents and 13 were patents outside of the United States. As of December 31, 2018, the company had 40 pending patent applications globally, including 20 in the United States and 20 outside the United States. Their patents expire between November 2024 and November 2034.

It is worth mentioning that Silk Road Medicine *"established a holding company, NeuroCo, Inc., to hold certain intellectual property and to undertake certain research and development activities."*

On December 17, 2018, Silk Road Medicine and NeuroCo entered into an Agreement and Plan of Merger pursuant to which they acquired all assets, including the assignment of all patents, and assumed all liabilities of NeuroCo.

Also, Silk Road Medical claims: *"Many of our employees and consultants were previously employed at or engaged by other medical device, biotechnology or pharmaceutical companies, including our competitors or potential competitors. Some of these employees, consultants and contractors, may have executed proprietary rights, non-disclosure and non-competition agreements in connection with such previous employment. Although we try to ensure that our employees and consultants do not use the intellectual property, proprietary information, know-how or trade secrets of others in their work for us."*

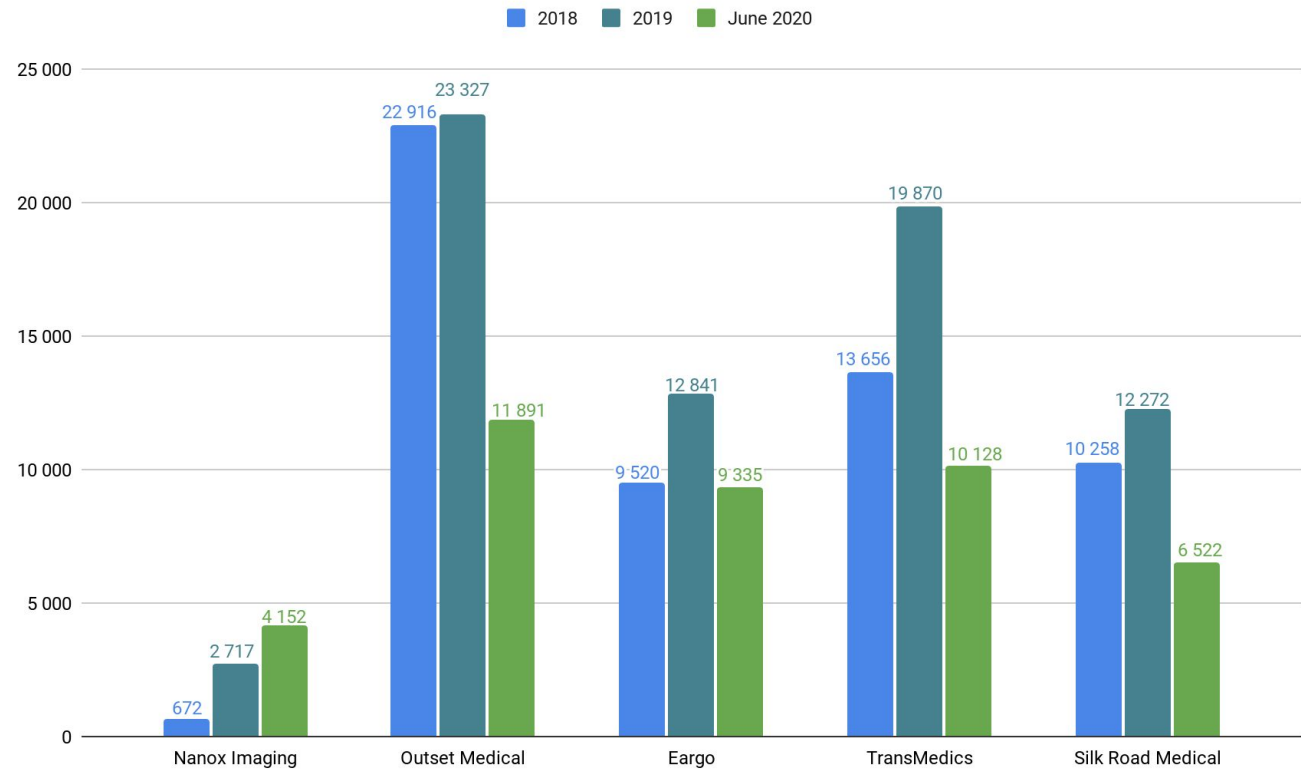
The company relies on a combination of contractual provisions, confidentiality procedures and patent, copyright, trademark, trade secret and other intellectual property laws to protect the proprietary aspects of their brands, technologies and data.

Source: [Silk Road Medical Prospectus](#)

Strengths <ul style="list-style-type: none">• Strong intellectual property portfolio, a long list of patent applications.• Overwhelmingly positive results of the TCAR Surveillance Project.	Weaknesses <ul style="list-style-type: none">• Increased operational overheads, possible cashflow risks.• Debts.
Opportunities <ul style="list-style-type: none">• Global market• Possibility to expand commercialization efforts and increase adoption of TCAR using our products, improve reimbursement for TCAR, and develop additional products.	Threats <ul style="list-style-type: none">• NeuroCo had had an access to intellectual property.• Cyber Attacks.• Company had a net loss of \$19.4 million, and \$37.6 million, respectively, and it's expected to continue to incur additional losses in the future. As of December 31, 2018, company had an accumulated deficit of \$139.1 million.

General Conclusions

Comparison data of R&D spendings: (\$ in thousands)



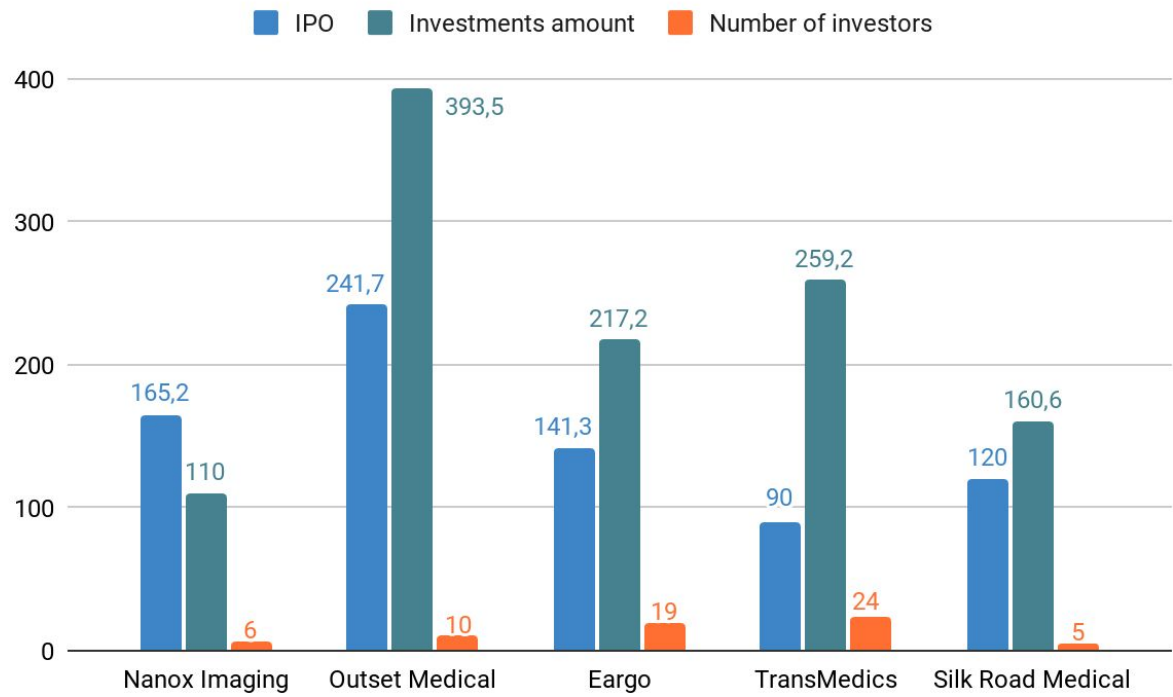
The growth in R&D expenses in the period from 2018 to 2019 increased by:

- Nanox Imaging 304%
- Outset Medical 2%
- Eargo 34%
- TransMedics 46%
- Silk Road Medical 20%

On average, the level of R&D expenditure for the medical device companies was \$157 million and just over \$540 million for the Big 100 (2018).

Total medtech R&D spending is seen growing by 4.5% to hit \$39 billion by 2024.

Comparison of Investment Rounds: (\$ in million)



From the total funding amount IPO amounted to:

- Nanox Imaging 60%
- Outset Medical 38%
- Eargo 39%
- TransMedics 26%
- Silk Road Medical 43%

Average investment amount per investor:

- Nanox Imaging \$ 18,3 M
- Outset Medical \$ 39,4 M
- Eargo \$ 11,4 M
- TransMedics \$ 10,8 M
- Silk Road Medical \$ 32,1 M

We have reviewed the 5 promising and impactful technologies in the medical device industry, and conducted assessment of the respective companies **Nano-X Imaging, Outset Medical, Eargo, TransMedics, Silk Road Medical** – all in the active development period of their existence and following recent IPOs in 2019-2020.

It is clear that the technologies reviewed and outlined in this report possess substantial value proposition to healthcare, and are of great potential impact on the global scale.

All the reviewed companies, in our opinion, possess strong R&D bases, have well-developed level of know-how and intellectual property, favorable growth drivers, and large total addressable markets for their products and services. The selected companies have strong innovative components and long histories of scientific or technological research, which give them tangible competitive edge in gaining market shares and positioning their brands on the global scale.

In the case of Nano-X Imaging, the company went to the initial public offering (IPO) in August 2020 without a commercially-ready product, having a prototype and validated technology. They have become a target for aggressive short-selling following the IPO as a result. Shortly after, in December, the company publicly demonstrated the product and its commercial readiness, thereby supporting its strong position and cementing perceived value of the assets and company attractiveness for the public market long trade practitioners.

We believe that these 5 promising, advanced and potentially disruptive technologies in healthcare, and 5 companies which are developing them, will provide substantial impact on healthcare industry and will help patients and consumers around the world. Besides, we also consider these 5 companies to be well-balanced, strong, and well-positioned enough to successfully implement product development and commercialization strategies, and achieve prominent growth dynamics.

DISCLAIMER

Our research institute does not have any direct or indirect relations with any of the parties mentioned in this document, any of its employees, affiliates, directors, partners, founders or suppliers. We do not hold any shares of companies mentioned in the document, either directly or indirectly and have no options, warrants, long or short positions in their equities or its derivatives. Our research is an independent review with no financial or other benefits to be derived from its publication. The information and opinions in this report were prepared by us as an independent organization. Though the information herein is believed to be reliable and has been obtained from public sources believed to be reliable, we make no representation as to its accuracy or completeness. Hyperlinks to third-party websites in this report are provided for reader convenience only. We neither endorse the content nor are responsible for the accuracy or security controls of these websites. This report is provided on an independent basis and should not be deemed as a recommendation to buy or sell any stocks.

CONTACT US

www.deep-pharma.tech
info@deep-pharma.tech