

Unlocking the life sciences potential

Key drivers to fully harvest the life sciences sector potential in the Netherlands

Realizing value series

There's an opportunity for the Dutch life sciences sector to maximize its contribution to global drug discovery, manufacturing and distribution by increasing funding, transforming research and development (R&D) and by more fully embracing this vital sector. With an educated and skilled workforce, strong infrastructure and a high standard of living, the Netherlands has the potential to become a life sciences powerhouse.

Dr. David Ikkersheim

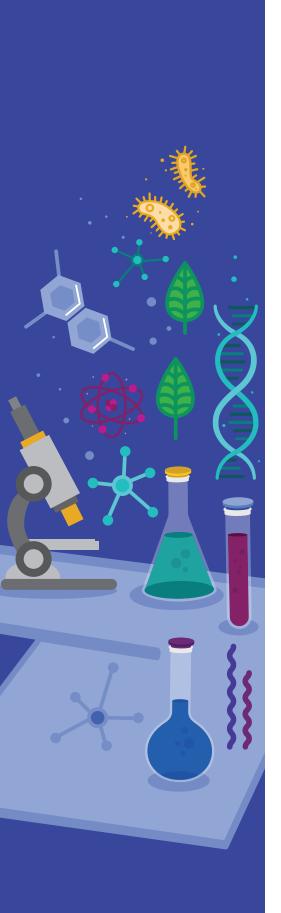
KPMG in the Netherlands

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Introduction

The life sciences sector in the Netherlands has experienced steady growth, but has some hurdles to overcome.

Life sciences contribute to arguably our most important asset: health, by discovering and producing solutions for preventing and curing diseases. And its global scope means the benefits can be spread to citizens worldwide. Yet life sciences is only the 9th largest sector in the country, contributing just 0.7 percent of gross domestic product (GDP). 1,2,3

The Dutch life sciences sector has shown consistent annual growth of approximately 4 percent since 2010, and is worth around €6 billion to the national economy in terms of 'gross value' (0.7% of GDP).^{4,5} Recent success stories include the rising biotech company Galapagos, Philips' evolution into a major medtech player, and the relocation of the European Medicines Agency (EMA) to Amsterdam. We have also seen the launch of several stimulation initiatives, an example being PharmaInvestHolland – a public-private partnership to attract R&D investment.⁶

Despite these exciting developments, the sector is still relatively modest in size, but has ambitious goals for further growth. HollandBio, the country's biotech industry association, has established a blueprint, which, if successful, will by 2030 create an ecosystem of more than 1,200 companies and 60,000 workers, with 350 clinical products in the pipeline and 30 high-quality products in the market.⁷

To reach this goal, the Netherlands (NL) should leverage its infrastructure, high density research footprint and strong position in key fields such as oncology, cardiology, immunology and neurology.

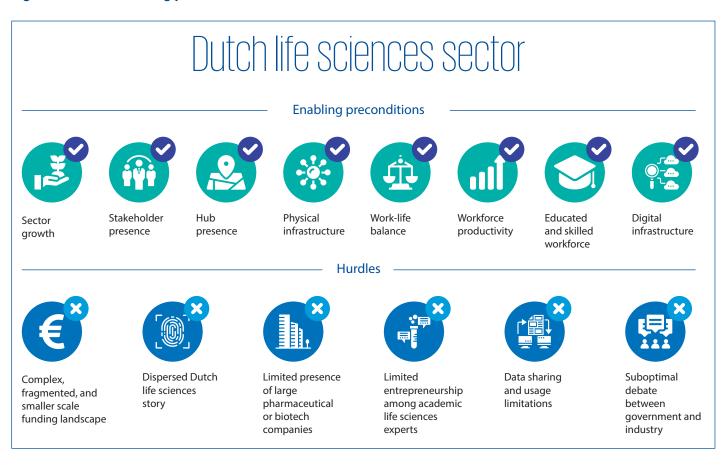
Although these capabilities fulfill all the preconditions of a life sciences hub, the sector needs to tackle several challenges in order to unlock its full potential:

- 1. A complex, fragmented and relatively small-scale funding landscape
- 2. Limited entrepreneurship among academic life sciences experts
- 3. Limited presence of large pharmaceutical or biotech companies
- 4. A dispersed life sciences story
- 5. Limitations in sharing and usage of data
- 6. Suboptimal debate between government and industry

Overcoming these hurdles calls for increased funding and a transformation of R&D. It also requires the willingness of government, academia and society at large to embrace the life sciences industry and recognize its huge potential as a force for good, both in terms of human wellbeing and economic prosperity.

This paper first considers the current enabling preconditions and hurdles, as well as the relevant trends that will impact the Dutch life sciences sector. We then look ahead to 2030, and imagine the Netherlands as a leading life sciences player, outlining the broad steps to reaching this objective.

Figure 1. Current enabling preconditions and hurdles for the Dutch life sciences sector



This publication is aimed at sector experts from industry, start-ups, governmental and financial organizations. The obtained input from the sector experts is enriched with the outcomes from desk research.

The Dutch life sciences landscape

There are currently many underlying strengths and hurdles to overcome.

The Netherlands provides fertile ground for life sciences innovation and is well-positioned for further advancement, as a home to many different players with healthy annual growth. However, there remains huge unfulfilled potential.

For me context is the key – from that comes the understanding of everything.

- Kenneth Noland (Painter, 1924-2010)

Between 2010 and 2016, the Dutch life sciences sector grew by approximately 25 percent in terms of 'gross value added' - an annual average rate of 4 percent.8 According to EMA projections, the number of people working in the industry is set to double from 30,000 to 60,000 in the next 5-10 years.9 However, despite these optimistic figures, life sciences remains the smallest of the nine designated 'top sectors' in the Netherlands.10

When you compare the Netherlands to Belgium and Switzerland – countries with similar regulatory regimes and business conditions and modest-sized populations - the latter two have significantly more pharmaceutical companies and workers per capita. Switzerland in particular outscores the Netherlands on virtually every area of the industry, whether it's biotech or medtech presence, clinical trials, patents, European market share or contribution to GDP.11

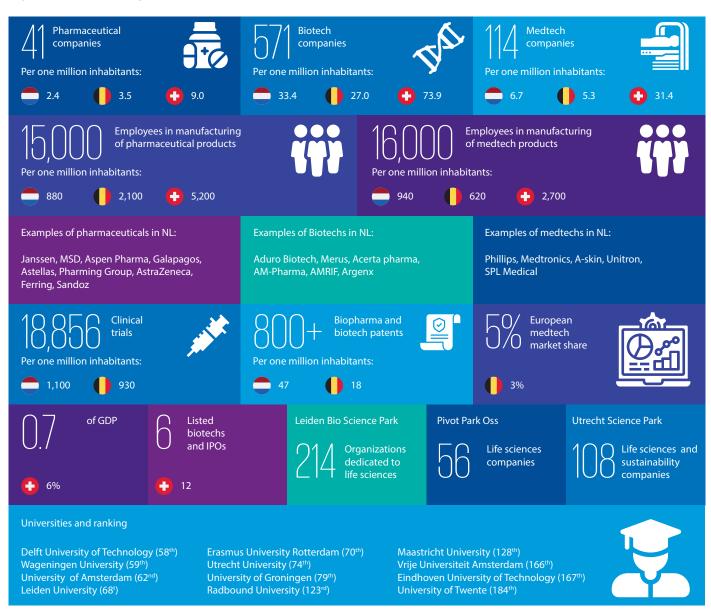
A variety of stakeholders but a lack of manufacturing and major players

The Netherlands is home to 726 life sciences companies, of which 571 are biotech, 114 medtech and 41 pharmaceutical businesses, reflecting the country's strong biotech credentials. 12 Most of these companies focus on research and commercial activities and there are relatively few manufacturing facilities. To date, major global pharmaceutical and biotech companies have not chosen to place their headquarters in the country. One shining exception is medtech, where the success of world player Philips has led to a strong ecosystem developing in the Amsterdam/Eindhoven area.

Emerging life sciences hubs

The majority of Dutch life sciences companies are situated in Eindhoven and the Randstad region (Amsterdam, Rotterdam, The Hague-Leiden, and Utrecht). Their presence has led to the emergence of three important life sciences hubs - Utrecht Science Park, Pivot Park Oss, and Bio Science Park Leiden – in which companies and research institutes co-locate their facilities. These networks provide the opportunity for close cooperation by sharing facilities and knowledge and jointly attracting talent within the ecosystem. Hubs also individually promote and market their potential benefits.

Figure 2. Facts and figures from the Dutch life sciences sector (2015 to 2019)^{13,14,15,16,17,18,19}



Sound preconditions

A competitive workforce and excellent infrastructure.

High quality, accessible education is an acknowledged national strength, with the Netherlands well placed in a number of global league tables. It ranks 9th out of 40 countries for student skills in the Organisation for Economic Cooperation and Development's (OECD) Better Life Index²² and 9th out of 119 nations in The Global Talent Competitiveness Index compiled by INSEAD Business School.²³ In addition, the 2018 World Talent Ranking from research specialist IMD places the Netherlands 5th out of 60, acknowledging its ability to develop local talent and attract people from around the world.²⁴ Life sciences benefits from such depth of talent in the form of an excellent academic research infrastructure, with a particular focus on translational research in oncology, as well as cardiovascular, immunology and neuroscience.25

The Netherlands has an outstanding reputation for productivity, ranking 6th in the world on the World Economic Forum (WEF)'s Global Competitiveness Index, reflecting efficiency in both the workplace and in capital investments, across many industries.26

And this has been achieved without excessive working hours, with the country coming top of the world when it comes to work-life balance, according to the OECD Better Life Index.²⁷

The overall quality of the Dutch road, railroad, and air transport infrastructure is ranked among the very best in Europe,²⁸ while the Netherlands is also a frontrunner in digital infrastructure. It is home to the world's biggest data transport hub, the Amsterdam Internet Exchange, and offers near 100 percent 4G coverage.29



Educated and skilled workforce.

7th & 8th place worldwide in attractiveness to highly skilled workforce and student skills



Workforce productivity.

3rd place worldwide in workforce productivity



Work-life balance.

1st place worldwide in worklife balance



Physical infrastructure.

High quality road, railroad, water and air transport infrastructure



Digital infrastructure.

Home to the world's biggest data transport hub and 98% 4G coverage

Six hurdles to overcome to accelerate Dutch life sciences

What will it take for the sector to truly fulfill its potential? We spoke to a number of leaders at start-up, industry, financial and governmental organizations within the life sciences industry in the Netherlands. Their responses, along with KPMG professionals, identified six key hurdles to clear.

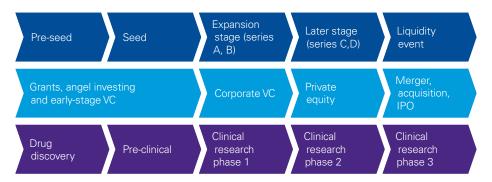


Hurdle 1:

Complex, fragmented, and smaller-scale funding landscape

Historically, public and private capital has been readily available in the Netherlands, with a primary focus on pre-seed, seed and expansion (and sometimes later) stages (up to approximately €50 million). However, life sciences companies often look internationally for funding, especially in later stages, as Dutch investors typically lack scale for late-stage investments.

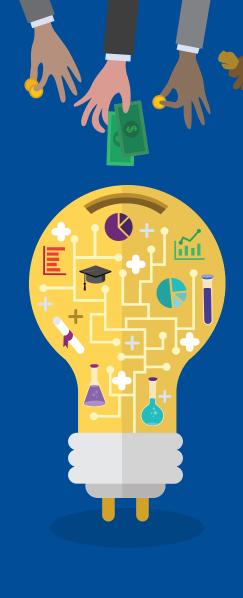
Figure 4. Schematic (simplified) representation of the relationship between investment stages, investment types and the drug development process^{30,31,32,33,34}



For each of the different investment stages there is potential to improve the funding landscape.

Pre-seed and seed stage. increase public funding to address lack of

scale: These investments primarily rely on public funds or angel investments. According to our interviewees, the risk appetite of Dutch angel investors is relatively low compared to other countries – especially the US. Add to this the limited number of high net worth individuals, and the availability of funds is modest. Public funding in the Netherlands is often provided in the form of loans, making start-ups less attractive for future rounds of financing, as investors generally are less inclined to fund debt-laden businesses. Countries like Belgium, for example, often use other forms of public funding such as grants, which generate better balance sheets and therefore greater willingness from investors to participate in subsequent financing rounds.



Furthermore, there may be an opportunity to increase coordination and selectivity in the selection process of start-ups awarded public funding, in order to increase the level of investment for each start-up, increasing the chances of longer-term success.

Expansion and later stage - attracting specialist VC and PE players from Europe and beyond: In these stages, investments often come from venture capitalists (VC) or private equity firms (PE). Although the Netherlands does have some strong specialist life sciences PE/VC players – such as LSP and Gilde Healthcare – investment by generalist VCs and PEs in the Netherlands appears to be limited, due to lack of sector knowledge. Furthermore, the ticket size per investment in later phases often exceeds €50 million - a sum beyond the reach of most Dutch investors. Indeed, the total pool of private life sciences funding in the Netherlands has been quite limited. For example, 13 larger Dutch VCs and PEs active in life sciences invested €134 million on average annually between 2015 and 2019 (see figure 5).35 This makes a single company investment exceeding €50 million a risk that most Dutch life sciences investors are unable to take, as they seek diversified portfolios rather than sinking all their funds into one sector/business. Figure 6 provides an overview of investments in the Dutch/Flemish company Galapagos, giving an example of the limited funding that has been raised in the Netherlands.^{36,37} However, there are signs of potential for larger ticket funding, as demonstrated by biotech company AM-Pharma which raised €116 million, mainly from three Dutch investors. LSP, Gilde Healthcare and Forbion.³⁸

Liquidity stage - balancing US funding power with a continued European presence: During this phase, funding is typically raised via mergers, acquisitions or initial public offerings (IPO). A merger or acquisition often leaves businesses in the hands of foreign companies and moves activities abroad. From a marketing and valuation perspective, IPOs via US stock exchanges (such as the NASDAQ) are considered more appealing than European exchanges.

A study into average volumes raised on the NASDAQ and European stock exchanges by European biotech companies showed that NASDAQ-listed companies raised on average six times more capital than their counterparts listed on European stock exchanges.³⁹ Consequently, in 2018 only a handful of biotech companies went public in Europe, while nearly 60, including companies originating in Europe, went public in the US.40 Registration at a foreign stock exchange is often followed by a focus shift or move of activities towards that country, weakening the domestic life sciences sector. US investors are typically interested primarily in US market activities (clinical trials, approvals, sales, etc.), and are attracted by the higher prices (and therefore margins) for pharmaceuticals in the US vis-à-vis Europe. As an example, following its IPO on the NASDAQ in 2014, UniQure moved its trials and manufacturing facilities to the US.41,42 Being listed on a US stock exchange also eases the path to acquisition for US based companies, 43 with the fast acquisition of Solexa (UK) by Illumina (US) a few months after its IPO on the US NASDAQ, being a good example.44,45

Across the different stages of the investment **continuum:** Stringent legislation and relative lengthy regulatory processes hamper the attractiveness of the Dutch life sciences sector for investors.

- Stringent legislation. A recent example that too strict regulation can lead to the exodus of companies is the example of gene therapy companies such as Orca Therapeutics⁴⁶ and UniQure.⁴⁷ These companies left the Netherlands due to the Dutch government applying European environmental legislation more strictly than other European countries.
- Relatively lengthy regulatory processes. The process from preclinical research to market registration takes approximately 10 to 16 years. Research shows that this process could be shortened by at least one year in the Netherlands by eliminating regulatory inefficiencies.⁴⁸

Figure 5. Funds raised by top Dutch-based life sciences focused investors between 2015 and 2019⁴⁹

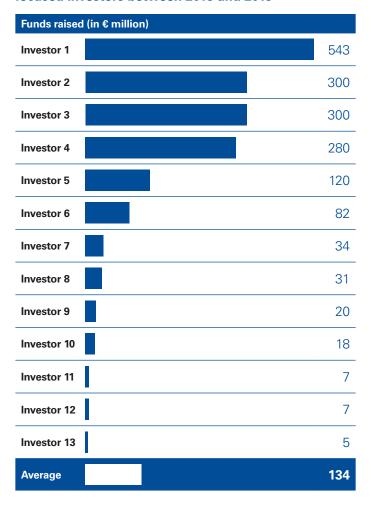


Figure 6. Overview of funds raised by Galapagos since its founding⁵⁰

Year	Funds raised (in € million)	Description	
1999	-	Founded	
2002	23.3	Private placement in NL	
2003	22.3	IPO. Euronext Brussels	
2007	4.4	Equity investment by GSK	
2013	279.0	IPO. Nasdaq (US)	
2019	1,110.0	Gilead equity investment	



Dutch life sciences is a 'high-density' sector, with a lot of activity within a 100-kilometer radius. However, despite these favorable geographic conditions, the industry is dispersed and fragmented compared to other countries and regions. Life sciences hubs such as Leiden, Utrecht and Oss often seem to compete with each other, rather than work together on collective positioning and marketing on a global scale. Additionally, most Dutch provinces have their own life sciences policies and investment agencies aiming to attract start-ups and scale-ups to their provinces. Take, for instance, the North-Brabant province 2018-2022 execution program, which only covers provincial focus areas and solutions.

It is a similar story with the other nine provincial funding agencies, which had a total budget of €630 million in 2014.⁵¹ To receive funding, almost all agencies require a company and in some cases its suppliers to be based in the province, thereby limiting funding possibilities.^{52,53,54,55,56,57,58,59,60} As a result, the Netherlands undersells its potential to stakeholders abroad and is unable to compete with stronger and larger conglomerate hubs such as New York / New Jersey, or the BioHealth Capital Region consisting of Maryland, Virginia, and Washington D.C., both of which have stronger branding and are better positioned to attract investment.





Hurdle 3:

Limited presence of large pharmaceutical or biotech companies

Typically, headquarters of large pharmaceutical or biotech companies create an ecosystem of suppliers, start-ups and spin-offs, which helps to attract and retain talent and to further grow the life sciences sector. This phenomenon is widely seen in the US, where companies with a high market capitalization, like Pfizer, Merck & Co. and AbbVie, are driving strong growth in their national sector. Closer to home, Switzerland and Belgium house several high market-value companies, like Roche (Switzerland), Novartis (Switzerland), Janssen Pharmaceuticals (Belgium), and UCB (Belgium). Sector Sector

The Dutch high tech sector is a prime example of the catalyzing effect of having large headquarters in an ecosystem. The 'Brainport' region around Eindhoven contains the research HQ of multinational companies such as Philips, ASML and NXP, amongst others. Brainport is considered a leading hub for high tech companies, and is lauded as the chief contributor to the strong economic growth of the Eindhoven region.



Hurdle 4:

Limited entrepreneurship among academic life sciences experts

Compared to other countries, the Netherlands displays relatively limited entrepreneurship amongst its academic life sciences community.

- The country does not have a broader, national education strategy for teaching entrepreneurial skills.⁶⁵
- Dutch universities and research institutes generally value scientific
 publications over valorization. This is reflected in the universities' appraisal
 methodology, which judge scientists primarily on academic key performance
 indicators (such as the Hirsch index) and the amount of funds raised,
 instead of rewarding them for translating scientific findings into commercial
 propositions.
- Several interviewees mentioned the limited entrepreneurship training for biomedical post-doctorate scientists and researchers at Dutch universities and research institutes. They indicated limited peer-to-peer support in understanding business, including financing rounds and insurance, in comparison with other countries.



Data sharing and usage is becoming an essential prerequisite of a thriving life sciences sector. Countries like Sweden already link hospital data with citizen service numbers, and launched a 2025 vision for eHealth. The Netherlands lacks such a connection between hospital, population, and research data, limiting the ability to share data and generate population-level insights. Despite significant steps being made through nationwide initiatives, challenges such as data privacy (GDPR) and systems interconnectivity remain.66 Health-RI, a publicprivate partnership of organizations involved in health research and care which aims to integrate health data research infrastructure, states that privacy regulation is a major hurdle to fast implementation. 67,68



Hurdle 6:

Suboptimal debate between government and industry

Following a product launch, industry parties and the Dutch government often end up in public pricing discussions. These are frequently tense, involving public accusations and polarizing public opinion. A recent example is the introduction of Spinraza®, in which a 2 year-old child with spinal muscular atrophy became the face of a national conversation about pricing.69

While public discourse can help to get to the 'right' price, the current debate may involve unrealistic expectations. For instance, some stakeholders hope that the industry will move to full transparency about cost prices of an individual product. Given the for-profit purpose and demands from shareholders, such a step may be unfeasible. There will inevitably be a trade-off between the life sciences industry – which aims to gain a return on investment – and health providers eager to keep costs down. Total public healthcare costs are projected to rise above sustainable levels in the coming decades, partly (but not solely) due to a large influx of sometimes valuable but expensive new medicines. Price will therefore remain high on the agendas of policy makers.

In addition to the price debate, the Dutch Ministry of Healthcare is launching initiatives to set up magisterial preparations of patented products at scale, and/or to use instruments like obligatory licensing for products that are deemed too expensive. Such a development could lead to infringement of intellectual property (IP). This, along with the ongoing price debate, may deter companies from investing in R&D or manufacturing activities in the Netherlands. Whilst one could argue that both R&D and manufacturing activities are not done solely for the Dutch market (in fact the Dutch market is only ~2% of global value for most companies/products) and therefore the pricing debate should not affect such decisions, in reality it seems it does.

Of course, such dilemmas are not exclusive to the Netherlands and impact life sciences markets worldwide. But, they must be addressed head-on if the sector should grow.



already has a substantial footprint, with particular strength in research and early stage development, and in high-impact therapy areas such as oncology. The sector is growing rapidly and has produced numerous successful scale-ups, supported by the Netherlands' excellent physical and digital infrastructure and highly skilled life sciences workforce. However, from the expansion stage onwards, we see life sciences companies exiting the country, in large part driven by the six observations above. The following sections discuss ways to start tackling these significant and pressing hurdles, to enable the industry to fulfill its potential.

Looking ahead

Three key global trends are impacting the Dutch life sciences sector towards 2030.

Creating a flourishing life sciences sector is not just a local matter. All the various stakeholders need to be aware of and address global trends impacting the formation of a robust ecosystem. In this chapter, we outline the three trends we estimate to have the biggest possible impact on the Dutch sector by 2030.

The world as we have created it is a process of our thinking. It cannot be changed without changing our thinking.

- Albert Einstein



1. Technology and digitalization



2. Fast-changing **R&D** environment



Advanced technologies are increasingly being adopted within life sciences, especially within R&D. Examples are the use of machine learning to find data about antibody usage⁷⁰ or 3D printing of artificial organ material. Furthermore, innovations in cellular, gene, and tissue engineering are replacing existing methods in areas like animal toxicity testing.

Data science and analysis has become a critical capability - in particular to shorten the R&D process. Cloud-based platforms are becoming commonplace and ever more data is collected remotely via medical devices and used in clinical trials. One example is biopharma research specialist Parexel, whose patient sensor solution collects data during clinical trials via wearables, enabling research subjects to continue with their normal lives and ensuring researchers collect data in a real-world setting instead of a clinical environment.71

As new technology and digitalization transform the world of research, the Dutch life sciences sector should be proactive in creating data platforms and developing appropriate legislation to enable new solutions.

The speed of change in R&D is driven by an increased understanding of the molecular basis of diseases, including proteomics, genomics, and metabolomics, along with advances in and availability of relevant data. Such developments are accelerating the shift to personalized medicine aimed at smaller groups of patients.

Many of today's financial, business, and operating models are not geared towards a more personalized offering. To adapt, R&D teams must become fully patient- and consumer-centric (rather than product-centric). Dutch life sciences companies urgently need to foster cultures that embrace new technologies and new approaches to research, as described in KPMG International's R&D 2030 publication.72

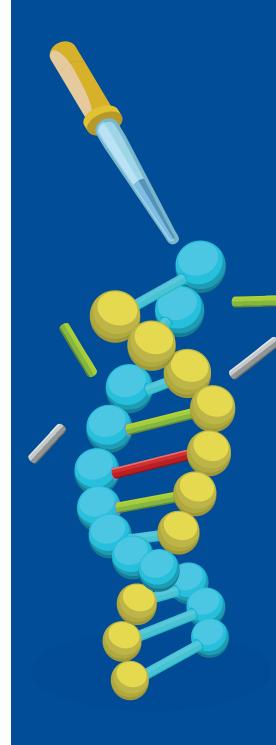


3. Pressure on return on R&D investment

Globally, the cost of bringing a product to market increased between 2010 and 2018 from €1,005 million to €1,950 million; in the same time period peak sales per asset declined from €734 million to €366 million. As a consequence, overall returns on R&D plummeted from 10.1 percent in 2010 to just 1.9 percent⁷³ – and some forecasts suggest they may fall further to 0 percent by 2020.74

Many life sciences companies' initial response was to reduce R&D through shared usage of certain capabilities. Industry and research parties are pooling their funds to rent specific technologies, talent and services from shared service providers. Crowdfunding has also emerged as a new way to distribute R&D risk.

As returns on R&D continue to fall, life sciences hubs with extensive shared research infrastructure and access to novel funding opportunities are likely to be better prepared for a more austere investment climate. It is, therefore, crucial that the Netherlands positions itself as such a hub.



The 2030 vision

A thriving life sciences sector will be one that makes the very most of the Netherlands' inherent strengths and overcomes the significant, but not unsurpassable, hurdles.

In this section we imagine the journey taken to achieve the 2030 vision.

What will a successful sector look like in 2030?

In the next decade, the sector will have continued its fast development to contribute 4 percent of GDP by 2030, a huge leap from 0.7 percent in 201675 and in line with other world leading life sciences economies like Switzerland (6 percent of GDP)^{76,77} and the US (4 percent of GDP). Major breakthroughs in conditions such as oncology and neuroscience therapies have made a hugely positive impact on the world's health. The Netherlands will be home to homegrown leading industry and research organizations, directly and indirectly employing over 60,000 people, meeting the goals set out by HollandBIO back in 2016.78 And three €10+ billion market value life sciences companies will be headquartered in the Netherlands, each creating an ecosystem of suppliers, spin-offs and start-ups around them across the entire industry's value chain. Partly supported by this entry of major players, the R&D landscape will have significantly improved, with an abundance of leading shared laboratories, a skilled workforce, and diverse financing opportunities.

Such rapid development will be the consequence of a sector-wide, long-term vision and goal alignment exercise, resulting in a 10-year outlook agenda (see figure 8) focused on.

Creating a life sciences data lake

Multiple stakeholders, including the Dutch government, academia, and industry parties will have collaborated to create a jointly funded data lake, combining data from biobanks, patient reported outcome measures, clinical research organizations, healthcare providers (from electronic patient records) and government.

With this resource in place, every patient in the Netherlands will contribute to a world of better health by sharing her or his data. The lake should place the Netherlands at the forefront of big data technologies and artificial intelligence (AI) in life sciences R&D, shortening the R&D process by more than 1 year and yielding increased return on R&D investment.

Eliminating regulatory inefficiencies

Eliminating the regulatory efficiencies as previously described on page 8 will have helped to shorten the average R&D process by another year.79.

Stimulating public-private partnerships

The roll-out of public-private partnerships between universities and industry will have played a big role in realizing the 2030 vision. Currently existing collaborations – for example OncoXL, in which both private and public parties perform fundamental and translational oncology research – will fully flourish. OncoXL would be closely aligned with the Dutch 10-year outlook agenda, with access to the life sciences data lake, leading research infrastructure, a global pool of research talent, and expansion and late-stage funding for successful initiatives.

Stimulating entrepreneurship

In addition, government, research institutes, and industry parties will have jointly initiated the Dutch Entrepreneurship Life Sciences (ELS) initiative, a program to develop talent and further stimulate entrepreneurship among academic and business professionals. All life sciences university programs will offer entrepreneurship courses, while universities and academic medical centers will agree new incentives and goals for their scientific staff, focusing on both academic excellence and commercialization of scientific breakthroughs.

Creating a transparent process for market access to higher-cost medicines

Although price pressure will continue, the heated moral discussion will have come under control by 2030, with each stakeholder appreciating the role and incentives of the other. Government and industry parties will have jointly formulated a transparent market access process for higher-cost medicines and refrained from polarizing public debate around the accessibility of expensive therapies.

Increasing available funding capacity and the variety of funding channels

As its life sciences sector grows, more and larger VCs will target the Netherlands. In addition, new investment vehicles, such as social bonds, will have gained in popularity. Dutch life sciences parties will increasingly choose to IPO via the Dutch stock exchange rather than abroad. Finally, public funding of R&D will have risen, as the government fulfills its pledge to increase available funds for life sciences.

Figure 7. The journey to a fully flourishing Dutch life sciences sector by 2030



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Steps towards the future

There are three steps to take towards a flourishing life sciences sector by 2030.

Of all the objectives in the 2030 vision, arguably the most important is to grow start-ups into three established life sciences companies with an annual revenue of at least €10 billion.

Such an achievement would signal the arrival of a major ecosystem able to compete on a global scale.

We see three key factors in realizing the overall 2030 vision:

- 1. Increasing available funding
- 2. Transforming R&D
- Embracing the life sciences sector



Increasing available funding

Funding is a virtuous circle. As the sector grows in size and reputation, it will attract more finance and a wider variety of funding channels. A number of steps can help meet this goal.

Define a country-wide ambition, supported by a longterm agenda and commitment from all stakeholders

As we discussed on page 2, the likes of HollandBio have already put together some system-wide goals, 80 but so far this has not yet led to a sector-wide focus - nor to a joint commitment on actions.

Figure 8. Steps to take towards a fully flourishing life sciences sector by 2030

Life sciences sector 2030

The key factor is the presence of three life sciences companies each with an annual revenue of more than €10 billion.



Increasing available funding



- Define a country-wide ambition, supported by a long term agenda and commitment from all stakeholders
- Create a strong brand for the Dutch life sciences sector
- 3. Develop and roll-out new financing vehicles
- 4. Increase public expenditure on life sciences R&D



Transforming R&D

- Realize a life sciences data lake
- 2. Eliminate regulatory inefficiencies



Embracing the life sciences sector



- Create a transparent process for market access of expensive medicines
- Form a life sciences ethical committee



A clear vision and agenda, agreed by a committed stakeholder community, should encourage investors and raise the risk-appetite of funders.

It is therefore encouraging to see the Dutch Ministry of Economic Affairs' planned national action program, 'New opportunities for the Dutch Life Science sector', which aims, amongst others, to create a national agenda jointly with all stakeholders for future growth of the industry.81

A good archer is known not by his arrows but by his aim.

-Thomas Fuller (Historian, 1608-1661)

Create a strong, single brand for Dutch life sciences

In the current, dispersed environment, each of the country's life sciences hubs is trying to compete alone. Pooling their resources would greatly enhance the chances of a strong, international brand. One recent, promising example of joint positioning and marketing is the economic mission of the Netherlands Enterprise Agency to Boston in July 2019.82 The Dutch life sciences sector presented itself as one brand and signed a memorandum of understanding with the state of Massachusetts, to kick off an international partnership aiming to jointly advance the Dutch and Massachusetts life sciences ecosystems.

Develop and roll-out new financing vehicles

Social bonds are a relatively new and promising form of financing vehicle, offering a variable rate of return based upon the achievement of specific social outcomes. For life sciences products, one social outcome could be increased quality adjusted life years (QALYs). As of June 2016, 60 social bond-financed projects had been launched in 15 countries.83 An example is the Philips' Sustainable Innovation Bonds which "focus on socially-beneficial innovation in healthcare, focusing on the Quadruple Aim of improved patient experience, better health outcomes, improved staff experience, and lower cost of care which together contribute to financially sustainable care.84 The first issuance of such bonds yielded €750 million in capital.85

Increase public expenditure on life sciences R&D

Such a stimulus should have a catalyzing effect by creating a more highly-skilled workforce, more spin-offs and more research infrastructure, which in turn can make the sector more attractive to private investors. The table below (which looks at the sciences as a whole) shows how greater public funding for R&D is generally accompanied by increased private funding.

Figure 9. Comparison of public and private R&D expenditure86

	Total R&D expenditures as a % of GDP	Publicly funded R&D as a % of GDP (relative to Dutch % of GDP)	Privately funded R&D as a % of GDP (relative to Dutch % of GDP)
The Netherlands	2.0	0.72	1.01
Denmark	3.0	0.86 (19%)	1.79 (77%)
Germany	2.9	0.86 (19%)	1.90 (88%)
US	2.7	0.89 (24%)	1.60 (58%)
UK	1.8	0.54 (25%)	0.82 (19%)

Note. Other sources of R&D funding, next to public funding and private funding, are higher education, private non-profit, and foreign funding.

Transforming R&D

The sector is evolving from blockbusters towards personalized offerings, and from trials in a clinical setting towards real-world data collection. At the same time, return on

R&D investment is nearing zero. In order to have a thriving R&D environment by 2030, the individual players in the Dutch life sciences sector need to transform the way they approach R&D in line with emerging trends. This calls for two key actions.

Realize a life sciences data lake

The most important action is the harmonization of data linkage and usage. Linkage increases data availability, making more real-world, evidence-driven research possible, and thereby adding value to the research process. As the example on this page shows, Sweden is a good example of how data linkage can be realized through a coordinated public-private effort.87 Health RI is a collaborative Dutch healthcare industry group that aims to develop a state-of-the-art infrastructure for data, samples and images. By supporting such initiatives, pharmaceutical and biotech companies can hasten the establishment of a data lake.

Eliminate regulatory inefficiencies

Such a step should shorten the R&D process and decrease required resources for R&D. To make regulation more efficient, all aspects of regulatory requirements in the R&D process should be periodically assessed by an independent party. An example of such an assessment is KPMG's research conducted for Dutch advisory body Actal (now ATR) in 2015,88 which showed how the R&D process can be shortened by more than a year in the Netherlands by eliminating regulatory inefficiencies.89



Sweden's success in data linkage and usage

In 2005, the Swedish Ministry of Education established the Committee for Research Infrastructures, tasked with creating a strategy for building a top-notch research infrastructure. The committee's work resulted in the Swedish Research Council's Guide to Research Infrastructure describing the necessary long-term conditions for the future development of the country's research. An expert group for Database Infrastructure was set up in 2006 to establish databases and develop effective tools for sharing research data. In addition, the Swedish National Data Service was set up in 2007, to perform more practical work like securing technical, administrative, legal and educational resources for the collection, storage, and reuse of research data. Furthermore, the government instructed the development of criteria for assessing the extent to which research data, fully or partially produced using public funds meet the FAIR Data principles (findability, accessibility, interoperability, reusability).

Embracing the life sciences sector

For Dutch life sciences to fully flourish by 2030, academia, government and society need to embrace the sector. Only then will the ecosystem be able to attract (and

retain) international top talent, the most promising startups, headquarters of renowned industry parties and, not least, investment. Three important steps can hasten such a shift.

1. Stimulate entrepreneurship in academia

Two important target groups have the potential to become entrepreneurs: scientists working in academia, and life sciences university students. There are a number of ways to foster their commercial acumen.

- Evaluate performance of scientific staff in academia not only on academic excellence (raised funds, h-index), but also on commercialization of scientific breakthroughs.
- Include entrepreneurship courses in the curricula of all life sciences university programs.
- Set up a national life sciences incubator (with international reach), similar to the successful Dutch technology incubator Yes! Delft.90

2. Create a transparent process for market access to expensive medicines

After market entry, industry parties and the Dutch government often end up in intense and extended pricing discussions that can polarize public opinion, and impact the image of the life sciences sector. A strict economic assessment process and smart procurement is acknowledged as leading practice, but should preferably be carried out in a harmonious, measured and pragmatic manner, to ensure constructive dialogue between government and industry.

3. Form a life sciences ethical committee

The current process of defining prices for medicines might be up for a fundamental refresh, to ensure a balance between funding and value. On one hand, healthcare insurers and government bodies negotiate to optimize medical healthcare value for every euro spent. On the other hand, life sciences companies aim to optimize revenue to fund R&D to discover new cures and meet shareholder expectations. Yet both parties are pursuing the same ultimate goal: to enhance the health and wellbeing of all citizens.

This joint, patient-centric goal is the cornerstone of creative solutions, which include value-based pricing, defaulting to generic medication at lower cost, and streamlining (procurement) processes to reduce inefficiencies.

The reality is that new treatments, and budget challenges, will always be with us, and payers and manufacturers will always seek to balance economic value with quality of life measures. To achieve broad support from society and industry, it is important to set agreed ground rules for the debate, encompassing medical and business principles to define the value of the intervention. Above all, the conversation should be led by ethics, and a national ethics commission could help provide wisdom, transparency and trust.

This commission can build on existing frameworks. For instance, the Advisory Commission Health Package (ACHP)⁹¹ of the Dutch Healthcare Institute already provides guidance on whether medicines are deemed to deliver enough increase in QALYs per euro spent. For severe pathologies, a maximum spending of 80,000 euros per QALY is deemed acceptable in the Netherlands. However, the ACHP does not employ a strict threshold with respect to euros spent per QALY. This subsequently leaves the door open for discussions in the political arena, often leading to healthcare expenditures exceeding the limit. While maximum price on treatments, backed up by politicians, could be one solution, the ethical commission could also investigate differentiation in thresholds.

This paper aims to unlock the full potential of the Dutch life sciences industry. By increasing available funding, transforming R&D, and embracing the life sciences industry, the Netherlands can overcome the identified hurdles and leverage the existing enabling preconditions towards a fully flourishing Dutch life sciences sector in 2030. This would allow the Netherlands to make a more substantial contribution towards a world of better health.

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