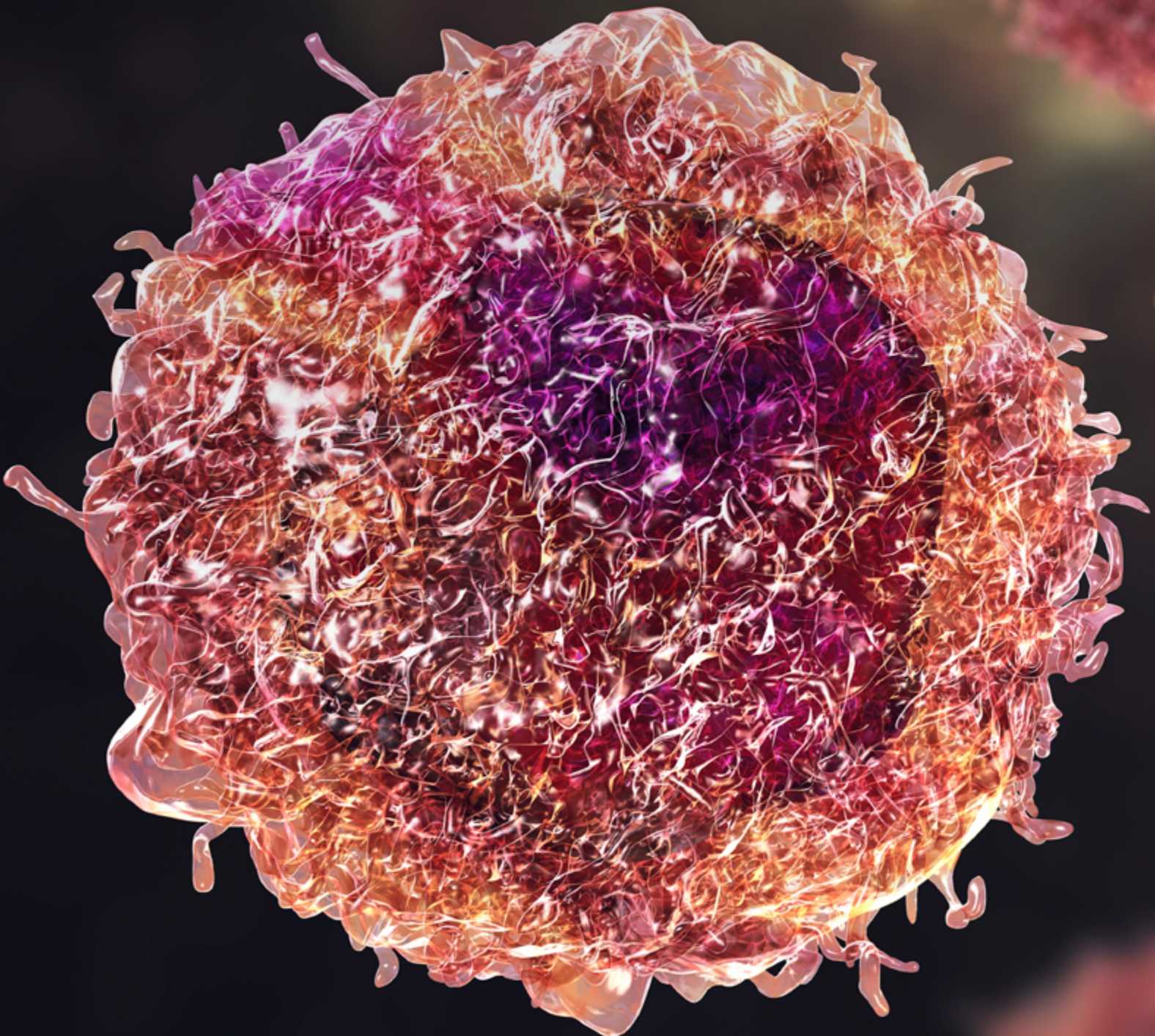


# EPO innovation case studies

OncoMark

May 2023



# Smarter prognostic tests for early-stage breast cancer

## Abstract

OncoMasTR is a multi-parameter prognostic test for early-stage breast cancer that can rapidly, accurately and reliably stratify patients into low or high risk of cancer recurrence. This aids clinicians confidentially determine the best treatment options, thus avoiding overtreatment with unnecessary and aggressive chemotherapies.

The test is based on patented technology that arose from a collaboration between Prof. Adrian Bracken at Trinity College Dublin (TCD) and Prof. William Gallagher at University College Dublin (UCD) in 2012 and was then exclusively licensed to OncoMark, a UCD spin-out, in 2014. OncoMark subsequently developed and validated the test which led to an acquisition of the company by a large US firm and the creation of a new start-up company.



Cepheid's GeneXpert platform, which will be used to deliver the OncoMasTR technology to the clinic



## A global problem

According to the World Health Organisation (WHO), there were 2.3 million women diagnosed with breast cancer and 685 000 deaths globally in 2020. Indeed, breast cancer is the most common cancer among adults, and it is the first or second leading cause of female cancer deaths in 95% of countries. In February 2023, the WHO released a new Global Breast Cancer Initiative Framework, recommending that countries implement early detection, timely diagnosis and comprehensive management of breast cancer to save 2.5 million lives from breast cancer by 2040.

While patient outcomes are consistently improving, the heterogeneous nature of breast cancer presents significant challenges for clinicians in determining disease

progression, especially when the disease is detected in the early stages. Approximately half of all new breast cancer diagnoses are in women with early stage, hormone receptor-positive and HER2-negative breast cancer<sup>1</sup>, and the majority are prescribed endocrine therapy in combination with chemotherapy following surgical removal of the tumour. However, chemotherapy may only benefit around 30% of women with early-stage breast cancer, while the remaining 70% may experience regression of the cancer without chemotherapy. Despite this, many women are still prescribed chemotherapy as a default treatment, even though it can have significant physical, emotional and psychological side-effects, only because it is currently quite difficult to determine a patient's risk of cancer recurrence.

## Founding OncoMark

Cancer biology, diagnostics and molecular therapeutics have always been central to the research interests of William Gallagher, Professor of Cancer Biology at UCD School of Biomolecular & Biomedical Science. His experience as a Marie Curie Fellow with Rhone-Poulenc Rorer (now Sanofi-Aventis) in the late 1990s sparked his interest in commercialising his research outputs. He started to consider setting up a spin-out company to address critical and unmet needs for cancer patients.

Steve Penny, who had previously worked in financial services and had joined Prof. Gallagher's lab as a mature student, shared this vision. Together they established OncoMark in May 2007, following participation in NovaUCD's Venture Launch accelerator programme, which provides academic researchers with the skills they need to set up a business, such as drafting a business plan, raising investment and IP protection strategies<sup>2</sup>.

<sup>1</sup> ER-positive, HER2-negative early-stage breast cancer is a common subtype of breast cancer. ER-positive means that the cancer cells have receptors for the hormone oestrogen, which can promote their growth. HER2-negative means that the cancer cells do not have an overexpression of the HER2 protein, which can also promote their growth.

<sup>2</sup> See <https://www.ucd.ie/innovation/researchers-and-students/venture-launch-accelerator/>



### Professor William Gallagher Co-founder of OncoMark

The company did not initially seek to raise investment via typical channels such as venture capital, but instead focused on grants available to SMEs under the European Commission's FP7 programme. Over the course of the following years, Prof. Gallagher, representing either UCD and/or OncoMark, was able to co-ordinate four Industry-Academia Partnership programmes in breast cancer, melanoma and prostate cancer, and one FP7 Collaborative Project programme focused on discovering new rationalised therapy options for difficult-to-treat subtypes of breast cancer. This use of the FP7 programme was quite innovative at the time: besides providing working capital, it ensured that the funding was not equity-diluting.

## The development of OncoMasTR

The OncoMasTR technology arose from a research collaboration between Prof. Gallagher representing UCD and Prof. Adrian Bracken, a leading expert in the field of cancer epigenetics<sup>3</sup>, representing TCD.

Prof. Bracken's research interests in understanding fundamental aspects of cancer cell biology complemented Prof. Gallagher's interests in translational cancer research. With Prof. Bracken as the lead Principal Investigator, they successfully applied for a Commercialisation Fund grant to Enterprise Ireland in 2012. Enterprise Ireland is an Irish government agency responsible for the development and growth of Irish enterprises in world markets and also funds academic

The involvement of Prof. Gallagher and OncoMark in these consortia had multiple benefits. The funding allowed the company to recruit researchers from across Europe and, growing to a team of 15 with expertise in oncology, it enabled OncoMark to establish its reputation as an innovative company and, importantly, facilitated the development of connections and networks with a pan-European range of academic institutions and companies in that field. The collaborations also opened up access to biobanks, which are large repositories of biological samples such as blood, tissue, urine and other fluids. These materials are collected from individuals with disease and they enable researchers to study the effects of new drugs and treatments on human biology and disease in a way that is both efficient and cost-effective. This would subsequently become important when validating OncoMark's future product, the OncoMasTR technology.

### TAKEAWAY

#### Research funding

Research grants can give more time and flexibility to develop technologies and leverage collaborations while at the same time preventing early dilution of equity in the spin-out company.

research projects with commercial potential. The objective of the project was to develop more accurate and reliable prognostic and predictive biomarkers to help both doctors and patients make better informed treatment decisions.

Using gene expression profiling, a technique which had been previously used to identify gene expression signatures found to correlate with different aspects of tumour progression, they succeeded in identifying "drivers" of cancer proliferation. When combined with additional biomarkers, these drivers had the potential to become a superior prognostic assay when compared to other pre-existing tests for early-stage

<sup>3</sup> Cancer epigenetics is the study of heritable changes in gene expression that are not caused by changes to the DNA sequence, but rather by alterations to the chemical modifications of DNA and histone proteins that regulate gene expression. Prof. Adrian Bracken was elected a European Molecular Biology Organization (EMBO) Member in 2021, having been nominated by Nobel Prize winner Thomas Cech, in recognition of his significant achievements in the field of life science research.

cancer. The inventors called this cancer proliferation signature OncoMasTR (derived from **O**ncology **M**aster **T**ranscription **R**egulators). The OncoMasTR test measures the expression of a number of prognostic genes, as well as reference genes, and estimates the probability of distant recurrence for breast cancer patients. This helps clinicians determine the best treatment options for their patients, avoiding the costs and severe side-effects of unwarranted chemotherapy.

#### TAKEAWAY

##### **Collaborate to innovate**

A research collaboration that brings together the diverse expertise and interests of multiple partners can lead to ground-breaking inventions with commercial potential.



Laboratory of OncoMark

## Commercialisation strategy

Recognising the commercial potential of OncoMasTR, Profs. Bracken and Gallagher submitted an invention disclosure to the technology transfer offices (TTOs) in TCD and UCD. Following review and consultation, the TTOs decided to file a joint priority patent application in the names of the two universities and in parallel signed a Joint Ownership Management Agreement (JOMA) to address issues such as the payment of patent fees and future revenue sharing. The joint patent application, for “A method for predicting risk of recurrence of cancer”, was filed with the EPO in 2014 ([EP3194621](#)).

The TTOs knew from experience the significant challenges in licensing diagnostic technologies to established companies at a low Technology Readiness Level (TRL) without supporting clinical validation data. One model to overcome this challenge was to license the technology to a spin-out company that could then secure the necessary investment to “de-risk” the technology by bringing it to a higher TRL and increase the potential for successful commercialisation.

Even before the patent filing, OncoMark had expressed interest in licensing the OncoMasTR technology. The company was a credible licensee from the perspective of the TCD and UCD TTOs as it was co-founded by Prof. Gallagher, who, in addition to being a co-inventor with expert knowledge of the licensed technology, was recognised as someone who had the drive and vision to bring research outputs to market. It was well-funded, had a strong research team, an extensive network of partners that could assist in clinically validating the technology and a strong advisory board comprising key opinion leaders. Importantly, the company had prepared a robust and comprehensive commercial plan that included external investment to support the development and validation of the technology. The proposed licensing of the OncoMasTR technology to OncoMark also had an additional benefit for UCD as it broadened the company's product pipeline, which could in turn increase the value of the company, thereby benefiting the shareholders, including UCD.

#### TAKEAWAY

##### **Spin-out to increase the TRL**

For university inventions, licensing the patented technology to a spin-out company can help increase the TRL and the probability of a successful commercial launch, as well as supporting the development of a long-term R&D partner.

Following negotiation and agreement of terms, the parties signed a licence agreement in December 2014, whereby TCD and UCD granted OncoMark a worldwide exclusive royalty-bearing licence, which included the right to sublicense the technology in all fields of use. The licensed technology included the patent application and related non-patentable technical information, which included an algorithm that was kept as a trade secret. The payment structure included a licence fee linked to the first sale of product, but was largely based on royalties of net sales, or net receipts in the case of sublicences. The agreed royalty rates reflected the stage of development of the technology and industry norms, and were based on a sliding scale linked to cumulative sales targets. In addition, the agreement allowed for royalty stacking, whereby the royalty rate could be reduced to a pre-agreed level in case OncoMark would have to license third-party IP to develop a product. The sublicense rates were also based on a sliding scale linked to cash investment in the licensed technology and structured in such a way that the sublicense payments to the licensors were high in situations where the licensee might seek to sell the company along with the licensed technology at an early stage of development, before the true value of the technology could be fully assessed.

Finally, OncoMark had the right to acquire the licensed technology five years following execution of the agreement, subject to reaching pre-agreed sales targets and provided the assignment fee was negotiated in good faith and reflecting fair market rates so as to be consistent with EU State Aid rules. In addition to the payment terms, the licence agreement included standard terms addressing a wide variety of issues, including rights to improvements, confidentiality, reporting, publication, infringement, warranties, liabilities, and termination provisions.

## Strategic patent prosecution

The TTOs elected to file the priority patent application with the EPO to take advantage of the comprehensive search report that is provided within the priority year. The EPO was also the preferred filing office, since it was clear from the outset that commercialisation efforts would target the European and US markets. OncoMark had responsibility for the prosecution of the application under the terms of the licence agreement and the application subsequently entered PCT the following year ([PCT/EP2015/071524](#)).

At the national/regional stage, OncoMark, in consultation with TCD and UCD, elected to validate the application in the major European markets and also to file in the US. In addition, the company took a strategic decision to file in other countries with a large addressable market and for which there existed a well-developed reimbursement system. Hence, the patent was also filed in Canada, Japan, Israel, New Zealand, and Australia.

## TAKEAWAY

### Patented IP is a key asset

Strong patent protection is an essential asset for a life science spin-out company in helping to secure initial investment.

While the claims in the granted European patent extend to a variety of cancers, the granted US patent is limited to a diagnostic of breast cancer. This difference in allowable claims between the EPO and the USPTO reflects the complexities arising from the 2012 US Supreme Court decision restricting eligible subject matter in the *Mayo v. Prometheus* case.<sup>4</sup> In an effort to overcome this limitation, Cepheid is pursuing two US continuation applications, one with broad claims that extend the patent to other cancers, and the second with additional claims in support of breast cancer.

## Securing investment and expertise

In 2014, OncoMark applied for funding under the EU SME Instrument to drive the development of the licensed technology. The SME Instrument formed part of the European Commission's Horizon 2020 suite of programmes with an objective to support high-risk, high-potential small and medium-sized enterprises and to develop and bring to market new products, services and business models that would drive economic growth. OncoMark and the OncoMasTR technology aligned well with the objectives of the SME Instrument, but while the company's application was favourably reviewed and scored well, it was not initially approved for funding. One contributing factor was that the evaluators considered that the OncoMark team at that point lacked commercial experience and a proven track record of bringing products to market.

At this same time, Des O'Leary, an industry veteran with over 25 years of experience in the diagnostic sector, was seeking to leverage his extensive commercial experience and explore opportunities with start-up companies. He started his career as a clinical biochemist in the 1980s before moving to industry in the early 1990s, where he held different roles in manufacturing, research and development. Most importantly, he spent 12 years with Biotrin, an Irish diagnostic company, where he rose to become its Chief Executive Officer and later General Manager of Diasorin Ireland.<sup>5</sup>

He joined Enterprise Ireland's Business Partner programme. This programme seeks to match individuals

with sectoral experience with spin-out companies to help them develop a business plan and then potentially take a senior management role with the company and raise investment. While he met with several companies, none of the opportunities really caught his interest. Fortuitously, he was introduced to OncoMark by his former boss in Biotrin, who was serving as a Board member of NovaUCD, the Centre of New Ventures and Entrepreneurs in UCD, where OncoMark was based. This introduction was timely. Dr Mairin Rafferty, who had been CEO of OncoMark since 2013 and had previously served as COO since 2009, was herself looking at other opportunities. As such, the company needed to recruit a new CEO and so Mr O'Leary and the management of OncoMark entered into discussions. Mr O'Leary was attracted by the commercial potential of the licensed technology. Concomitantly, OncoMark recognised that Mr O'Leary would greatly strengthen the identified gaps in the SME Instrument application given his extensive management and commercial experience in the diagnostics sector.

After Mr O'Leary joined the company as CEO in 2015, OncoMark immediately reapplied for the SME Instrument funding, this time successfully securing €2.7m in June 2015. At this stage, the company employed approximately 15 people, but they were predominantly researchers with little product development experience. Therefore, Mr O'Leary pivoted the company's strategy from research to product development and made a number of key hires to enable this. In addition, knowing the significant costs

<sup>4</sup> See A. Sasha Hoyt, "The Impact of Uncertainty Regarding Patent Eligible Subject Matter for Investment in U.S.", *Medical Diagnostic Technologies*, 79 Wash. & Lee L. Rev. 397 (2022).

<sup>5</sup> He led the development of the company's infectious disease portfolio, successfully securing CE marking and launching over 15 new patent protected diagnostic tests, two of which achieved FDA Pre-Market Approval including a test for Parvovirus B19 which captured 70% of the worldwide market. Following the 2008 acquisition of Biotrin by Diasorin, an Italian diagnostics company, he became General Manager of Diasorin Ireland, a position he held until he decided to pursue new opportunities in 2013.



required for the clinical validation, regulatory approval and launch of a product, he sought to leverage the SME Instrument funding to secure further investment. The proposition was attractive to investors, because not only was Mr O’Leary well known and respected within the investment community, but the potential of the licensed technology was also persuasive, and the SME Instrument funding was in the form of a grant without dilutive impact on the company’s equity. In 2017, the company successfully raised an additional €2.1m from a syndicate of Irish investors including Kernel Capital, Irrus Investments, HBAN MedTech and Enterprise Ireland to fund the transition of the test from clinical validation to regulatory approval and full commercialisation.

#### TAKEAWAY

##### Experienced senior management

The appointment of a commercially experienced CEO with relevant sectoral experience can be key to the company’s ability to raise investment and drive product development.

*“The OncoMasTR test is designed to enable a more personalised approach to patient care, helping clinicians to determine which patients should not receive chemotherapy, ultimately improving their quality of life.”*



Des O’Leary  
CEO at OncoMark

## Moving closer to the market

With the €4.8m in resources at its disposal and new hires, the company narrowed down the test from the initial 10-11 candidate OncoMasTR genes in the patent application to 3 prognostic genes and made steady progress in developing and validating the OncoMasTR test for breast cancer in accordance with the Clinical and Laboratory Standards Institute (CLSI) guidelines. In 2016, the company also applied for a word (TM12158EU01) and a figurative (TM12157EU01) trade mark for OncoMasTR.

In 2018, the OncoMasTR test was CE-marked under the CE-In Vitro Diagnostic Directive and three independent external clinical validation studies were initiated using specimens from over 2 000 women with ER-positive, HER2-negative early-stage breast cancer. Key conclusions from these studies indicated that OncoMasTR was prognostic for distant cancer recurrence and provided superior prognostic value when benchmarked against the “gold standard” Oncotype DX Recurrence Score (RS) which analyses the level of 21 genes that have been linked to tumour progression and response to treatment.

In parallel, the company initiated market due diligence and networking within the diagnostics sector. As part of the company’s due diligence efforts, Mr O’Leary and key members of his team attended the American Society of Clinical Oncology (ASCO) conference in Chicago in 2016. At the conference, Mr O’Leary actively sought to engage with potential partners and he initiated discussions with company representatives of Cepheid, a leading molecular diagnostics company headquartered in the US with over 2 000 employees that was established in 1996. While mainly known for its product lines in infectious diseases, sexual health and healthcare-associated infections, Cepheid did have tests for leukaemia, breast and bladder cancers. Wishing to broaden its oncology portfolio, the company had made a strategic decision in 2016 to expand its oncology business unit with a focus on urological and breast cancers. As part of this strategy, Cepheid was scouting for suitable opportunities.



**TAKEAWAY****Finding partners**

Attendance at medical and industry conferences is essential to keep abreast of market trends and to network with key stakeholders. Having a reliable network of collaborators can also greatly assist clinical validation.

This initial meeting was followed by a further meeting with senior Cepheid representatives later that same year. Coincidentally, Prof. Gallagher struck up a conversation with an Austrian oncologist whom he sat beside on a flight on his return from a major breast cancer conference in the US. It transpired that the oncologist acted as a consultant to Cepheid. On learning of Prof. Gallagher's research interests, and in particular the OncoMasTR technology, he indicated that the technology potentially would be of interest to Cepheid.

These interactions put OncoMark and the OncoMasTR technology firmly on Cepheid's radar. While it was important to Cepheid that patent applications had

been filed in support of the OncoMasTR technology in key countries, this alone was not sufficient to "close the deal". The company primarily wanted to see clinical validation. Thankfully, OncoMark did have the relevant data, having conducted initial clinical studies, leveraging its network of partners that had been developed during the previously referenced FP7 grants, and the validation data was persuasive enough for the parties to recognise the potential synergy of integrating the OncoMasTR technology with Cepheid's GeneXpert molecular diagnostics platform which aligned with Cepheid's strategy of extending its oncology portfolio.

**TAKEAWAY****Clinical validation**

For technologies related to diagnostics, clinical validation is often a prerequisite for partners to really consider the business opportunity. Partnering can be instrumental to achieve that at reasonable costs.

## Securing the deal

Ensuing discussions took place with the Danaher Group, Cepheid's parent company, on the acquisition of OncoMark over the course of 2017 and 2018. Ultimately, Cepheid chose to "de-risk" the deal by first investing in the company to fund a proof-of-concept study to demonstrate that OncoMasTR could be successfully integrated into Cepheid's GeneXpert platform. This led to a substantial investment offer from Cepheid and an option to acquire OncoMark at a future date and at a pre-agreed price as part of the investment terms.

Cepheid's investment offer posed a dilemma for OncoMark. Its own development and validation efforts had progressed very well. A number of key academic papers supported the use of OncoMasTR in predicting the risk of tumour recurrence in patients with early-stage node-negative breast cancer and the results of independent external clinical validation studies were positive. In addition, the company had successfully secured the CE mark for the OncoMasTR test, had agreed terms with a leading manufacturing partner and had developed labelling and packaging material in advance

of the product launch. However, Mr O'Leary knew the significant barriers associated with the launch of a new product, and the investment required to recruit a sales force necessary to access new markets and gain market share. Cepheid had an established diagnostics platform and a decentralised model with the US hospital system that would enable the quick adoption of the OncoMasTR test. The Board of OncoMark had to consider the pros and cons as to whether to have "a big slice of a small pie, or a small slice of a big pie". Ultimately, the Board voted to approve Cepheid's offer and OncoMark's own plans for a product launch were cancelled.

Using existing funding and bolstered with the new investment provided by Cepheid, OncoMark further validated the OncoMasTR test. The company initiated real-world, decentralised evaluations of the OncoMasTR test at a number of sites in Ireland and the Netherlands, which confirmed that the overall precision of the OncoMasTR test was high. The company also successfully completed the proof-of-concept study demonstrating that OncoMasTR could be successfully integrated into

Cepheid's GeneXpert platform. This provided Cepheid with the confidence to exercise its option and it acquired OncoMark in March 2021.



**Scott Campbell**  
Senior Vice President and  
General Manager,  
Oncology, Cepheid

*"A GeneXpert version of the OncoMasTR test is a very important part of our portfolio plan for breast cancer diagnostics and it has been a pleasure working with the former OncoMark team on this programme."*

Presently, Cepheid is completing further clinical studies in advance of a submission to the US Food and Drug Administration (FDA) for registration, with plans to launch the OncoMasTR test under the brand name Xpert Breast Cancer Insight. The impact of this product will be a more tailored treatment plan, based on the disease recurrence risk of an individual patient that will hopefully reduce the need for unnecessary chemotherapy with associated adverse effects for thousands of women diagnosed with breast cancer.

## Creating another business opportunity

In 2021, the founders and management of OncoMark chose to reinvest the money they realised from the sale of OncoMark and established a new diagnostic start-up company called OncoAssure. Based in NovaUCD, OncoAssure is developing new panels of cancer biomarkers for applications in prostate cancer, melanoma and other cancers. OncoAssure plans to create new employment opportunities and develop new prognostic tests, both through its own internal research efforts and also via collaborations with UCD, other academic institutions and companies. These different collaborations will potentially improve the quality of life of cancer patients and positively impact patient outcomes.

## MAIN PLAYERS INVOLVED

### Source of IP

William Gallagher

- co-inventor
- researcher of Cancer Biology in UCD and a former Director of the UCD Conway Institute of Biomolecular and Biomedical Research (2016-2021)
- co-founder of OncoMark
- Chief Scientific Officer of OncoAssure
- selected awards: 2019 Science Foundation Ireland (SFI) Entrepreneurship Award

University College Dublin and Trinity College Dublin

- collaborative research project resulted in the invention
- owners of the patented technology

### IP commercialisation

OncoMark

- company established in 2007 with headquarters in Dublin, Ireland
- products/services: OncoMasTR, a multi-parameter prognostic test for early-stage breast cancer
- market and technical area: research in cancer diagnostics
- acquired by Cepheid in 2021

Cepheid

- leading molecular diagnostics company, headquartered in the US
- investment in OncoMark and subsequent acquisition of the company in 2021
- preparing product launch of OncoMasTR under the brand name Xpert Insight Breast Cancer

OncoAssure

- diagnostic spin-off company founded in 2021

**Table 1: Relevant intellectual property portfolio**

### Patent families

No.	Title	Priority	Patent number
1	A method for predicting risk of recurrence of cancer	19.09.2014	EP3194621 <u>PCT/EP2015/071524</u>

Some of the EP applications listed are still pending and no decision to grant has been taken. Granted patents may also undergo an opposition or appeal procedure, in accordance with the procedures laid down in the European Patent Convention, which could limit the scope of protection of the patent. Legal events are published in the European Patent Register and can be accessed via [www.espacenet.com](http://www.espacenet.com) under legal status.

### Trade marks

No.	Title	Application	European Union Trade Mark (EUTM) number
1	OncoMasTR	20.12.2016	<u>016188278</u> <u>016188336</u>

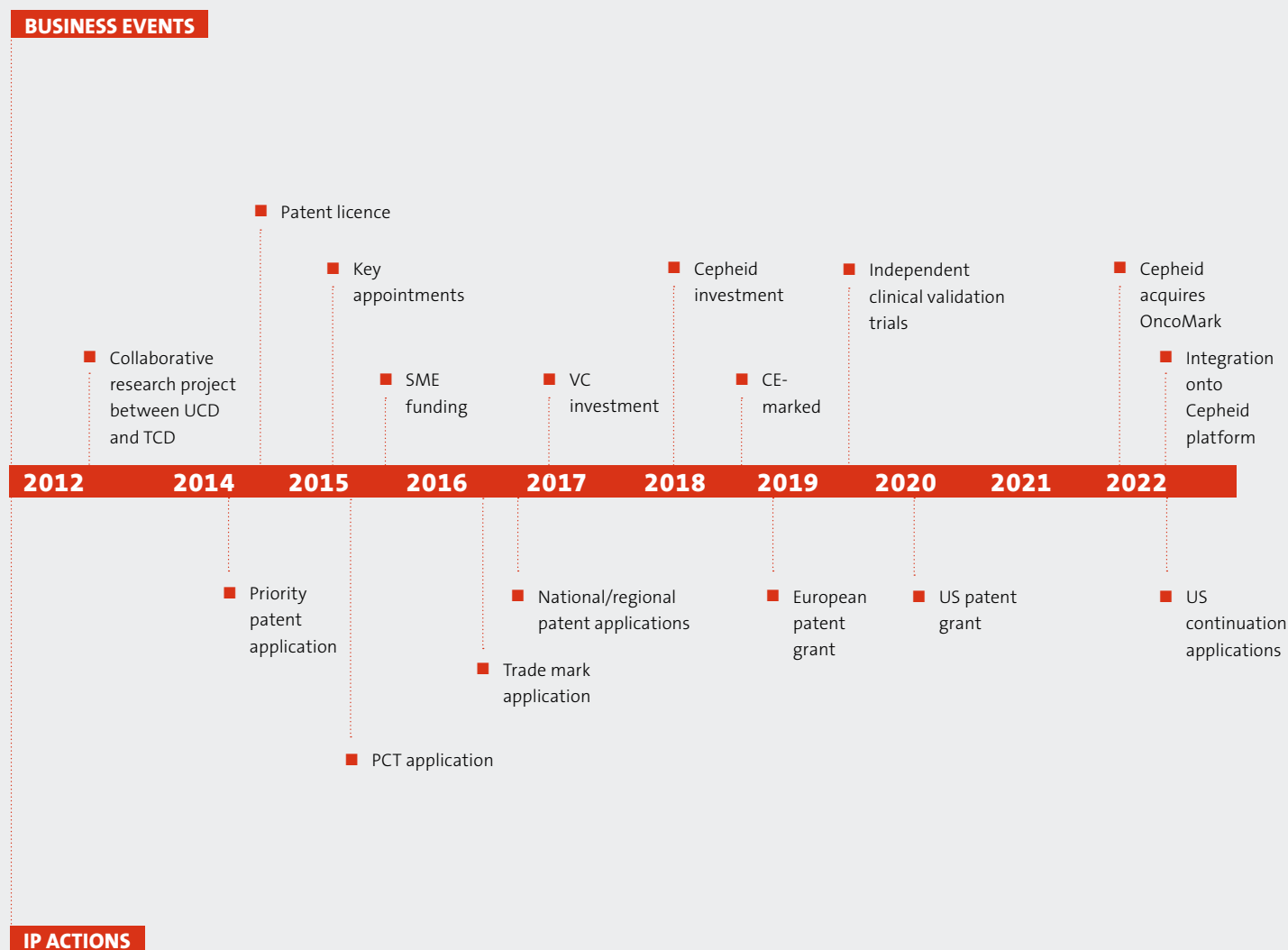
### Key dates and milestones associated with OncoMasTR technology

Year	Business events	IP actions
2007	OncoMark founded	
2012	Collaborative research project between UCD and TCD	
2014	Licence of technology to OncoMark	Original invention relating to the OncoMasTR technology was jointly filed by UCD and TCD at the EPO.
2016	Development of OncoMasTR by OncoMark. Training and verification of OncoMasTR assay was completed, with poster presentation of the data at the San Antonio Breast Cancer Symposium.  Further development and validation studies were conducted according to Clinical and Laboratory Standards Institute (CLSI) guidelines.	
2018	The OncoMasTR assay was CE-marked under the CE-IVD directive. Three independent external clinical validation studies were initiated, using specimens from over 2 000 women with ER-positive, HER2-negative early-stage breast cancer. Key conclusions: – OncoMasTR was significantly prognostic for distant recurrence (DR) in all three studies. – OncoMasTR provided superior prognostic value to Oncotype DXTM Recurrence Score (RS) in two of the studies. Cepheid and OncoMark begin collaboration discussions to develop a GeneXpert version of the OncoMasTR assay.	European patent granted and validation in several European countries.



2019	<p>OncoMark initiated real-world, decentralised evaluations of the OncoMasTR assay in Ireland and the Netherlands.</p> <p>Key conclusions from the beta-site testing and analytical validation indicated that:</p> <ul style="list-style-type: none"> <li>– overall precision of OncoMasTR was high</li> <li>– OncoMasTR scores were consistent across a &gt;100-fold RNA input range</li> <li>– OncoMasTR displays robust analytical performance and is potentially suitable for decentralised use</li> </ul> <p>Cepheid and OncoMark enter into a formal collaboration to develop a GeneXpert version of the OncoMasTR assay.</p>	
2020	<p>Cepheid assigns Xpert Breast Cancer Insight trade name to GeneXpert version of OncoMasTR assay.</p> <p>Cepheid demonstrates analytical equivalency of Xpert Breast Cancer Insight assay to OncoMasTR assay.</p> <p>Cepheid demonstrates the fidelity of risk score reporting between Xpert Breast Cancer Insight and OncoMasTR in characterised specimens.</p>	<p>US patent granted</p> <p>Cepheid filed two US continuation applications</p>
2021	<p>Cepheid demonstrates clinical equivalency of Xpert Breast Cancer Insight to OncoMasTR.</p> <p>Cepheid initiates real-world evidence and clinical validation studies for the Xpert Breast Cancer Insight prototype test.</p> <p>OncoAssure founded.</p>	
2022	<p>Integration of OncoMasTR onto Cepheid's GeneXpert platform.</p>	

## OncoMasTR technology – timeline



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