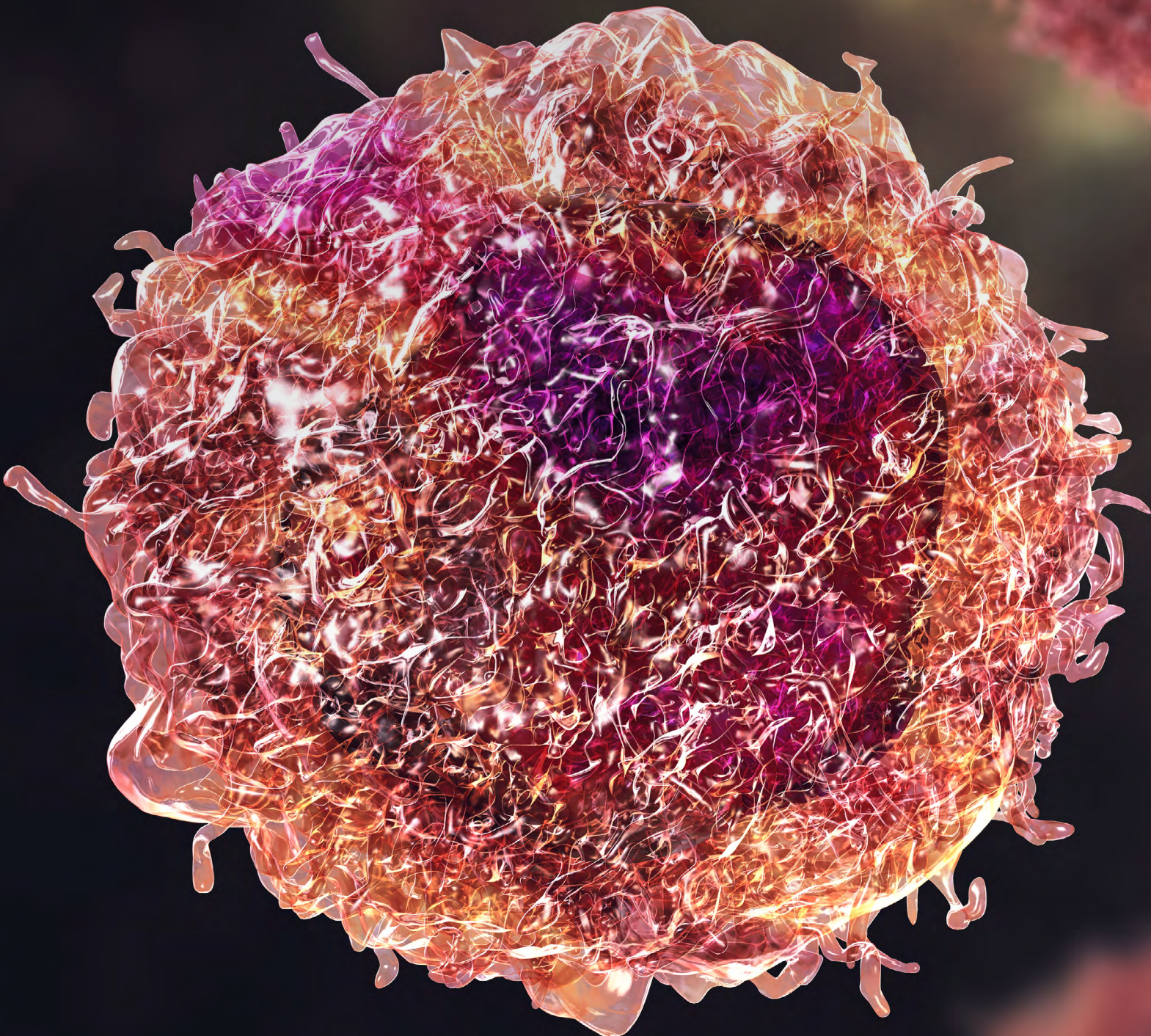


EPO innovation case studies

Damae Medical

May 2023



A new dimension to skin cancer diagnosis

Abstract

The company was spun out from Institut d'Optique Graduate School, Palaiseau, France in 2014 by a team of photonics researchers. They have taken a patented technology with applications in biological and medical imaging and used it to create a new medical device for real-time diagnosis of lesions from all types of skin conditions, including skin cancer.

The technology is a new advanced medical imaging system, which is protected by a suite of six patent

families and other IP rights. It is currently making a high impact in over 40 centres around the world including onco-dermatology clinics. Close collaboration with key opinion leaders in the world's top dermatology centres is driving new developments to provide dermatologists with artificial intelligence (AI) algorithms for diagnostic support.

Figure 1: Line-field Confocal Optical Coherence Tomography (LC-OCT) device – deepLive



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Founding Damae Medical

Damae Medical can trace its origins back to over 20 years of cutting-edge research in the field of optical coherence tomography (OCT) by Professor Arnaud Dubois and a patent application filed by him in 2013 for an invention relating to an optical tomography apparatus for the visualisation and examination of biological tissues arising from his research in the Biophotonics group at Charles Fabry Laboratory, a research unit of Institut d'Optique Graduate School.



Professor Arnaud Dubois
Chief Scientific Officer at Damae Medical

During 2013, Prof. Dubois began collaborating with two graduate students to develop a commercial application for his OCT-based technology. The students, Anaïs Barut and David Siret, were specialising in biophotonics with a major in entrepreneurship. They singled out Professor Dubois's technology from several innovative ideas and technologies presented as non-confidential information to the entrepreneurship group by researchers and companies, as potential options for a final year project to create a business proposition for a start-up company.

They engaged with Prof. Dubois at both the technical and business level to develop the idea and explore possibilities for the technology in the biomedical field. After rigorous research and analysis of the medical imaging market, they were convinced that the technology held tremendous potential for clinical applications in dermatology. It appeared to offer the best product/market fit, promising to achieve a significant level of clinical impact, as well as offering a commercial opportunity for a new medical imaging device.

"Our job as engineer-entrepreneurs was to develop the technological proofs-of-concept while performing medical imaging market research to identify the most relevant clinical applications and target markets for the technology. We pinpointed the dermatology market as the best product-market fit for a first application in terms of unmet medical needs, the technical capabilities and clinical potential of the technology, level of impact and benefits of the innovation, business opportunities and market-entry barriers."



David Siret
Chief Technology Officer at Damae Medical

Confident in the feasibility of the business proposition - confirmed by validation of both the business and technical opportunities – Prof. Dubois initiated a priority patent filing at the end of 2013. The three partners subsequently decided to create a start-up and in 2014 they established Damae Medical.

The patent application, which became the cornerstone for this new start-up, was filed and owned by a consortium of three partner institutions that supported the research and commercialisation of the technology, namely Institut d'Optique Graduate School, Paris-Saclay University and Centre National de la Recherche Scientifique (CNRS). As joint owners, the mandate to commercialise the IP rests with the technology transfer office CNRS Innovation, whose goal was to find partners, negotiate exploitation contracts and ensure effective implementation of the IP rights. Damae entered into negotiations with CNRS Innovation and obtained an exclusive licence to the core patent family in return for royalties on sales.

However, depending on a licence agreement for a business's core IP can prove risky in the long term, as potential future differences may arise surrounding the interpretation of the licensing terms, patent costs and prosecution decisions, inventorship and ownership issues. It can make more sense to acquire the patent family, as

this gives a company full control over managing all aspects of its IP. So Damae subsequently - and with increasing business success - acquired outright ownership of this patent family in 2019 through a purchase agreement in return for equity.

Revolutionising the management of skin cancer

Skin cancer is one of the most common cancers globally and its number of cases has risen sharply in recent decades. Today, the dermatologist examines a patient's skin abnormalities with the naked eye (clinical examination) and then with a dermoscope. In case of doubt, the dermatologist takes a sample called a biopsy. The biopsy is sent to a laboratory for microscopic histology examination, which provides a diagnosis within 15 days. This process gives rise to anxiety and leaves the patient with a scar. The majority of biopsies turn out to be healthy and have resulted in avoidable costs for healthcare systems. However, some melanomas are not

diagnosed at the earliest stage because surface signs are not obvious enough to perform a biopsy.

Damae is reinventing skin imaging by revolutionising the detection, management and follow-up of skin cancers (melanoma and carcinoma) with its optical biopsy solution. Its equipment, which trades under the brand of deepLive, is a Class IIa medical device complying with EC regulation 2017/745¹. The deepLive probe is a non-invasive imaging system comprising a unique imaging modality adapted to capturing 3D "optical histological images" to analyse multiple skin conditions.

Figure 2: Hand-held deepLive probe²



¹ This EU Directive applies to medical devices and their accessories. Such devices are typically used for the diagnosis, prevention, monitoring, treatment or alleviation of a disease, injury or handicap, or investigation, replacement or modification of the anatomy. You can consult the Directive online at <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A01993L0042-20071011>.

² Presentation video of deepLive: <https://youtu.be/29MCBEzgLgQ>

Visualisation of suspect tissue is at the cellular level, with a depth of penetration down to the dermis. deepLive allows easy imaging of a patient's entire lesion. By using deepLive dermatologists can detect malignant tumours early, increasing patient survival statistics while reducing the number of benign biopsies and healthcare costs.

Accurately identifying tumour margins prior to surgery allows maximum tissue preservation while avoiding possible revision surgery.

Offering multiple business models

Damae is responsible for manufacturing the deepLive product. However, some of the fabrication is outsourced to two different manufacturing partners in France, each responsible for different sub-assemblies of the product. Damae completes the final integration, quality control and product release.

Damae is cautious about entering into joint IP agreements. Every possible research cooperation that may give rise to an IP claim by a third party is reviewed and evaluated by the research team led by Dr Jonas Ogien. The majority of existing research collaborations allow both parties to maintain and improve their own IP and avoid complex management of joint IP. All strategic subcontracts also include a clause protecting Damae's IP rights by stipulating that all IP arising from the subcontracted work conducted becomes the property of Damae.

TAKEAWAY

IP and supply partners

Exercise caution in agreeing to joint IP arrangements with supply partners, which can dilute value for both parties and create unnecessary dependencies.

Currently, the marketing and sales functions are mostly integrated within the Damae organisation, selling directly to its customers. The company offers a user training programme, as well as maintenance and service contracts to access the latest innovations developed by the company.

The main market for Damae's medical imaging device is dermatology, which focuses on the diagnosis, treatment and management of skin conditions relating to cancer and other skin pathologies. Damae adopts different business models to generate revenue depending on its customers – mostly hospitals, clinics and liberal practices - and their needs, which range from purchase, rental, leasing and revenue sharing to services such as maintenance and image analysis services (3D segmentation and quantification).

Another key market that has emerged for Damae comprises companies in the cosmetics and pharmaceuticals sectors that invest heavily in researching and evaluating the benefits and impact of new products for skincare and skin treatment respectively. Companies in these sectors recognise the high-performance imaging capabilities of deepLive and the benefits of this non-invasive application for analysing the cellular structures and physiological mechanisms of skin in clinical studies. Damae either rents or sells the equipment to these companies, while supporting them in defining their studies and acquiring images from the study volunteers.

Finally, Damae applies AI algorithms to the captured images in order to derive relevant metrics and interpretations. The study protocols of these clients frequently cover a broad range of objectives, from optimising preclinical research, developing or characterising the benefits of the active ingredient or molecule, or improving the efficacy of formulations to evaluating products to support marketing claims and assessing and improving the safety of their products.

Damae's first revenues were generated in 2019 from clients in the cosmetics market when the LC-OCT 3D device was launched. Since then, revenues have been divided equally between the dermatology and cosmetics/pharmaceutics markets, with sales doubling year-on-year. However, sales from the dermatology business are beginning to exceed those generated by the cosmetics and pharmaceutics business.

Since the commercial launch of the *deepLive* trade mark in 2020, there has been strong demand from European dermatologists, particularly in the German, Italian and French markets. To date, the company has a market

presence in more than ten countries in Europe, the United States and Asia. In the United States, the first systems are being installed mainly in the context of clinical research. Damae's patent filing strategy has ensured protection for all of these territories from the outset.

TAKEAWAY

Strategic alignment

Align the geographical scope of patent protection with your long-term marketing strategy.

Innovative technology

Traditional visualisation and analysis of skin tissue and cells relies on the preparation of histology slides from biopsy material and inspection using advanced microscopy techniques applied by a specially trained anatomical pathologist or histologist. It is a technique that provides a two-dimensional image of a sample section. The process is slow, complex and potentially risky, particularly during surgery where speed is crucial and tissue excision can have consequences.

The initial innovation that led to a device for non-invasive medical imaging adapts and combines state-of-the-art optical coherence tomography (OCT – used by ophthalmologists to detect retinal pathologies) and confocal microscopy (CM – used in research for high-resolution imaging of biological samples). It gave rise to a completely new method of real-time imaging and the new term *Line-field Confocal Optical Coherence Tomography* (LC-OCT).

LC-OCT lies at the heart of Damae's innovative approach to dermatological diagnostics and was first protected by a French priority patent application (FR 136324) filed by CNRS and partners in 2013. The application describes an optical tomography apparatus, in which both the illumination and detection optics of a microscope are coupled with dynamic focusing of the lens over a site on the skin to enable the capture of a two-dimensional image of a biological tissue.

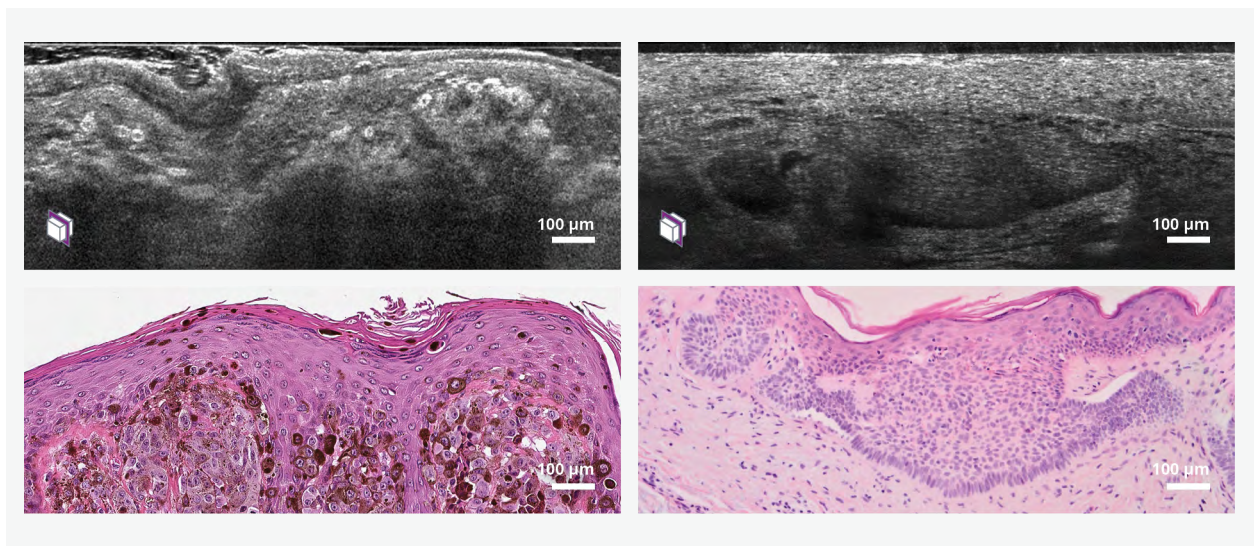
The patent filing strategy for broad international protection, was to establish a priority date nationally, followed by a PCT application within one year ([PCT/EP2014/078867](#)). This provided a timeframe of 30 months (or 31 for an EPO regional application) before decisions with respect to designating international territories had to be made, giving Damae more time to build prototypes, test the technology and ascertain the best market fit. The patent has since been granted in nine international territories and is now validated in eleven European countries covered by the EPO.

The importance of agility

In 2014, Damae first began work on developing a commercial product according to the system described in the patent it had just licensed. The company was initially located in a laboratory space at Institut d'Optique *Graduate School* and carried out all its research there, before eventually moving to incubator premises in Paris. In the ensuing period, Damae developed a 2D system for

vertical section analysis and integrated it into a hand-held probe. The probe was clinically evaluated on patients by their clinical dermatology partners in 2018. Compared to conventional OCT, the technology had the main advantage of achieving higher image resolution down to single cell level. It was thus able to provide similar images to those produced by histology.

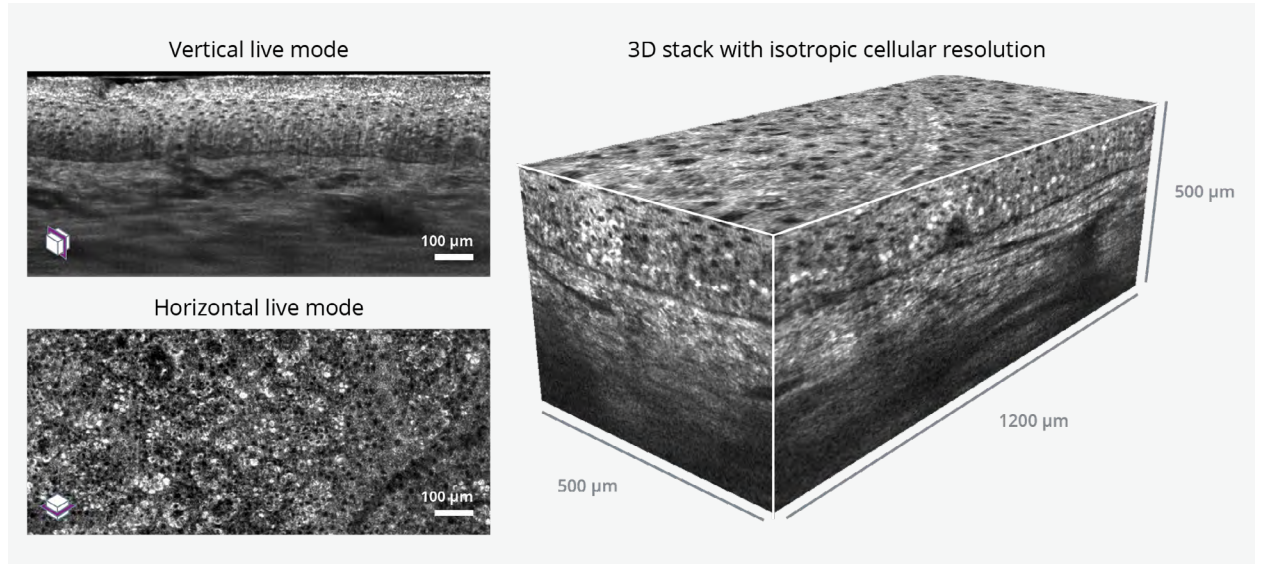
Figure 3: LC-OCT vertical images of a melanoma (left) and a superficial basal cell carcinoma (right) with corresponding histology images. Image taken from the Journal of Biomedical Optics publication - <https://doi.org/10.1117/1.JBO.23.10.106007>



Parallel research into another approach led to a significant technological breakthrough with a lab-scale model for a new configuration of the LC-OCT system that enabled 2D images to be captured in both vertical and horizontal sections of the sample site. This enabled the stacking of images in a 3D format, providing

dermatologists with a 3D visual of the skin section being analysed. This was hailed as “revolutionary and a game-changer with major clinical advantages” according to the key opinion leaders of Damae’s clinical partners.

Figure 4: LC-OCT vertical (top left), horizontal (bottom left) images and 3D stack (right) of healthy human skin in vivo. Image taken from the Biomedical Optics Express publication - <https://doi.org/10.1364/BOE.385303>



The huge potential of this new innovation presented a business strategy dilemma for Damae. Should it proceed with commercialisation of the near-complete 2-dimensional imaging system or change tack at this late stage and take a step back to develop the lab-scale 3-dimensional imaging system? A fortuitous injection of fresh finance swayed Damae's decision towards the 3D option. Its R&D team had grown by that stage and the entire team was tasked with developing the lab-scale proof-of-concept to full-scale commercial development, clinical testing and product launch. Twelve months later, a first prototype of the 3D-LC-OCT medical device was ready for evaluation and a patent application quickly followed to secure protection for this new business-critical innovation (EP4070144A1).

TAKEAWAY

Value of patient capital

Appropriate funding can open up opportunities to prioritise long-term strategies with high potential over short-term gains with lower risk.

This new technology from Damae adds a “third dimension” to the inspection of skin tissue. Application of the deepLive probe allows a non-invasive visual inspection and analysis that far exceeds traditional histological methodology. Simultaneous vertical and horizontal imaging of the skin at a depth of down to 500 micrometres is possible, enabling a 2D profile of the examination site with a resolution of one micrometre to be captured in real-time as a “digital-optical biopsy”, dispensing with the need for often awkward, unpleasant or risky excision of a tissue sample. These 2D images may subsequently be stacked to provide a 3D “optical histology”, which generates a more accurate and informative visualisation of skin layers, lesions and cells. This, in turn, enables diagnosis of various skin conditions and enables differentiation between carcinoma types such as basal cell carcinoma, squamous cell carcinoma and melanoma.

TAKEAWAY

Optimal filing strategy

Filing a patent application too soon can lead to a set of claims that don't provide cover for the final product. Filing too late can result in the invention being superseded by the competition.

“We strive to maintain an agile and iterative development process. In fact, finalisation of our 2D and 3D systems arose from eleven different versions that were developed, prototyped and tested with end-users over a period of four years. Building on user-feedback, market responses and new ideas from the R&D team, each version was an improvement on the previous and new patent applications were filed to capture the major innovations that solved the technical setbacks.”

David Siret, Chief Technology Officer (CTO)

Securing funding

Since its creation, the company has invested more than €20 million in its activities. In 2017, an initial investment of €2 million seed funding was closed with a consortium of VC firms including Kurma Partners and Eurazeo, and private investors. This was followed by a round of Series A financing in 2021, with a further injection of €5 million led by BNP Paribas Développement joining the original consortium. Additional funding came in the form of an EU grant in 2019. Under the Horizon 2020 research and innovation programme Damae was awarded €2.4 million towards a €3.5 million SME instrument project to develop a novel approach to non-invasive and personalised skin cancer diagnosis.

TAKEAWAY

IP and funding

For technology start-ups, IP rights are key assets for securing funding.

TAKEAWAY

Strategic patenting

Product development paths can change, so think strategically about when and what to patent along the way. Adapt your IP strategy to the innovation process and identify the best stage at which to build or revise the patent claims.

The company's patent portfolio clearly reflects its R&D success. However, as a start-up company, Damae's technology and IP were the main intangible assets on offer to investors and played a key role in influencing their decisions. During both the seed and Series A funding rounds, investor due diligence focused on an audit of Damae's complete IP portfolio. This was performed by an independent IP firm that delivered a report on the status of patents, trade marks, know-how, domain names and copyright in software and databases. It also examined how IP rights were managed in contracts and provided a freedom-to-operate statement. The strength of the business proposition lay in the business plan. However, the section of the report on IP strategy was closely studied by investors and played a key role in their decision. It remains an agenda item during Damae's board meetings with investors.

IP and portfolio development

Soon after its foundation, the company's research team set about expanding its IP portfolio by developing improvements to the original technology and creating new inventions directed towards commercial applications. Most notably, they focused on developing a revolutionary system for visualising deep layers of

skin at the cellular level in a three-dimensional format, which would provide dermatologists with new, advanced medical imaging systems. Since then, five new patent families have been added to the portfolio, which comprises of no fewer than 31 patent applications to date (see Table 1).

TAKEAWAY:

IP in high-tech sectors

Companies operating in high-tech sectors need a robust patent portfolio to ensure technological exclusivity and secure a lasting advantage over competitors.

“Damae’s growth and success will depend in part on its ability to protect its products and inventions, in particular by obtaining and maintaining patents in the territories targeted by its business activities, mainly in Europe, the United States and Australia.”

David Siret, CTO

As the focus on implementing commercial applications of the medical device intensified, intellectual property protection was also extended to other important aspects of the business. These included design right protection, which has been filed for the company’s handheld probe (RCD 007439419-0001) and several trade marks, including DAMAE MEDICAL (EUTM 1452479), deepLive (EUTM 018239168) and LC-OCT (EUTM 018237600), used in the branding and marketing campaigns for its imaging systems. Copyright for the company’s software, databases and AI solutions is also safeguarded and the domain names it uses in web-based media activities have been registered.

TAKEAWAY

Complementarity of IP rights

IP rights, such as patents, trade secrets, trade marks, designs, copyright, or domain names are often complementary and should be combined to secure optimal IP protection.

Figure 5: Medical probe RCD 007439419-0001



Damae’s patent filing strategy is purely focused on protecting inventions relevant to its business strategy, i.e. cover for products in those territories and markets where they will be commercialised. It doesn’t intentionally engage in filing blocking patents, but some patents on aspects of the technology that have been superseded by improvements are still maintained, as they serve to prevent the competition from using these solutions.

Damae has devised a system for categorising inventions as high-impact and low-impact patents. High-impact patents contain claims covering a wide scope of embodiments for Damae’s core technology to prevent competitors from accessing it by developing around the patent. These patents are filed in most of the international markets where Damae is aware of similar research and medical device development. They typically cover at least 20 countries worldwide, including the main EPO member states.

Low-impact patents emanate from improvements to the core technology that provide additional functional modalities for the final product. Such improvements are not only important for quality and performance, they also make the products more appealing than others in the same market. These patents also deter other companies with non-competing technologies from adapting Damae’s inventions for use in their own products. The aim is to file for protection only in those markets targeted by Damae’s commercial strategy, which are not as extensive internationally as those for its core patents.

Currently, Damae’s patent filing strategy is to gain patent priority with a French national application followed by a PCT application within twelve months. This defers the decision for selection of international states in the National Phase of the PCT application until 30 months after the priority filing (and 31 months for an EPO Regional Application), giving the company time to gather further research data, test prototypes, and delay costs for patent prosecution. The EPO and other international territories of interest are then designated for examination and, after grant, the EPO application is validated in the European countries of strategic importance to the business.

With the Unitary Patent system due to take effect in June 2023, this may provide an alternative and more beneficial route to protection in European countries for Damae.

This route simplifies national validation procedures and enables uniform protection in up to 25 EU member states through a single application at a much lower cost. Moreover, in the event of litigation, a single action may be taken before the Unitary Patent Court (UPC) with the potential to gain a ruling that covers all member states of the Unitary Patent system, allowing users to benefit from

the associated harmonised and centralised enforcement mechanisms. This may be an attractive alternative for Damae, and a matter of case-by-case decisions, considering the trade-off between the benefit of unified protection in up to 25 EU countries at lower costs and the risk of central revocation at the UPC.

IP management

Responsibility for IP management at Damae rests with its CTO, David Siret. He is supported by a lead research engineer, Dr Jonas Ogien, who dedicates about 25% of his time to IP matters. This involves capturing inventions relevant to Damae's IP strategy by monitoring research results and completing the company's invention disclosure form, discussing new patent opportunities with the CTO, and engaging with patent attorney firms outside in the drafting and prosecution of patent applications.

Internal IP management systems include procedures for maintaining confidentiality, lab notebooks for recording research outputs and invention disclosure forms for capturing and evaluating new inventions. Patent database monitoring is mostly performed on the Espacenet³ database, which Damae's researchers are very familiar with and which they use regularly for prior art⁴, competitor watch⁵ and freedom-to-operate⁶ searches. Technology and competitor watch also extends to vigilant monitoring of literature, conference and exhibition activities. Researchers maintain a list of competitors in the field of optical technologies for non-invasive skin imaging, closely following their patent activities and monitoring competing products for potential infringement of their patents. Damae's IP policy advocates policing and defending its patents, guided by the advice of its patent attorneys as to appropriate action against infringers.

Damae works closely with two patent attorney firms in France: one was selected for its expertise in the

field of optics and the other specialises in the medical sector. Although these firms are not involved directly in formulating the company's IP strategy, they are nonetheless advised of the strategic importance of new inventions to its business strategy during discussions on invention disclosures. Their role is to assess the relevance of prior art and draft applications with a set of patent claims that ensures broad protection for the scope of the invention and product applications strategic to the business. They take into account the company's technology roadmap and its publication objectives to advise on the optimal timing of a priority application and to ensure that no disclosures are made prematurely. Regular discussions on inventions and patent prosecution enables the patent attorneys to identify IP opportunities relevant to Damae's business and translate them into relevant IP strategies, which Damae takes on board.

Patents, along with associated research results and clinical studies, hold important media and marketing significance for Damae and constitute a valuable asset in terms of engaging with customers and the dermatology community. Damae derives much benefit from its ambitious scientific communication plan. The goal of this plan is to publish its research outputs in prestigious scientific and medical journals. This not only aims to increase the visibility and credibility of its technology and products in the medical community, but also to persuade clients of the clinical advantages of its products and support clinical dossiers in applications for regulatory approval. Over 80 scientific and medical papers have been published to date.⁷

³ Espacenet is the EPO's free online patent search tool and is one of the single largest sources of technical information available today with over 140 million patent documents. It provides access to worldwide patent applications, granted patents, complete patent families, the current legal status of applications and a register of all prosecution documents, see <https://worldwide.espacenet.com/>

⁴ Prior art refers to all citations including literature, patent specifications, as well as public disclosures of any kind that are relevant to the specific invention under consideration.

⁵ Competitor watch is the process of performing searches to identify, review and analyse patent applications and other publications released into the public domain by competitors.

⁶ Freedom-to-operate is the process of analysing the claims of a third party's patent to ensure that no aspect of a company's own product falls within the scope of such patent claims.

⁷ The LC-OCT publication-library is available under this link: https://www.zotero.org/groups/2551566/damae_medical/library

TAKEAWAY

Avoiding unintentional disclosures

Patents and scientific publications can significantly enhance a company's reputation, but should be accompanied by a strategy to avoid unintentional disclosures.

IP strategy

Control of the company's core IP is paramount for Damae. As a result, its IP policy is geared towards maintaining complete ownership of its patents and building an IP portfolio independent of third-party access rights. So transitioning from an exclusive licence to acquisition of its first patent was a key transaction, as it brought ownership under Damae's full control. This was a strategically important business decision, particularly with respect to raising finance, as many investors prefer to see major IP assets registered to the company.

Like most business opportunities arising from a disruptive technology, the early phase of the start-up tends to be in a "technology push" mode, so building Damae's patent portfolio has mostly been determined by its R&D outputs. However, its IP strategy is now focused on exploiting a patent portfolio that supports the right products for the right markets and is heavily influenced by user-needs and market intelligence. As a result, customer and clinical feedback is now beginning to influence a "market pull" and determine the direction of R&D, improvements to the technology and the design of Damae's next-generation products.

"We have listened to customer needs during R&D phases to achieve the best product/market fit and are still listening to their feedback and input to improve the current product or develop new products. This has inspired recent work on a second generation deepLive probe."

David Siret, CTO

The company is single-minded in its approach to innovation and allocated a substantial budget in the early phase of R&D to capturing inventions and extending its patent portfolio. Damae's corporate values encourage teamwork, open communication and transparency. Researchers working in multidisciplinary teams exchange ideas freely on all

Damae's policy of open publication means that capturing secret know-how in the medical research field does not feature highly in the company's IP portfolio. Damae derives trade secrets primarily from its engineering and manufacturing processes, which are all naturally captured in its process designs, specifications and methods of manufacture. These are recorded both electronically and in production documents and are guarded as important trade secrets for the business.

aspects of innovation, including IP and related discussions on potential patents, competitor monitoring and prior art. An annual off-site "strategy thinking week" for all staff is an important forum in the company calendar. It involves collective brainstorming and planning strategic objectives and roadmaps for the following year, which form the basis for strategic IP decisions.

Researchers are recognised for their contributions to the IP portfolio and rewarded by a staff incentive scheme. A three-step remuneration bonus is awarded on the basis of achieving the following milestones: patent filing, grant and commercialisation. This is an important incentive mechanism for inventors, but is also governed by a legal requirement for inventor remuneration in France.

The company attaches great importance to collaborating with clinical partners in the testing and validation of dermatological applications for its products and associated software services, such as AI-based clinical decision support software and cloud-based patient data management services. To this end, Damae has established a clinical committee comprising six dermatology centers in Europe, and collaborates with key opinion leaders in the field of non-invasive imaging of the skin at the world's leading academic hospitals to gain support for its technical developments and clinical validation studies.

The deepLive system has been installed in more than 40 centres around the world to date, and mainly by university hospitals, which use it in their own clinical investigations. As early-adopters of the technology, Damae receives valuable updates and feedback from these "referral centres", who also contribute to raising deepLive's profile through their clinical work and publications.

Future technology developments

Damae is looking for potential applications of its technology in “microscopic imagery-guided” dermatology procedures in the future. Clinical applications may enable dermatologists to map entire lesions in a tissue with LC-OCT that will automatically define the margins of a skin tumour with precision. This, in turn, will enable the surgeon to minimise scarring and reduce the risk of recurrence and necessity for revision surgery.

Damae has already developed several AI solutions and tools that are integrated into its deepLive platform to aid dermatologists with image interpretation through data analysis and diagnostic prediction of skin pathologies. It will continue to develop further AI tools and services based on web applications that users of the deepLive system can access to store and manage patient data and will extend its patent portfolio to include applications that support these new solutions.

“We will collaborate with more and more centres to position our artificial intelligence (AI) tools as routine companions for dermatologists to facilitate and accelerate diagnosis.”



Anaïs Barut
Chief Executive Officer at Damae Medical

Damae has scope to broaden aspects of its future IP strategy to include protection for its new software and AI technologies by filing applications for “computer-implemented inventions”, where both software algorithms and technical functions are combined in patent claims. With a continued commitment to pursuing its research and innovation goals, Damae will create a vast amount of knowledge and know-how that is critical to many technical, manufacturing and business functions in the company, but may not be either strategic or appropriate to patent.

This core knowledge will not only add considerable value to the company’s IP portfolio, but also to its balance sheet in terms of intangible assets. Such knowledge needs to be documented securely, so that it is accessible for due diligence during investment rounds and in preparing for company valuations. As Damae expands its manufacturing operations, both its patent and know-how portfolios will strengthen its proprietary technology position in sub-supply agreements and provide options to enhance its supplier base.

TAKEAWAY

Patents and software

Inventions involving software and AI are considered “computer-implemented inventions” (CII) and can be patented at the EPO as long as they have a technical character⁸.

⁸ For further information, see Guidelines for Examination in the EPO: <https://www.epo.org/law-practice/legal-texts/html/guidelines/e/j.htm>

MAIN PLAYERS INVOLVED

Source of IP

Arnaud Dubois

- main inventor
- researcher at Charles Fabry Laboratory

The Institut d'Optique *Graduate School*, Paris-Saclay University and CNRS

- partner institutions involved in research, innovation and education
- owners of the first patent application

Tech transfer catalysts

CNRS Innovation

- negotiated patent licence and purchase agreement with Damae

Consortium of VC firms (including Kurma Partners, Eurazeo and BNP Paribas Développement) and Horizon 2020 research and innovation programme

- provided funding through investments and grants

IP commercialisation

DAMAE MEDICAL, www.damae-medical.com

- company established in 2014 with headquarters in Paris, France
- staff: 30 employees
- management: Anaïs Barut CEO, David Siret CTO, Arnaud Dubois CSO
- products/services: medical device and research and analysis services in the field of dermatology using a non-invasive optical imaging probe.
- market and technical area: medical devices, medical imaging, onco-dermatology, dermo-cosmetics and pharmaceuticals, research
- customers: hospitals, universities, dermatology clinics, cosmetic and pharmaceutical industry
- selected awards: 2022 Winner of the Ivy Award for Young Tech Leader; 2021 Eurostars collaborative Totem European project; 2020, Winner of a contest organised by Health Data Hub; 2019 Winner of Horizon 2020 SME Instrument programme European Commission; 2018 Winner of the World Competition of Innovation organised by Bpifrance; 2017 Anaïs Barut awarded Youngest French Innovative CEO under 30 by MIT Technology Review; 2016 Winner of the Digital Innovation Competition organized by Bpifrance

Table 1: DAMAE MEDICAL's intellectual property portfolio

Patent families

| No. | Title | Priority | Patent number |
|-----|--|------------|--------------------------------|
| 1 | Optical tomography apparatus and method | 20.12.2013 | EP3084345B1 |
| 2 | Dynamic focusing system for an optical device | 12.01.2018 | EP3714309B1 |
| 3 | Devices and methods for line-scanning microscopy | 03.12.2019 | EP4070144A1 |
| 4 | Systems and methods for performing microscopic analysis of a sample | 22.07.2020 | WO2022017784A1 |
| 5 | Devices for ex vivo microscopic analysis of samples and in vivo microscopic analysis of the skin | 29.01.2021 | WO2022161816A1 |

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.

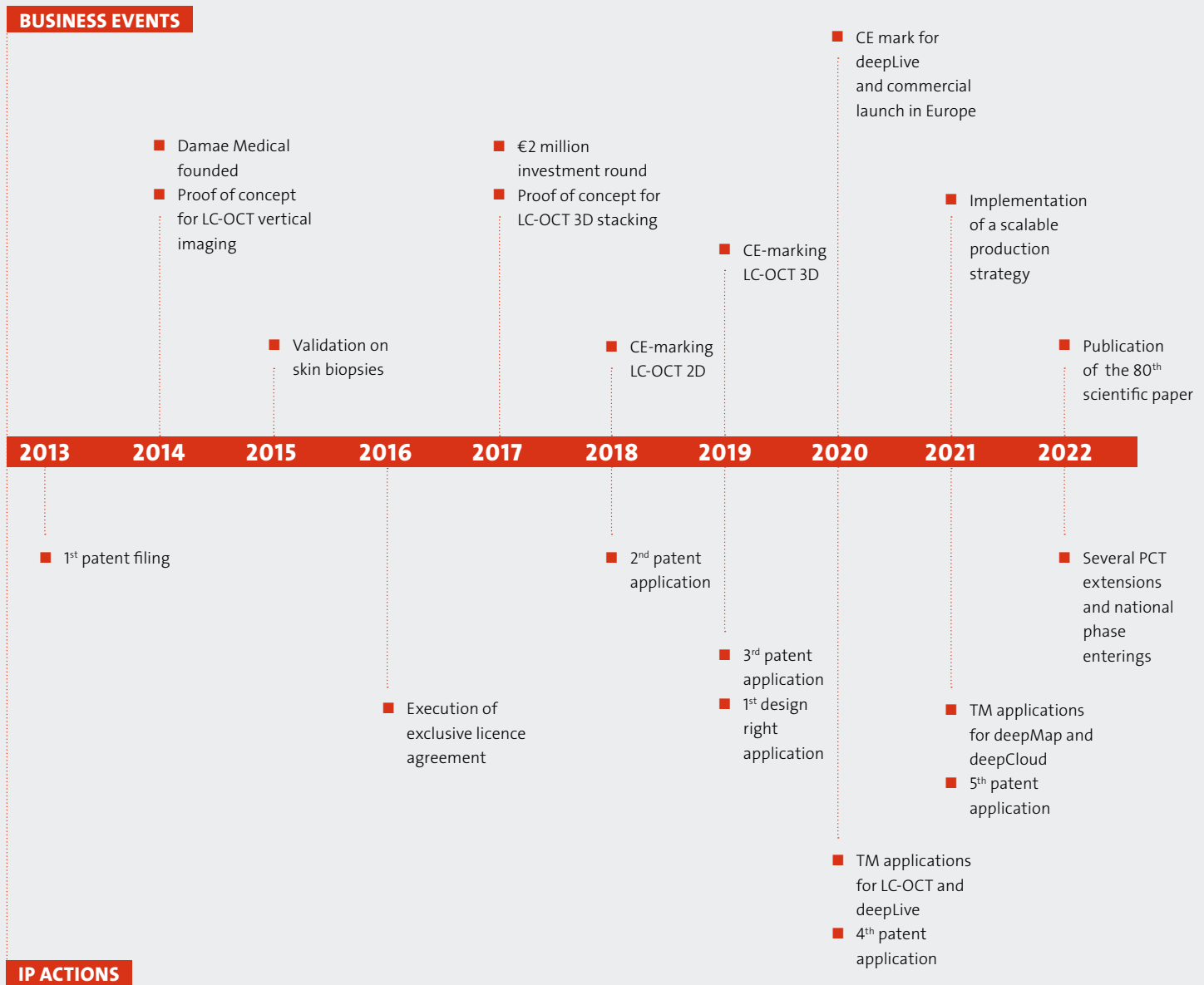
Trade marks

| No. | Title | Application | Granted | European Union Trade Mark (EUTM) number |
|-----|---------------|-------------|----------------------|---|
| 1 | DAMAE Medical | 16.08.2018 | EU, Australia, US | 1452479 |
| 2 | LC-OCT | 12.05.2020 | EU (AUS, US pending) | 018237600 |
| 3 | deepLive | 13.05.2020 | EU, Australia, US | 018239168 |
| 4 | deepMap | 26.10.2021 | pending | 1664667 |
| 5 | deepCloud | 26.10.2021 | pending | 1666270 |

Design rights

| No. | Title | Application | Granted | Registered Community Design (RCD) number |
|-----|---|-------------|-----------------|--|
| 1 | Medical Probes – design for hand-held deepLive imaging probe. | 20.12.2019 | EU, AUS, CN, US | RCD 007439419-0001 |

DAMAE MEDICAL's timeline



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