An Investigation into the Logistic Feasibility of the Business Model Proposed by Cortilens

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Index Terms

Cortisol, Smart contact lenses, Addison's Disease, Cushing's syndrome, continuous monitoring, feasibility inquiry

CONTENTS

I. Abbreviations

SCL : Smart Contact lens

PET : Poly(ethyleneterephthalate)

PDMS : Polydimethylsiloxane

NFC : Near-Field Communication

NAD : Nicotinamide Adenine Dinucleotide

NADH : Nicotinamide Adenine dinucleotid + Hydrogen

11β-HSD2 : 11β-Hydroxysteroid Dehydrogenase Type 2

RF : Radio Frequency

WPT : Wireless Power Transmission

R&D : Research and Development

SME : Small and Medium-sized Enterprises

CFO : Chief Financial Officer

CLO : Chief Legal Officer

II. Introduction

This report offers an in-depth evaluation of the viability of Cortilens Ltd's proposed business model, with a particular focus on the flagship product, C-β®. This assessment appraises the company's feasibility through a comprehensive, multi-faceted approach where analyses are taken for the model's market potential, financial viability, technological innovation and overall longevity. Each of these aspects is analysed in isolation from the others such that a cumulative analysis can be conducted as a final summary. The objective of this report is to ascertain whether the Cortilens Ltd business model aligns with economically sustainable business practices while effectively meeting the needs of the identified market. This report further aims to offer useful insights and suggestions to address any identified shortcomings, thereby enhancing the company's chances of success.

A. Overview of Cortilens Ltd

Cortilens is an innovative healthcare technology startup company consisting of eight founding members all of whom are Durham University alumni. The company plans to pioneer a novel approach to cortisol monitoring using its latest product C-β®, a smart contact lens. Cortilens emphasises the utility of such a product to address neglected diseases such as Addison's disease and Cushing's syndrome. These afflictions are rare in the population, so development into their monitoring and treatment is limited. The core values of Cortilens are encapsulated by their mission statement: "enhancing patient care and outcomes in the rare disease community". This ethos highlights a dedication to serving an often overlooked segment of the population, indeed a noble cause that could have the potential to improve the livelihood of any patient affected by the symptoms of cortisol imbalances. Despite this clear medical benefit, economic considerations concerning the potentially narrow market, consequent to the rarity of the diseases, begs the question regarding the profitability and long-term sustainability of the endeavour.

B. The Target diseases

As previously discussed, Cortliens provides a means of continuously monitoring the cortisol levels in the body. This is useful as cortisol is an important biomarker. Commonly referred to as the stress hormone [Thau, 2023], cortisol is synthesised from cholesterol in the zona fasciculata layer of the adrenal cortex [Thau, 2023]. Cortisol is provided with its colloquial name as it is a peripheral output of the major stress response system [King and Hegadoren, 2002]. It is a steroid hormone, and as well as being important in the mediation of the stress response system has roles in metabolic regulation, inflammatory response and immune function [Oakley and Cidlowski, 2013]. Addison's disease is a severe condition characterised by the body's inability to produce sufficient levels of cortisol. The disease is commonly caused by an autoimmune response that damages the adrenal cortex of the host and subsequently limits cortisol production. The cause of this immune response is unknown. The early-stage symptoms include muscle weakness and fatigue which are often mistaken for common health conditions such as influenza [NHS, 2023]. These symptoms can develop in severity if the disease is left unchecked and can cause an Addisonian crisis. In this event, an individual can expect to experience rapid shallow breathing, severe dehydration, severe vomiting, diarrhoea and potentially loss of consciousness. Diagnosis of Addison's disease is only normally made after the manifestation of one such adrenal crisis [Munir, 2024]. An adrenal crisis can even be fatal. It is estimated that each year, 8% of those with adrenal insufficiency have an adrenal crisis and that the rate of death is about 6% [Rathbun, 2023]. Managing Addison's disease involves a lifelong commitment to hormonal replacement therapy and coping with periodic phases of fatigue. These factors can have a significant effect on an individual's life. [NHS, 2023][Munir, 2024]. On the other end of the spectrum is Cushing's syndrome. This condition is a result of cortisol excess. Typically a result of the intake of synthetic cortisol to the body, normally from steroid medicines. In rarer cases, the imbalance can be caused by tumours of the adrenal or pituitary glands that lead to excessive cortisol production from the body itself [NHS, 2021]. Cushing's syndrome can cause an increase in body fat surrounding the neck, torso and face as well as easily bruised skin. Further, the disease can lead to complications regarding blood pressure and diabetes. Like Addison's disease, Cushing's syndrome can be incredibly dangerous and potentially fatal if left untreated.

The detriment to the quality of life that both Addison's disease and Cushing's syndrome can cause emphasises the benefit that an accurate and continuous cortisol monitor could have. A product such as C-β has the potential to improve a patient's management of their illness by providing constant real-time data as well as offering the capacity for an improved treatment plan tailored to an individual. The product's implementation would have significant benefits to Addison's patients in particular as it could aid in the avoidance of adrenal crisis, as such it could even save lives.

III. Technology

A. Proposed Innovation and a Competitor Analysis

Cortilens Ltd presents the C-β® product, shown in figure 1, as a representation of the future development for the integration of biosensor technologies into everyday lifestyles. The product is presented with the ambition to address the described gap in the healthcare market by providing a novel, alternative method for monitoring both Addison's disease and Cushing's syndrome. The innovation of a cortisol sensor working within a contact lens, utilising tear fluid analysis, promises continuous and non-invasive measurement giving it distinct advantages compared to traditional methods such as urine, blood and saliva testing. The convenience and autonomy provided to the user are key selling points put forward by the company.

A detailed competitor analysis undertaken by Cortilens highlights the presence of several alternative products and methods of measuring cortisol levels in the body including the traditional methods mentioned as well as novel technologies like the 'Microsweat' and 'Patches' developed by the University of Calgary and Stanford University respectively. Notably, however, there are no readily available methods that offer accurate continuous monitoring. This is a property identified as a crucial benefit for people who suffer from cortisol imbalances, particularly concerning those suffering from Addison's disease where maintaining normal cortisol levels prevents severe health risks. Cortilens Ltd have subsequently identified a niche competitive edge that could see their product identified as a superior means of monitoring.

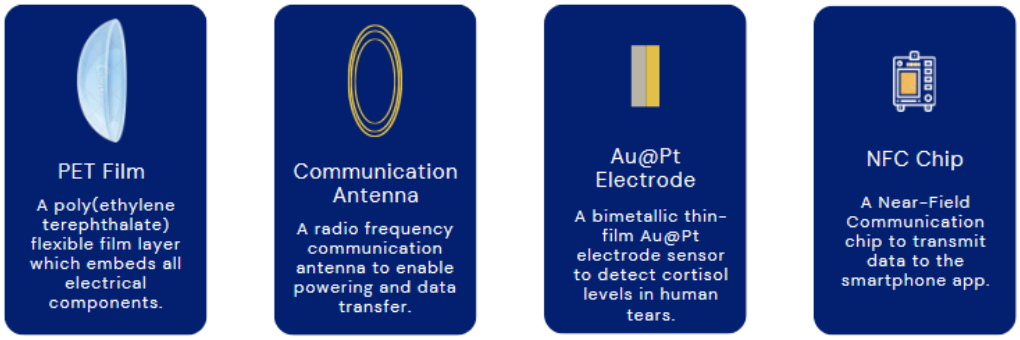

Fig. 1: The proposed components of the C-β® contact lens

B. An Analysis of the Viability of the Technologies Associated with the C-β® SCL

The successful development of C-β hinges on the integration of an unobtrusive sensor that is compatible with the proposed PET polymer as well as the incorporation of an effective RF communications antenna. The company offers that they take inspiration and a knowledge transfer from the work of a technologically similar product used for the monitoring of glucose which is being developed out of Pohang University - South Korea [Han et al., 2023]. This indicates that at a fundamental level, the use of a biomarker sensor within a contact lens is viable. The key question, therefore, is whether the sensor promoted by Cortilens Ltd has a valid scientific foundation. The company offers their variation of the technology which is founded in the implementation of the chemical reaction displayed in Figure 2. The key scientific basis is that in the presence of oxygen, the reduced enzyme co-factor $NADH_2$, a product of the cortisol oxidation reaction, is itself oxidised quickly at the surface of the electrode, generating H_2O_2. Subsequently, the electrochemical oxidation of H_2O_2 can occur, generating two free electrons. This would, in theory, allow for the detection and measurement of a current. The cortisol concentration in tears may therefore be indirectly determined in real time from the perceived changes in the electrical signals.

This method is supported by evidence that 11β-HSD2 does indeed convert cortisol into the inactive cortisone [Gomez-Sanchez et al., 2001]. As such, the catalytic processes could plausibly offer an indirect measurement of the cortisol concentration. Assuming a similar implementation of the sensor into a PET contact lens as with the work of Han et al. [2023]. In this respect, the sensor technology offers exciting prospects at a fundamental level.

The use of the other components is logical but not without fault; A WPT antenna means that an obtrusive battery is avoided, however, the system proposed by Cortilens is ambiguous. They do not appear to have considered that using an

antenna generates heat. This could have damaging effects on corneal tissue. The heat produced is dependent on several aspects of the design and functionality of the antenna. These include its shape and operating frequency band. Reports suggest that higher frequencies allow for a more efficient and smaller-sized antenna but are liable to cause greater heating [Mirzajani et al., 2022]. This does not rule this out as a possibility for the company but is an oversight they would need to address. Similar utilities have reported the effectiveness of a single loop antenna, capable of powering the system and data transfer at a frequency of 433 MHz [Jeon et al., 2020]. Nevertheless, Cortilens Ltd would need to allocate time and resources in their R&D phase to ensure the viability and safety of their antenna, finding an optimum operating frequency and shape that complements the other components' requirements.

Additionally, while the PET film is a promising choice in polymer due to its transparency and relatively easy means of thermoforming into a film containing complex structures, the film is known to lack gas permeability. As such the lens can be uncomfortable for long-term wear. Considering Cortilens proposes the usage of these lenses throughout the entire day and predicts them to be replaced every month, this aspect could significantly affect user comfort. Fortunately, there is an alternative polymer type that the company could investigate. PET-PDMS is a bio-compatible and air-permeable polymer and could therefore prove to be less irritating [Ma et al., 2021]. This of course will demand further resources and time expenditure outside of the allocated distribution during the R&D phase.

Overall the technological innovation proposed by the company Cortilens, though sound in theory, requires extensive refinement. The company needs to ensure that all of the components indicative of C-β have been adequately explored and proven to function as the product requires them to. This would mean significant alterations to the R&D phase and unforeseen expenses to the company. These refinements in the understanding of what the product is composed of will have further unknown consequences on the subsequent predictions made by the business model, namely the predicted cost of manufacturing which is currently estimated to be £15 per lens.

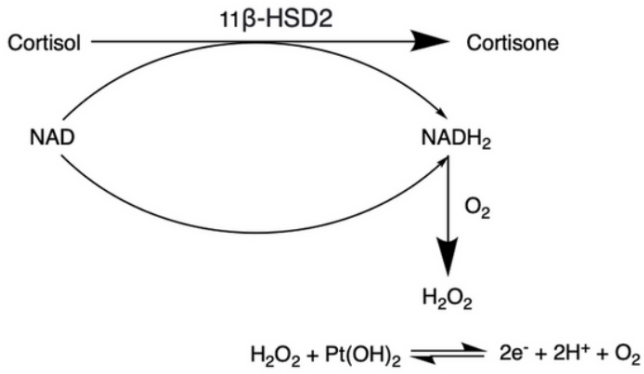

Fig. 2: A reaction scheme displaying the oxidation of cortisol to cortisone utilising the enzyme 11β -HSD2

IV. Analysis of the Proposed Market and Expansion Potential

Cortilens outlines the growing field of wearable health technology and the increased trust in smart contact lenses. The company is confident in its ability to draw the majority of the applicable customers in the early stages of its existence as a result of the primary market research survey undertaken and the knowledge acquired from the competitor analysis that the current competitors are few and use inferior methods. The results of the primary research survey found that 76% of the public would be extremely likely to consider the use of C-β should they receive a medical diagnosis that would benefit from the use of cortisol monitoring.

Despite this promise, the company has acknowledged the awareness of the financial challenge posed by the limited initial customer base available to them in the early stages of their existence. They estimate a population of less than 14 individuals per 100,000 to be affected by Addison's disease and Cushing's syndrome to be even rarer (less than 15 new cases per million per year). This of course aligns with the company mantra of aiding the rare disease community. Concerns arise however, due to the risk placed on the economic sustainability of the venture given that in their current plan, the financial viability of Cortilens hinges on a dangerously narrow market segment, exposing the business to significant financial uncertainty.

A mitigating proposal has been put forward by the company. This would involve a large-scale expansion into the stress management field once an established product has proved its utility in aiding Addison's and Cushing's patients. An alternate future avenue envisioned as a post R&D option is the development of a multi-functional contact lens that could detect multiple biomarkers present in tear fluid.

It should be noted that some estimates for the number of people affected by either of these diseases are even less than those suggested by the Cortilens business model. It is further important to understand that not all patients will immediately recognise C-β as an improved service to them. It is therefore a more reasonable line of thinking that the best approach for Cortilens is using rare diseases as an initial proof of concept with limited monetary profit for the company. The product would instead serve as a precursor for knowledge acquisition and the development of company status and trust. This could then allow a smoother expansion into the services described above. This approach would enhance the longevity and scalability of Cortilens. The developments made would introduce a broader market to the product. For instance, the consideration that 74% of the adult population have felt so stressed they feel overwhelmed or unable to cope [Mental Health Foundation, 2019], suggests that the alternative function of C-β could meet the demand for a widespread stress monitoring tool. In this way, the company can take pride in their contribution to the rare disease community while ensuring the potential for the evolution into a widespread medical enterprise.

V. Financial Summary

A. Analysis of the project start-up and R&D expenses

Cortilens offers an in-depth estimation of costs during their research and development phase. The company predicts a coverage of 56% of their total 3-year expenses to be covered by the Innovate UK grant. They offer that they are eligible to apply for the 'biomedical catalyst grant'. This is a flagship funding mechanism targeted at enabling small businesses to develop healthcare solutions in different capacities. Importantly this includes medical devices [Innovate UK, 2024a]. The company is correct in their assessment given that the grant offers up to £2 million in the support of R&D of SMEs. However, this grant is offered under the condition that the project will enhance the competitiveness and productivity of at least one other UK SME. The grant also requires evidence of technical and commercial feasibility [Innovate UK, 2024b]. The remaining 44% is anticipated to be covered by a combination of shareholder investments, an angel investor, and a commitment from their favoured strategic partner AstraZeneca.

Cortilens anticipates an average expenditure of £273,000 for each of the projected 3 years of R&D. This cost is forecast to cover:

- Research staff wages
- Lab space
- Travel
- Lab consumables
- Ineligible costs

These ineligible costs include:

- Legal costs
- Office spaces
- Office supplies
- Non-research staff wages

These are categorised as such because ineligible costs cannot be covered by any funding received from the Innovate UK grants. These estimates are taken outside of any costs associated with clinical trials as Cortilens believes that this cost can be attributed entirely to the partner under the assurance that they could claim 100% of any costs back from a similar Innovate UK grant to the one utilised by Cortilens.

At first glance these estimates appear promising, however upon examination the wages are questionable, for example, the firm offers a research scientists wage of £29,200 per annum during the R&D. This is taken as an average of the £438,000 allocation

for 5 staff members across 3 years. This is flawed in and of itself as it doesn't compensate for the inflated wage of the CEO whose wage would be a part of this fund. Even still, this figure is only 75.4% of the average research scientist salary quoted by Indeed [2024]. This wage offer may deter experienced researchers from joining the company as the pay packet is considered entry-level for wages associated with research scientists [National Careers Service, 2024]. As such more lucrative opportunities would not be hard to find. If key personnel are attracted to other companies, subsequent to more competitive wages, it would be detrimental to the conformance to the allocated time-frame for the R&D of C-β outlined by Cortilens which in turn could have damaging effects on the progression of Cortilens as a business. A loss of key staff would also result in further expenses to the company to provide necessary training and to compensate for any delays in the timeline. A deeper analysis reveals that the company feels that the work of a CFO only warrants a payment of £33,600 over the entire 3-year project. This is less than a third of the base pay per year for a CFO as supplied by Glassdoor [2023a] in which 209 salaries of CFOs are averaged. This discrepancy is a result of Cortilens assuming that the work of a financial officer would only be needed a single day per month. This is entirely unrealistic. In actuality, the average weekly workload of a CFO frequently exceeds 50 hours [CFO Editorial, 2015]. Similar cases can be made for the CLO and Marketing Director where Cortilens estimate a workload warranting £8,904 and £9,600 per year respectively but annual base salaries sourced by Glassdoor [2024] and Glassdoor [2023b] are £47,000 and £65,000 respectively. Taking these three average wage figures as an amended guideline, the ineligible costs estimate of the company could need to be increased by approximately £500,000.

While it is difficult to evaluate these estimates with greater specificity it is abundantly clear Cortilens has underestimated the cost of staff. It is also apparent that the successful progression of Cortilens from the research phase to becoming a commercial product is dependent on outside investors and grant funding. This reliance poses a risk to the financial stability concerning the early stages of R&D. Especially in the first year where Cortilens plan to operate solely from the Innovate UK grant and shareholder investments.

B. Analysis of the initial profitability forecasts

Cortilens forecast that they will not make a profit until the year 2027. During this year they anticipate a profit to the company of £100,000 with a subsequent 13% increase annually aligning with the percentage growth of Addison's disease prevalence. This is calculated with the optimistic assumption that a total of 7,500 of the Addison's and Cushing's community would have interest in the C-β product at its immediate release. Cortilens proposes that they would partner with the NHS to effectively distribute the C-β product, this is seen as a mutually beneficial exchange because if successfully integrated, C-β could nullify the necessity for 6 monthly blood tests and hydrocortisone day curves which cost the NHS £50 and £300 respectively per procedure. Cortilens predicts a manufacturing cost of £15 per product, following the assumption that the company would supply C-β to 7,500 people every month it is proposed that 15,000 lenses be produced per month. This would cost Cortilens £2,700,000 to manufacture the entire year's worth. Cortilens proposes that the NHS would pay £2,800,000 for this product in its entirety. This evaluation suggests that the NHS would make a revenue of £74,950 by selling the product at the current prescription cost of £9.95 per product. Totalling £899,400 over the year. This leaves the NHS in a shortfall of £1,900,600. This is mitigated by the assumed £400 saving made per person per year as the need for blood tests and hydrocortisone day curves is made redundant. This would save the NHS £3,000,000 annually. After covering the shortfall, Cortilens would save the NHS £1,099,400 annually.

Following the forecast of Cortilens, even allowing for the extravagant assumptions made, the net profit to Cortilens is less than 4%. Considering the significant saving to the NHS it seems financially irresponsible to sell the product at only £100,000 more than the manufacturing cost. At this rate, Cortilens would make only 55 pence on each contact lens sold. Taking the NHS savings as comparable exactly to the potential profit made by Cortilens, it would be a more sensible decision to sell the product to the NHS at a cost of £3,200,000. This modified distribution of funds would retain significant savings on behalf of the NHS (£699,400) encouraging the widespread implementation of C-β, while simultaneously increasing the worthwhile of the venture for Cortilens as they earn 500% of the profit supposed by the previous model.

VI. Analysis Summary and Suggested Action

A. Summary of Commercial Viability at the current stage of the Business Model

Overall it is clear that the Cortilens business model faces a plethora of issues that will inevitably affect the feasibility of the company's commercial success. These include but are not limited to the ambiguity associated with their proposed technology, the

narrow market consequent to the rarity of Addison's and Cushing's disease and the financial naivety regarding both expenditure and earnings.

B. Suggested Action

The company must provide a clearer means of achieving its goal to confidently promote the C-β product as anything more than a pipe dream. At current the technology they propose though intriguing and theoretically plausible lacks any refinement past a surface-level idea. The company must also reconsider their evaluation of staff wages and availability ensuring realistic competitive wages and schedules. They must consider more sensible figures for their product value to be a successful enterprise. Should they rectify these oversights, they must then navigate the initial market challenges strategically. Adaptability will be crucial. The company must pursue alternative applications for its technology to broaden its market appeal and create additional revenue streams from a larger customer base. One approach could involve exploiting functionalities of C-β that could cater to a wider audience, such as stress monitoring for the general population. This would significantly increase market size and product appeal and would not require a great deal of upheaval to the product itself, given that stress and cortisol levels are known to be closely associated [Vedhara et al., 2003]. Further development such as multi-functional lenses would further broaden the market by incorporating other medical conditions that would benefit from continuous monitoring. Notably, the redirection to stress monitoring would require a complete change in marketing strategy and a distancing from the company's current mantra. The multi-functional approach however, would require further R&D investigating the utility of the other biomarkers found in tear fluid this could include health monitors for conditions such as glaucoma, diabetes, Alzheimer's and even cancer [von Thun und Hohenstein-Blaul et al., 2013]. This approach, while remaining true to the bettering of neglected diseases, could involve a long-term investment and require further assistance from big medical companies in trial phases and development.

The above strategies could be integrated into Cortilens's business model to mitigate the risks associated with its currently limited target market and ensure a more robust and sustainable growth trajectory.

VII. Conclusion

The Cortilens business model is an interesting prospect with a good-intentioned product, which if released commercially could benefit the lives of thousands, potentially saving some. It has to be concluded, however, that in its current form, the business model does not present a feasible business option. This is a result of the cumulative addition of several major oversights that will need significant work to rectify. There is the potential for Cortilens to re-brand itself as more generalised for public consumption as a stress monitoring tool which could prove more lucrative. However, this option could be to the detriment of the initial mission plan of aiding neglected diseases. It would therefore be a decision between the company's morality and its economic sustainability unless an ideal medium could be established.

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