THE CONTENT OF THIS DOCUMENT HAS NOT BEEN APPROVED BY AN AUTHORISED PERSON WITHIN THE MEANING OF THE FINANCIAL SERVICES AND MARKETS ACT 2000. RELIANCE ON THIS DOCUMENT FOR THE PURPOSE OF ENGAGING IN ANY INVESTMENT ACTIVITY MAY EXPOSE AN INDIVIDUAL TO A SIGNIFICANT RISK OF LOSING ALL OF THE PROPERTY OR OTHER ASSETS INVESTED. SEE IMPORTANT INFORMATION ON PAGE 5.

IF YOU ARE IN ANY DOUBT ABOUT THE CONTENTS OF THIS INFORMATION MEMORANDUM YOU SHOULD CONTACT YOUR FINANCIAL ADVISER, STOCKBROKER, BANK MANAGER, LAWYER, ACCOUNTANT OR A PERSON AUTHORISED UNDER THE FINANCIAL SERVICES AND MARKETS ACT 2000 AND WHO SPECIALISES IN ADVISING ON INVESTING IN UNLISTED SHARES.

redecol

Respiratory innovation for life

# Investment Memorandum

# Transformational Respiratory Self-Care Monitor

Opportunity for 15x ROI
£4m raise on £8m pre-money value
Respiratory Digital Health/MedTech
Innovative low-cost lung function monitor
Unique sensor developed and clinically tested
Sensor has 3 patents granted in Europe and USA
Reduces healthcare costs and improves outcomes
600m potential users of easy-to-use selfcare device
Agile company with commercial partner licensing model
Additional DTC, research and elite sports sales opportunities

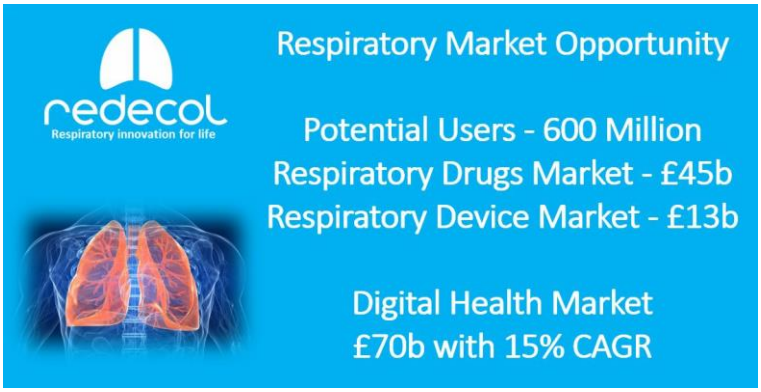
# Executive Summary

**Investment Opportunity**

Redecol is seeking an investment of £4m to complete the development of its transformational low-cost self-care respiratory monitor.

**The Respiratory Market**

Nearly one in ten people in the world suffer from a chronic respiratory condition and yet there is no easy way for them to assess their lung function. Current respiratory monitors (spirometers and peak-flow meters) are difficult to use (they require 'forced exhalation' to generate a reading) and results depend upon the user's technique.



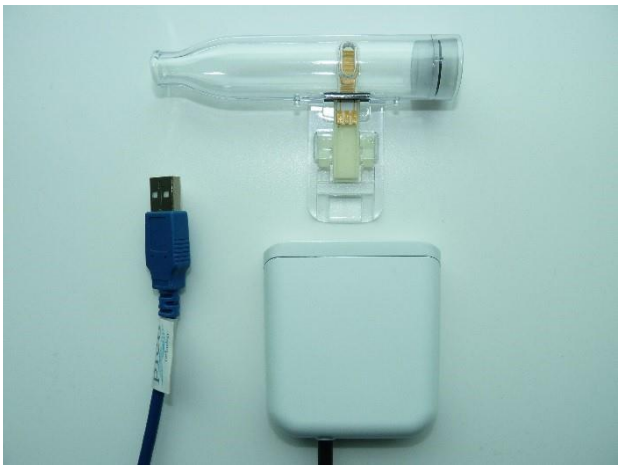

The cost of treating respiratory conditions globally is huge (about £45b per year for medicines with the respiratory device market costing a further £13b).

Covid-19 has recently accelerated the trend towards remote monitoring and home-based care. The digital health market is already valued at £70b per annum and growing at 15% CAGR. This is the market in which Redecol works.

Redecol has developed and clinically tested a novel, patent protected lung function monitor which is based on normal tidal breathing (just like we do all day every day). It is easy to use (not technique-based) and can be used by anyone, including people with really compromised lung function and also by young children. Importantly, it is low-cost. It measures the way the user exhales during normal breathing. Exhalation is a key indicator of inflammation and obstruction within the lungs.


Redecol's device is not disease dependent. It measures lung function so it can monitor asthma, chronic obstructive pulmonary disease (COPD), lung cancer, cystic fibrosis, idiopathic pulmonary fibrosis and long-Covid. Redecol's management team have estimated the market potential for its technology at over £800m per year. The team has chosen asthma as its first target market.

**Redecol's Exhaled Breath Condensate Respiratory Monitor (EBCRM)**



The technically-challenging development of the sensor and breathing pathway have been completed. The clinical studies have demonstrated that results from Redecol's

Redecol has already developed and clinically tested a proof-of-concept Exhaled Breath Condensate Respiratory Monitor. This has now completed four independent clinical studies with over 400 participants. The results have been published and presented at clinical conferences.

EBCRM are equivalent to the current 'Gold standard' for assessing lung function, FEV1, but are delivered easily and conveniently.

**Commercialisation Plan**

With self-care in the community as the primary use for the EBCRM, due to the global nature of the opportunity, **Redecol intends to contract with strategic commercial partners with established respiratory reach**. The company has already had some positive early exploratory discussions with both respiratory MedTech companies and pharmaceutical companies.

From the outset, **Redecol's technology has been developed with commercialisation at the centre**. The same core devices and consumables can monitor different respiratory conditions with different price points by disease and country. **It will deliver long-term consistent revenues to the company, save costs for the healthcare payer and improve clinical outcomes for the users.**


The commercialisation plan includes the UK (as home market), EU markets (focusing first on the ones that are early adopters of remote monitoring and digital health) and the US market.

In addition to the above route to market, there are three other opportunities which the team intends to develop concurrently. Importantly, the first two opportunities can be addressed once the company has secured Class I UKCA/CE status.

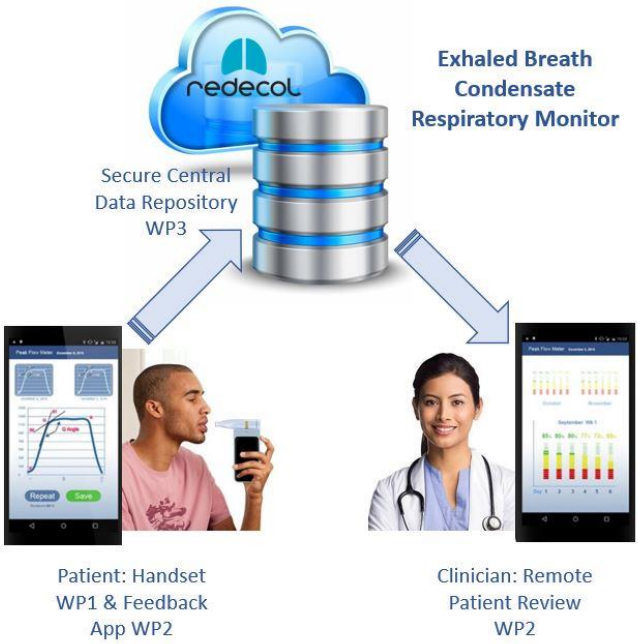
- **Direct to Consumer:** Once the Class I medical device license has been granted, the company could start developing a user-base through consumer purchase of the device as a lung function monitor. This could also be the primary commercialisation route in some markets.
- **Clinical Research:** There is a defined requirement for a reliable, easy-to-use lung function monitor during clinical studies. IQVIA reported that one of the primary reason for participants not completing respiratory clinical studies was failure to meet the spirometry requirements.
- **Elite Sports:** This is a niche market with potentially significant benefits, especially with its impact on young people. Monitoring lung function is a critical element of elite sport performance.

**Completing the EBCRM Development**

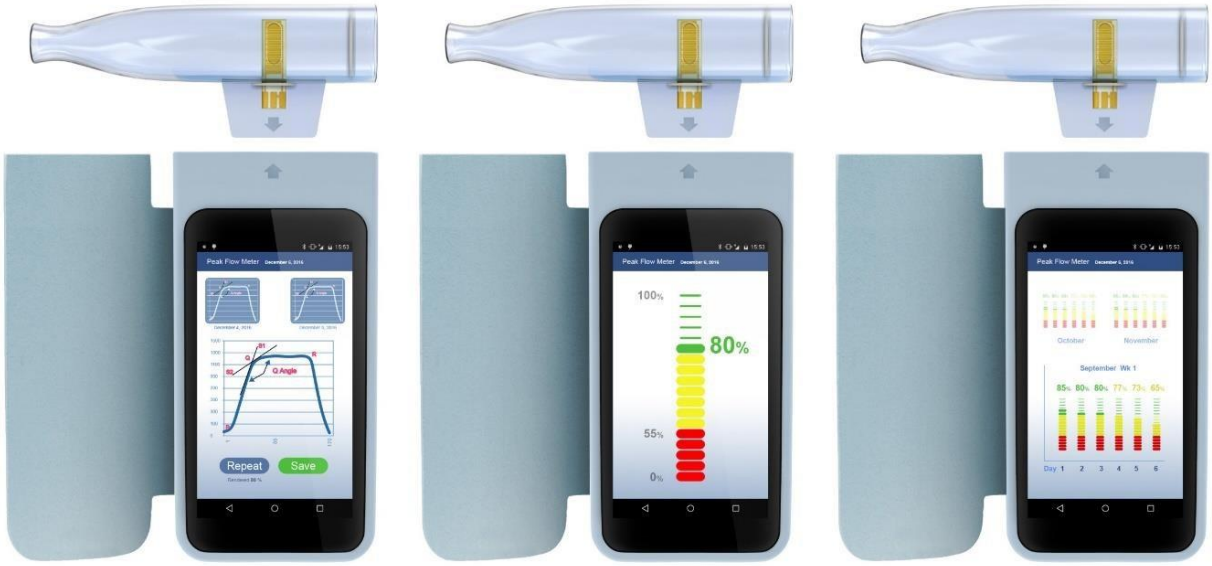
**Phase 1:** The team have focused on a plan to develop the 'minimum viable product' (MVP) which can then be enhanced, through embedded software, into a self-care monitor for any chronic respiratory condition.

The team has three primary deliverables for the MVP development project, which will position Redecol's innovative technology for the second development phase - a pivotal study for use in the monitoring of respiratory performance in asthma with both adults and children/young people (CYP). The three deliverables in Phase 1 are:

1. Develop the **user handset** from data-collector to pre-production respiratory monitor.
2. Develop a **feedback module** configurable to meet the needs of adults, CYP, parents/guardians/carers and clinical professions.
3. Develop a **secure central data repository** which can be used to provide access by the clinical team to the respiratory records of the EBCRM users.



**Phase 2:** The pivotal clinical studies will evaluate the EBCRM in comparison to the 'current standard of care'. These clinical studies will generate the data and the algorithm to upgrade the MVP so that it can be used as a self-care asthma monitor in Europe and the USA. Each study will take 21 months to complete, however the preparatory work will commence before the MVP is completed. Redecol will use its Class I device as the data collector device through the studies, with each study participant using the device at least once per day for a period of at least six months. At the end of this phase, the EBCRM will be registered as a Class IIa (Class 2) medical device for the self-care management of asthma.




**Redecol and Its Core Management Team**

Redecol Limited was formed in February 2017 to research, develop and commercialise unique sensor technology for the monitoring and managing Asthma and COPD. Redecol obtained a perpetual field of use licence for Asthma and COPD from Anaxsys Technology Limited (Anaxsys), which had developed the sensor technology over a number of years previously. In September 2019 Redecol acquired Anaxsys, and as a result now owns the three patents and all the IP relating to sensor technology.

Redecol has a strong core management team, knowledgeable board, trusted suppliers and experienced advisers.

- **Jeremy Walsh, CEO:** Jeremy has 30+ years' experience in healthcare information systems, MedTech and Digital Health. He has been a life-long innovator, holding leadership positions in both publicly-quoted companies and emerging SMEs. Jeremy has been involved in two successful healthcare information NASDAQ IPOs.
- **Zia Mursaleen, Finance Director:** Zia is a chartered accountant and corporate financier. As well as bringing his financial expertise to Redecol, Zia has been 'hands on' during the technical and clinical development of its technology.
- **Margaret McQueen, Quality Assurance Manager:** Margaret has in depth knowledge of the technology and processes, she has developed and implemented the company's quality system, securing ISO 13485 accreditation.
- **Dr Graham Hine, Board Chair:** Graham has broad leadership experience across a range of medical equipment, nanotechnology and sensor companies including listed and VC backed entities. As a serial CEO, Graham spun out, ran and exited companies from universities including Capteur Sensors (UCL), Microsaic (Imperial College), P2i (MOD, Porton Down) and Hardide (Moscow).
- **Barbara Lead, Non-Executive Director:** Barbara is the CEO at Oval Medical, a drug delivery device company. She has more than thirty years wide and varied experience in pharmaceutical and medical device industries at a VP and board level.
- **Tim Coutts, Non-Executive Director:** Tim has over thirty years of leadership experience in the MedTech sector, with senior roles in both multi-national (Boston Scientific) and SME organisations (including the "launch" CEO for Redecol).

The core team will be expanded during the development process, with commercialisation at the heart of the expansion.

## Financial Forecasts

Redecol benefits from a £8m corporation tax loss carry-forward. The management team has developed detailed financial forecasts for the company which are based on assumptions which the team believe are realistic and achievable. The dates assume that the finance is secured in 3Q-2021, although the finance could be in two tranches.

| Summary Profit and Loss | £ | £ | £ | £ | £ | £ |
|---|---|---|---|---|---|---|
| | 2021 | 2022 | 2023 | 2024 | 2025 | 2026 |
| Sales (net of commercial partner margin) | - | - | 2,295,000 | 10,232,100 | 23,515,673 | 53,007,959 |
| Cost of Sales | - | - | 1,032,750 | 4,188,321 | 9,356,021 | 19,864,738 |
| Gross Profit | - | - | 1,262,250 | 6,043,779 | 14,159,652 | 33,143,221 |
| Profit after tax | (663,498) | (1,178,810) | (956,377) | 4,078,176 | 7,637,893 | 20,894,457 |

| Summary Cash Flow | 2021 | 2022 | 2023 | 2024 | 2025 | 2026 |
|---|---|---|---|---|---|---|
| | £ | £ | £ | £ | £ | £ |
| New Funds raised (Net) | 3,846,400 | (4,800) | (4,800) | (4,800) | (4,800) | (4,800) |
| Net cash flow | 3,324,861 | (1,203,650) | (949,809) | 1,920,912 | 10,770,252 | 26,189,496 |
| Balance b/f | 30,456 | 3,355,317 | 2,151,667 | 1,201,858 | 3,122,770 | 13,893,022 |
| Balance c/f | 3,355,317 | 2,151,667 | 1,201,858 | 3,122,770 | 13,893,022 | 40,082,517 |

| Summary Balance Sheet | 2021 | 2022 | 2023 | 2024 | 2025 | 2026 |
|---|---|---|---|---|---|---|
| | £ | £ | £ | | | |
| Net Assets | 3,646,993 | 2,468,183 | 1,511,806 | 3,596,931 | 11,234,825 | 32,129,281 |
| Shareholders Funds | 3,646,993 | 2,468,183 | 1,511,806 | 3,596,932 | 11,234,825 | 32,129,282 |

## Use of Funds

The first £1.5m of the investment will develop the UKCA/CE Class I MVP. The remaining £2.5m will be primarily focused on funding the asthma pivotal clinical studies and commercialisation for the Class IIa (Class 2) asthma self-care device.

## Exit Opportunities

Redecol's technology will be an attractive acquisition to three groups of companies, each of which are also potential commercial partners:

- **MedTech Companies**, such as Trudel Medical, Aptar, ResMed and Philips
- **Pharma Companies**, such as GSK, AstraZeneca, Circassia and Chiesi
- **Healthcare Data Companies**, such as IQVIA, Amazon and Google

Redecol has already had early-stage exploratory discussions with many of these companies with respect to commercial partnerships. Although the Board believes that the best shareholder value will be delivered by completing the development of the technology through to commercialisation, they also envisage that the company will attract offers of increasing value as soon as UKCA and CE marking as a Class I device are granted.

- **Mid-2022:** UKCA and CE-marked Class I EBCRM. Exit catalysed before the second tranche investment at a target value of £15m or more.
- **Early 2024:** Completion of the pivotal asthma selfcare clinical study with UKCA and CE-mark for Class IIa selfcare monitor for asthma, at a target value of between £25m and £40m.
- **Late 2024:** With FDA marketing approval for asthma selfcare in the USA, at a target value in excess of £75m or more.

## Indicative Term Sheet

Redecol's shareholding consists entirely of Ordinary shares, including an EMI Share Option Plan. The fully diluted share capital is 5,760,234 shares. Redecol is raising £4m of new equity funds (possibly in two tranches). This equates to 2,880,117 Ordinary Shares at £1.39 each. The issue of the Ordinary shares will attract EIS.

# Contents


Important Information ..... 8
Redecol's Market ..... 10
People with Chronic Respiratory Diseases ..... 10
Treatment of Respiratory Conditions ..... 12
The Challenge – Improving Patients' Self-Care ..... 13
Digital Health Self-Care Transformations ..... 13
Market Opportunity (SAM, SOM) ..... 14
Redecol's Respiratory Self-Care Technology ..... 15
A Monitor Based on 'Normal' Tidal Breathing ..... 15
Fully-Developed, Unique Patented Sensor ..... 15
Easy-to-Use Respiratory Self-Care Diagnostic ..... 16
Intellectual Property ..... 17
Stakeholder, Patient and B2C Proof-of-Market Research ..... 17
Exploratory Clinical Research ..... 19
First Clinical Study ..... 20
Second Clinical Study ..... 20
Third Clinical Study ..... 20
Fourth Clinical Study ..... 21
Expressions of Support for EBCRM ..... 21
Commercialisation ..... 23
Overview ..... 23
Strategic Commercial Partners ..... 23
Exploratory Commercial Partner Discussions ..... 24
Designed for Commercialisation ..... 24
First Target Market - Asthma ..... 25
Competitive Advantage ..... 25
US Market Entry & Reimbursement ..... 25
Reimbursement Assessment ..... 26
Plans which have long-term health commitments ..... 26
Completing the Development of the EBCRM ..... 27
Redecol's Respiratory Digital Health Solution ..... 27
Development Timeline ..... 27
Phase 1: Minimum Viable Product (MVP) ..... 28
Handset and Feedback App Design ..... 28

MVP Project Plan ..... 29
MVP Risks Have Been Mitigated ..... 31
Phase 2: Pivotal Asthma Self-Care Management Clinical Studies ..... 33
Current Standard of Care ..... 34
Expected EBCRM Marketing Claims ..... 35
Redecol's Core Team ..... 36
Management Team ..... 36
Redecol's Board ..... 36
Adding Breadth and Depth ..... 37
Specialist Consultants ..... 38
Specialist Subcontractors ..... 39
Company and Financials ..... 40
About Redecol ..... 40
Forecast Financials ..... 40
Forecast Summary Profit and Loss ..... 41
Forecast Summary Cash Flow ..... 41
Forecast Summary Balance Sheet ..... 42
Use of Funds ..... 42
Key Investment Facts ..... 42
Potential Shareholder Exits ..... 43
Recent Respiratory MedTech/Digital Health M&A Activity ..... 43
Contact Details ..... 44
Redecol Limited ..... 44

# Important Information

Purpose of Document

This Information Memorandum (the "Document") has been prepared to assist the Recipient in making its own evaluation of Redecol Limited ("Redecol" or the "Company") and the investment opportunity (the "Transaction"). The Recipient is to rely solely on its own knowledge, investigation, judgement and assessment of the matters that are the subject of this Document and in deciding whether or not to proceed with a Transaction.

This Document does not constitute an offer or invitation to subscribe, purchase, or otherwise acquire any financial product including shares or any assets of Redecol. This Document is not intended to be, and does not constitute, a prospectus, an investment statement, a product disclosure statement or other disclosure document whether under the Financial Markets Conduct Act 2013, or otherwise. It is not intended for this Document to form the basis of any contract.

Confidentiality

This Document contains confidential information about the Company's development plans. It is made available specifically to assist the Recipient in the evaluation of Redecol Limited and the Transaction. It should not be disclosed to any third party except to the Recipient's advisers about the Transaction.

Forward-Looking Information

Certain information in this Document contains "forward-looking information", including "future-oriented financial information" and "financial outlook", frequently referred to as "forward-looking statements". Except for statements of historical fact, the information contained herein constitutes forward-looking statements and includes, but is not limited to, the (i) projected financial performance of the Company; (ii) completion of, and the use of proceeds from, the sale of the shares being offered hereunder; (iii) the expected development of the Company's business and projects; (iv) execution of the Company's vision and growth strategy; and (iv) future liquidity, working capital, and capital requirements. Forward-looking statements are provided to allow potential investors the opportunity to understand management's beliefs and opinions in respect of the future so that they may use such beliefs and opinions as one factor in evaluating an investment.

These statements are not guarantees of future performance and undue reliance should not be placed on them. Such forward-looking statements necessarily involve known and unknown risks and uncertainties, which may cause actual performance and financial results in future periods to differ materially from any projections of future performance or result expressed or implied by such forward-looking statements.

Although forward-looking statements contained in this Document are based upon what Redecol's management believes are reasonable assumptions, there can be no assurance that forward-looking statements will prove to be accurate, as actual results and future events could differ materially from those anticipated in such statements. The Company undertakes no obligation to update forward-looking statements if circumstances or management's estimates or opinions should change except as required by applicable securities laws. The reader is cautioned not to place undue reliance on forward-looking statements.

Disclaimer

The information contained in this Document has not been independently verified by Hyman Capital Limited ("Hyman"). No representation or warranty, express or implied, is or will be made as to the accuracy or completeness of the information and opinions contained in this Document or of any written or oral information and opinions provided now or in the future to any interested party or its advisers. In particular, no representation or warranty is given as to the achievement or reasonableness of any plans, future projections, management targets, prospects or returns and nothing in this Document is or should be relied upon as a promise or guarantee as to the future.

No responsibility or liability (whether for negligence, under statute or otherwise) is or will be accepted by Redecol or any of its respective directors, shareholders, employees or advisors for any loss or damage of whatsoever kind (whether foreseeable or not) which may arise from any person acting on the information and opinions relating to Redecol contained in this Document or any information which is made available in connection with any enquiries.

Nothing contained in this Document is intended to be legally binding; only the specific terms which are contained in a final Transaction agreement will have any legal effect.

This Document does not purport to contain all of the information that may be required to evaluate the proposed transaction and any Recipient should conduct its own independent analysis of the businesses and the data contained or referred to herein or therein. Neither Redecol nor Hyman undertakes or expects to update or otherwise revise this Document or other materials supplied. No information set out in this Document will form the basis of any contract. Any acquirer will be required to acknowledge in the Transaction agreement that it has not relied on, or been induced to enter into such agreement by, any representation or warranty, save as expressly set out in such agreement.

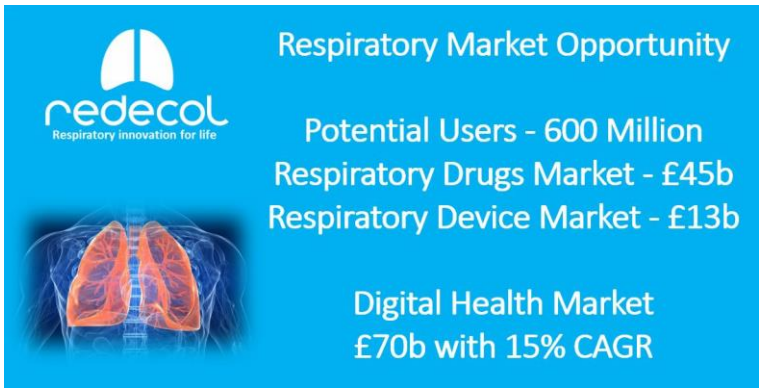
# Redecol's Market

## People with Chronic Respiratory Diseases

**Nearly one in ten people in the world suffer from a chronic respiratory condition.** Even with adherence to the global climate treaties such as the Paris Climate Agreement, the numbers are expected to grow due to increasing allergies, the continued impact of smoking, cooking with wood stoves and industrial pollution.

> "At least 2 billion people are exposed to indoor toxic smoke, 1 billion inhale outdoor pollutant air and 1 billion are exposed to tobacco smoke. The truth is that many of us are naïve to these stark realities."
>
> The Global Impact of Respiratory Disease, WHO[1]

The most prevalent conditions can be well managed by medication. However, adherence to respiratory medication is poor, partly due to lack of easy-to-use lung function monitors. Existing devices are difficult to use and often make the users feel worse. Inadequate self-care monitoring results in poorly used medication, resulting in greater patient distress, unnecessary deaths, avoidable hospitalisations and increased healthcare costs.




Hospitalisation for a respiratory condition typically results in immediate treatment at an emergency facility, leading to the administration of oral steroid drugs. It may also trigger the intervention of further drug treatments such as nebulisers, further oral treatments and ongoing monitoring. Depending upon the condition, these may result in several days of in-patient treatment before discharge to recuperate at home. The impact of this economically is significant with people away from work, unable to support themselves, hospital and community support costs along with the extended monitoring and recovery period once the patient has been discharged.

| Chronic Respiratory Condition | Global Prevalence | Annual Deaths |
|---|---|---|
| Asthma | 339,000,000[2] | 375,000[3] |
| Chronic Obstructive Pulmonary Disease | 251,000,000[1] | 3,200,000[4] |
| Lung Cancer | 2,100,000[5] | 1,800,000[5] |
| Idiopathic Pulmonary Fibrosis | 750,000[6] | 200,000 |
| Cystic Fibrosis | 70,000[7] | |
| Long Covid (numbers for UK only) | 300,000[8] | Unknown |
| Total | >593,220,000 | |

[1] World Health Organisation. Global Impact of Respiratory Disease. 2017
[2] Global, regional, and national incidence, prevalence, and years lived with disability for 328 diseases and injuries for 195 countries, 1990–2016: a systematic analysis for the Global Burden of Disease Study 2016. Lancet 2017; 390: 1211–59.
[3] The Global Asthma Report. Global Asthma Network, 2018 (www.globalasthmanetwork.org)
[4] World Health Organisation, Burden of COPD. (Over 3m people died from COPD in 2005, to be the third leading cause of death by 2030.)
[5] The Cancer Atlas. https://canceratlas.cancer.org/the-burden/lung-cancer/ accessed March 2021. Figures for 2018.
[6] Market Spotlight: Idiopathic pulmonary fibrosis (IPF) (researchandmarkets.com)
[7] Cystic Fibrosis Foundation. About Cystic Fibrosis | CF Foundation Accessed December 2020
[8] Office for National Statistics, January 2021. People with COVID-19 symptoms lasting between 5 and 12 weeks.

Asthma: 339 million people globally have asthma[2], including 25 million in the USA[9] and 30 million in the EU[10], resulting in over 1,000 deaths per day.[2]

Correct use of current asthma prescription medicines can control most asthma. Doctors provide Personal Asthma Action Plans to people with asthma explaining how to use their preventer (long term therapy, step-up and step-down) and reliever drugs. However, in general, compliance and adherence to asthma medication is quite poor, partly due to lack of easy-to-use convenient self-care lung function monitors. Currently there are no monitors that children can use, resulting in an extremely high hospitalisation rate in the young, as evidenced in Figure 1 (US figures).

In addition to the direct costs of €19.5b (£16.6b) for treating asthma in Europe in 2011, the indirect costs of lost employment and early retirement were estimated at €14.4b (£12.3b).[11]

In the UK, 5.4 million people have asthma[12]. Every day 185 emergency UK hospital admissions (costing over £50 million per year) relate to asthma; 75% are avoidable[8]. About 17,500 UK GP and nurse appointments daily are about asthma[13]. Two thirds of asthma related deaths in the UK are preventable [14] . Independent research indicates that better asthma self-care will reduce avoidable deaths, as well as saving the NHS over £130 million in healthcare costs each year.[15]

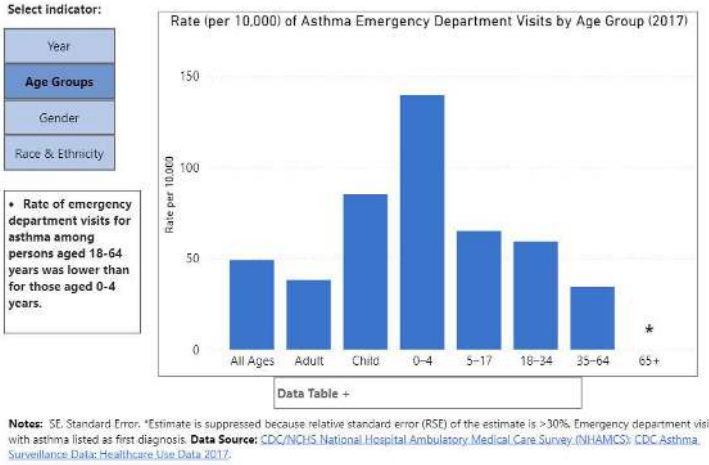



**Figure 1: US asthma hospitalisation rates by age (Source: CDC)**

NICE say that asthma outcomes have not improved in the past 15 years and the personal and economic costs of poor control are high. "The efficient use of distance monitoring systems and the integration of new technologies into healthcare are important for patients and for healthcare systems in terms of convenience, costs and outcomes."[16]

Chronic Obstructive Pulmonary Disease (COPD): 251 million people globally have COPD, 16 million in the USA [17] and 44 million in the EU[7], resulting in 8,750 deaths per day[3]. COPD is generally associated with smoking and the effects of inhaling wood smoke. The numbers of people with COPD are increasing due to pollution, smoking and allergies. Since COPD is a progressive and debilitating disease, the primary requirement it to provide advance warning of lung function deterioration which can lead to an exacerbation.

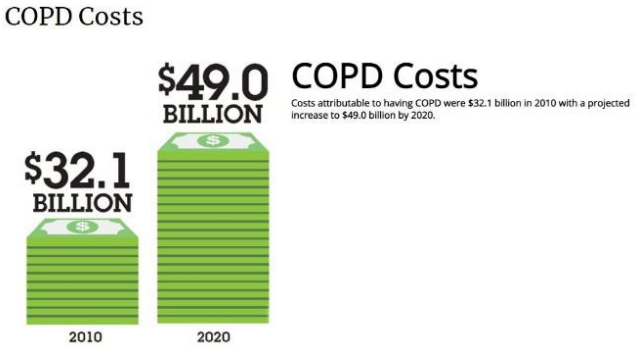



**Figure 2: US COPD Healthcare Cost Escalation (Source: CDC)**

In the United States, the costs of treating COPD have risen from $32.1b (£23.2b) in 2010 to an estimated $49b (£35.5b) in 2020. In addition to the direct costs of €23.3b (£19.8b) for treating COPD in Europe in 2011, the indirect costs of lost employment and early retirement were estimated at €25.1b (£21.4b).[18]

---

[9] Center for Disease Control and Prevention, National Center for Health Statistics, Asthma. 2018 (FastStats - Asthma (cdc.gov))

[10] European Respiratory Society. The European Lung White Book, Chapter 11 Childhood Asthma, Chapter 12, Adult Asthma. (https://www.erswhitebook.org/) April 2019.

[11] European Respiratory Society. The White Book - The economic burden of respiratory disease.

[12] Asthma UK Facts and Statistics. Asthma facts and statistics | Asthma UK

[13] Asthma UK. Study estimates that asthma care costs at least £1.1bn per year | Asthma UK

[14] Asthma UK. July 2017. Asthma UK calls for action to end preventable asthma deaths | Asthma UK

[15] York Health Economics Consortium & The School of Pharmacy, University of London. Evaluation of the Scale, Causes and Costs of Waste Medicines. 5.3 Asthma Findings. 2010

[16] NICE Asthma Guideline NG80 (November 2017)

[17] Center for Disease Control and Prevention. (CDC - Basics About COPD - Chronic Obstructive Pulmonary Disease (COPD))

[18] European Respiratory Society. The White Book - The economic burden of respiratory disease.

In the UK, it is estimated that 1,200,000 have COPD; about 4.5% of the population over 40 live with diagnosed COPD[19]. The prevalence per 100,000 people has increased by 27% in the last decade. The UK is in the top 20 countries for COPD mortality worldwide.

COPD is managed with a mixture of inhaled drugs and steroids. Patients with poorly controlled COPD can suffer debilitating exacerbations which result in hospitalisation. The exacerbation will have a permanent effect on lung function and it can take patients weeks or months to recover. Hospitalisation costs for COPD exacerbations range from between £1,900 to £5,000 each time for the NHS[20] to approaching $40,000 (£29,000) in the USA[21]. Both from patient outcome and cost management perspectives, reducing exacerbations is a primary objective in the treatment of COPD.

Lung Cancer: It is estimated that 2.1m people globally are living with a diagnosis of lung cancer. 1.8m people each year will die of the disease.[4] However, incidence and mortality rates vary 20-fold between regions. The variation is similarly large across countries. The highest incidence rates among men are in Europe, particularly in Eastern European countries such as Hungary (77 cases per 100,000 male population) as well as Western Asia (particularly in the former Soviet Union) and in certain countries in Asia such as Turkey and China.[4]

About 85,000 people living in the UK have received a lung cancer diagnosis, which includes those cured and also those in remission. Lung cancer prevalence in the UK has risen by 23% since 2004. The age-adjusted mortality rate in the UK for lung cancer is the 11th highest in Europe. About 35,000 people per year in the UK die from lung cancer[22].

Idiopathic Pulmonary Fibrosis (IPF): About 750,000 people globally have IPF, with 180,000 new diagnoses annually[4]. IPF is a rare, progressive respiratory condition. Medicines can be used to slow the progression of the disease, but these medicines are expensive. Life expectancy with IPF is generally about three years.

Cystic Fibrosis (CF): About 70,000 people globally are affected by the serious condition, Cystic Fibrosis, of whom about 30,000 live in the USA[5]. About 1,000 new cases are diagnosed in the USA each year[5]. About half of the CF sufferers are aged 18 and over.

## Treatment of Respiratory Conditions

Most chronic respiratory conditions can be well controlled or managed in the community by current medicines. **The global spend on respiratory drugs was estimated at £45b in 2020, growing at 6% CAGR**.[23] The five companies with the largest sales of respiratory products (pre-Covid-19) account for about 45% of the total market and were GSK ($11.4b - £8.2b), AstraZeneca ($5.5b - £4.0b), Hoffman La Roche (£4.7b - £3.4b), Vertex ($4.2b - £3.0b) and Novartis ($2.0b - £1.4b)[24]. However, most of the costs in treatment of lung disease are due to poor medicines adherence from patients themselves, which results in emergency hospitalisation.

> "Hospital admissions for lung disease have risen over the past seven years at three times the rate of all admissions generally and remain a major factor in the winter pressures faced by the NHS."
>
> NHS 2020 Long Term Plan

In the UK alone, **treating lung disease costs the NHS and patients £10b a year**. **It is the 4th most costly disease area** to the UK, after mental health, muscular skeletal and heart disease.[25]

---

[19] British Lung Foundation. www.statistics.blf.org.uk/copd accessed March 2021

[20] Prevention of Admission for COPD Exacerbations (PACE). The AHSN Network, 2015

[21] Dalal AA, Christensen L, Liu F, Riedel AA. Direct costs of chronic obstructive pulmonary disease among managed care patients. International journal of chronic obstructive pulmonary disease. 2010;5:341–9. pmid:21037958

[22] British Lung Foundation. www.statistics.blf.org.uk/lung-cancer accessed March 2021

[23] Technavio. Respiratory Drugs Market 2018-2022

[24] GlobalData. Top Pharma Companies by Respiratory Sales, 2020

[25] British Lung Foundation. The Battle For Breath. 2017

## The Challenge – Improving Patients' Self-Care

Current devices used to monitor lung function, spirometers and peak-flow meters, are based on measuring proxies, effectively 'how hard you can blow'. **These devices are difficult to use**, technique dependent, deliver inconsistent results and, when used properly, can make the user feel significantly worse. Importantly, they provide highly unreliable results with young children, because they cannot be taught the techniques required. Understandably, patient **monitoring adherence is poor**. **Gradual changes in lung function over time are missed**, resulting in too many patients ending up in hospital with exacerbations, such as asthma attacks. **These are distressing for the patient, costly for the healthcare provider and result in avoidable fatalities**.

It is recognised that regular, long term self-monitoring of lung function needs to improve to deliver better patient outcomes.[26]

The respiratory device market (excluding inhalers) was valued at £13b in 2020, growing at 12.5% CAGR.[27] This market includes the costs of ventilators, CPAP machines, supplemental oxygen, capnometers, spirometers, peak-flow meters and pulse-oximeters. Although the market is slowly consolidating, no single company is dominant. Leading respiratory device companies include Phillips, ResMed, Becton Dickinson, Fisher Paykel, Hamilton Medical, BREAS, Carefusion, Henry Schein, Smiths Medical, Trudell Medical and Sibel. The monitoring of lung function is dominated by two technologies:

**Spirometers** were invented in 1840's by English Surgeon, John Hutchinson, who wanted to monitor patients with tuberculosis in sanatoriums. He coined Vital Capacity as the term for lung volume, also identifying restriction in the lungs. In the 1950's Dr Tiffeneau of France identified the current metric of Forced Expiratory Volume in 1 Second, FEV1. He also identified obstruction in the lungs, enabling use for both asthma and COPD. In the 1960's, Jones Medical developed the first modern "waterless" spirometer. Spirometers need three matching 'forced expiratory manoeuvres' to deliver reliable lung function readings. The training for respiratory nurses in the use of the devices is three days.[28] It is recognised that there are many ways to generate unreliable results in self-care[29] and it is also nearly impossible for children to master the technique to use this device.

**Figure 3: Digital spirometer**

**Peak-Flow Meters** were developed in the 1950's, pioneered by the company, Martin Wright. They use the concept of Peak Expiratory Flow as an index of lung function. This 'forced expiratory manoeuvre' identifies obstruction by measuring airflow through the bronchi. In the mid-2010's digital peak flow meters were introduced. Peak flow meters are recommended as part of asthma management plans because they are inexpensive. However, again they are technique dependent and only measure a proxy of respiratory function.


**Figure 4: Inexpensive peak flow meter**

## Digital Health Self-Care Transformations

The digital health market is developing rapidly, a beneficiary of both market evolution and acceleration due to the Covid-19 pandemic. Other conditions have been transformed in their self-care management. The most notable of these is with the management of diabetes. Self-monitoring of blood glucose has been integrated into self-care monitors with automated dispensers.[30] As well as substantial patient benefits and improved quality of life, this has resulted in the significant reduction in diabetes-related hospitalisation.

[26] NICE Asthma Guideline NG80 (November 2017)
[27] Markets and Markets. Respiratory Devices Market, 2020
[28] Standardization of Spirometry 2019 Update. An Official American Thoracic Society and European Respiratory Society Technical Statement
[29] Spirometry Quality Assurance: Common Errors and their Impact on Test Results. CDC NIOSH
[30] Flex. Blood glucose meters – 50 years of transformation. July 2020

With the launch of the iPhone in 2007, and the growing trend in wearable fitness monitors, patients now have the ability to support their medical conditions through convenient and reliable technology. Whilst not universal, the smart phone now dominates the personal communication market, even in the elderly. The public in general now relies on smart phones for personal banking, on-line shopping, social media and news. Digital health is playing catch-up in most markets.

One of the impacts of the Covid-19 pandemic has been to accelerate the acceptance and demand for remote monitoring of chronic conditions[31], with a special focus on cardio-respiratory conditions. **The digital health market for all conditions was valued at £70b in 2020, growing at 15.1% CAGR**.[32]

## Market Opportunity (SAM, SOM)

Redecol has assessed the market opportunity based on its Average Selling Price (ASP) by condition and by market, the Global Prevalence of each condition, the percentage of the population who are target users, the ability to pay (level of healthcare funding), compliance, adherence, market price modifier and the maximum market penetration[33]. This was used to reduce the Total Available Market to the Serviceable Available Market (SAM) and the Serviceable Obtainable Market (SOM). (Please note that the company has not assessed market opportunity for Long Covid and has marked it as N/A.)

| Chronic Respiratory Condition | Global Prevalence | SAM (£M) | SOM (£M) |
|---|---|---|---|
| Asthma | 339,000,000 | £3,119 | £493 |
| Chronic Obstructive Pulmonary Disease | 251,000,000 | £1,187 | £229 |
| Lung Cancer | 2,100,000 | £38 | £15 |
| Idiopathic Pulmonary Fibrosis | 750,000 | £119 | £66 |
| Cystic Fibrosis | 70,000 | £12 | £6 |
| Long Covid (numbers for UK only) | 300,000 | N/A | N/A |
| Total | >593,220,000 | £4,475 | £809 |

Redecol's Serviceable Available Market is £4.475B and its Serviceable Obtainable Market is £809M. The company's initial target market is the largest respiratory condition - the management of asthma.

The time is right to transform respiratory self-care monitoring.


[31] Deloitte Centre for Health Solutions. Digital Transformations: Shaping the future of European Healthcare. September 2020
[32] Grand View Research. Digital Health Market.
[33] Details of the market potential are available on request.

# Redecol's Respiratory Self-Care Technology

## A Monitor Based on 'Normal' Tidal Breathing

Simplistically, **the lungs inhale oxygen and exhale carbon dioxide and water vapour** (the two exhalation products of the respiratory cycle). **The way in which the lungs are functioning can be assessed through monitoring normal tidal breathing.**[34] Historically CO2 has been measured, capnography, during anaesthesia, but this technique has never been used for either diagnosis nor self-care monitoring, even though there are clear differences between healthy lungs and those with asthma.[35]

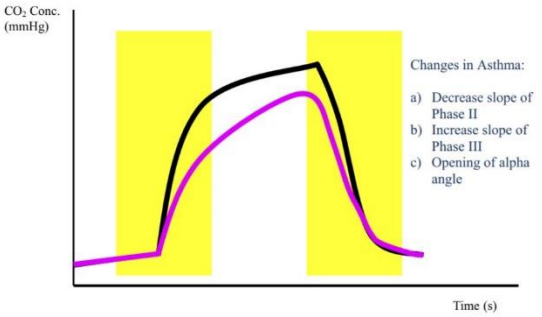



**Figure 5: Schematic of the differences between the CO2 waveform shape for asthma (red) and healthy (black)** (Reference 35)

Measuring exhaled CO2 is expensive as the sensor is compromised by water vapour. **Redecol has developed a low-cost, fast-responding, patented humidity sensor for monitoring the exhaled water vapour**. This sensor is at the heart of our technology.

Redecol's self-care respiratory monitor (EBCRM – Exhaled Breath Condensate Respiratory Monitor) will be **easy-to-use** and provide **easy-to-understand** information to enable patients to control their asthma by increasing their dose of preventer medication when lung function deteriorates, in line with a prescribed management plan, **reducing exacerbations and emergency admissions**.

## Fully-Developed, Unique Patented Sensor

Redecol's EBCRM is based on the company's unique Nafion sensor, which has been developed to measure **Exhaled Breath Condensate (EBC),** which is a direct output of the respiratory cycle, similar to $CO_2$. Our unique sensor, though technically complex to develop, can be produced at low cost and is patent protected. The way that the sensor works is illustrated schematically in Figure 6.

| Ion | Typical concentration |
|---|---|
| Na | 90mM |
| K | 60mM |
| Cl | 100mM |
| Urea | 0.5uM |
| Ammonium | 6mM |
| pH | 7.4 |

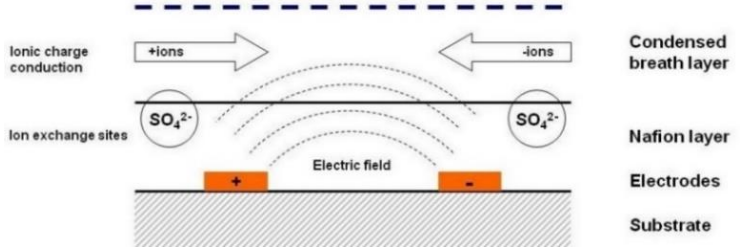



**Figure 6: Schematic of Mode of Operation of Redecol's Nafion Sensor**

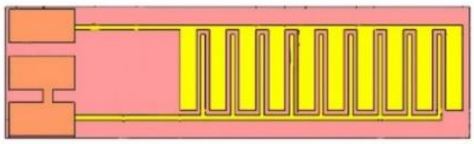


**Figure 7: Sensor Schematic**

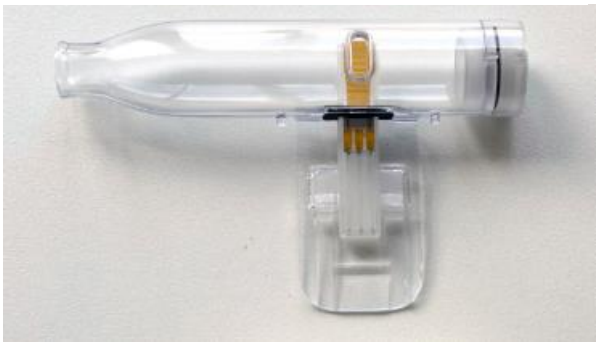


**Figure 8: Breathing Tube and Sensor Assembly**

Through extensive technical and clinical evaluations, it has been developed into the format shown in Figure 7 and has been incorporated into a breathing tube, shown in Figure 8. **The most technically challenging components of the technology, the replaceable sensor and breathing tube, are fully developed.**

[34] B. You, R. Peslin, C. Duvivier, V. Dang Vu, J.P. Grilliat. Expiratory capnography in asthma: evaluation of various shape indices. ERS Journals 1994.

[35] Howe TA, Kamaruddin J,Ahmad R, Chew KS, Hisamuddin NAR; The use of end-tidal capnography to monitor non-intubated patients presenting with acute exacerbation of asthma in the emergency department. The Journal of Emergency Medicine, Vol. 41, No. 6, pp. 581–589, 2011

# Easy-to-Use Respiratory Self-Care Diagnostic

Redecol's proof-of-concept device (Figure 9) has already been subjected to human factors research assessment and used in clinical studies. It has been CE-marked as a Class I respiratory data collector device. The respiratory waveform data can be displayed in real-time on the PC-based proof-of-concept software (Figure 10).

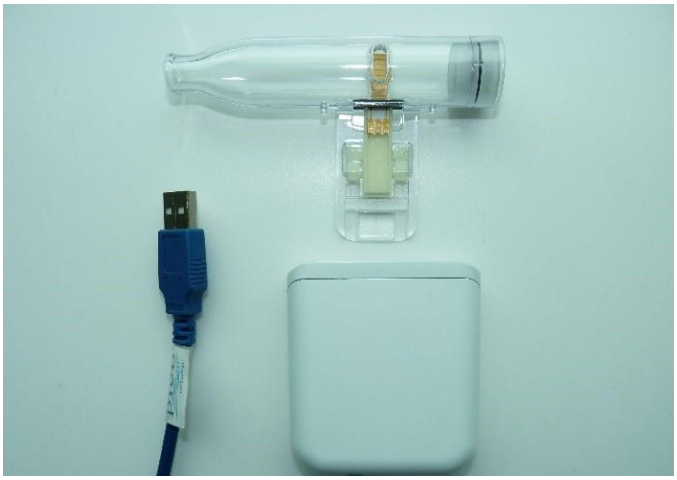


**Figure 9: PoC Class I data collector device**

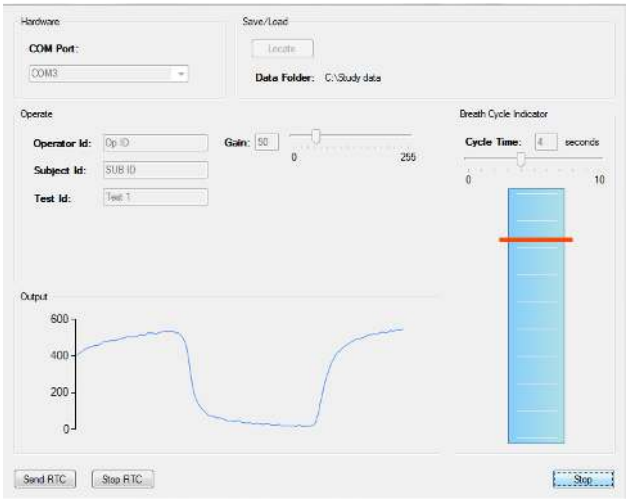



**Figure 10: Real-time output from data collector device**

The device is easy and relaxing to use. It is not technique dependent. The user forms a seal with their lips around the end of the breathing tube tube, then breathes deeply and steadily through it for 30 seconds. Each breath produces a breath profile and an average breath profile is then produced to indicate the user's current lung function.

The science that underlies the use of EBC for detection of respiratory function is that all exhaled air has a moisture content, created by during the respiratory cycle, which can be detected using our sensor as described above. The scientific hypothesis underlying our technology is that the lungs of people with respiratory conditions, such as asthma, have restricted (inflamed or obstructed) airways. Due to this restriction, the rate of deposition (concentration) of moisture from exhaled air onto the sensor is slower than for patients without asthma. The device generates reliable and consistent data. Importantly, there are key characteristics in the dataset which demonstrate a strong relationship to accepted diagnostic standards, particularly FEV1. (See Clinical Studies)

The resulting EBC respiratory profile, called a 'humidogram' (Figure 11) is conceptually very similar to a tidal breathing $CO_2$-based capnogram. It may be characterised as a curve having various points of inflection indicated as points A, B, C, D and E, which generally separate four phases.

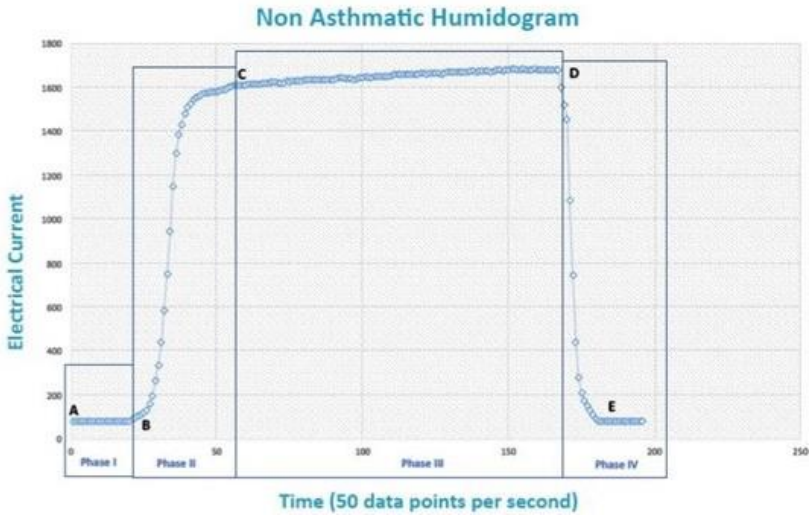



**Figure 11: EBC Humidogram profiles for healthy users**

**Phase I (A-B)**
Volume of gas that is substantially free of water vapour produced by the subject at the very start of exhalation, the gas having the humidity of the atmosphere being breathed by the subject.

**Phase II (B-C)**
Ascending phase characterised by a rapid increase in the content of water vapour, and represents the transition from gas having the background humidity to the gas expelled from the early emptying portions of the lungs of the subject.

**Phase III (C-D)**
(Alveolar) Plateau phase and corresponds to the gas expelled from the later emptying portions of the subject's

lungs, during which the content of water vapour in the gas being expelled continues to rise slowly with time. Point D is generally indicated to be the end-tidal content of water vapour.

**Phase IV (D-E)**
Final inhalation stage, during which the content of water vapour falls rapidly to that of the ambient gas composition.

## Intellectual Property

Redecol has both intellectual property protection and a clear Freedom to Operate with its innovative and novel technology, as demonstrated by the fact that the Nafion sensor has already been granted three patents:

1. The first gas sensor patent was granted US patent US 8,449,473 B2 on 28th May 2013. The sensor uses a Nafion layer to determine respiratory function using Exhaled Breath Condensate (EBC), a direct product of respiration, like carbon dioxide. Since EBC is based on water vapour, it is not affected by condensation which compromises most medical CO2 sensors.
2. Since the water vapour in the breath is a direct product of respiration, the sensor delivers a respiratory signature (a "humidogram") which is comparable to a standard CO2-based capnogram from a capnometer. A European patent for a "water vapour sensor" has recently been granted, reference EP 2 548 505 B1. This covers the sensor and the innovative way that it operates. This patent was granted in January 2020.
3. The third granted patent is US patent US 8,403,861 B2. This patent relates to the sensor's ability to detect lung lesions. Our research indicates that a particular type of humidogram obtained by the sensor is an indicator of a lung lesion. This patent was granted on 26th March 2013. Research continues in this use of Redecol's sensor in lung cancer detection.

Each of the above patents has also been filed in key markets to ensure that the patent protection is widespread. Redecol has unambiguous ownership of the above three patents, since the inventors have assigned all rights in the IP to the company. The company has completed several FTO searches, with the most recent being during the grant of its European patent application.

Although the manufacturing cost of the sensors is low, there is significant 'know how' involved in the manufacturing process to ensure that the sensors deliver reproducible information in a reliable and consistent manner. This know how is retained as 'company secret' which creates additional barriers to competition and protects the business in the longer term.

## Stakeholder, Patient and B2C Proof-of-Market Research

Redecol's technology has been subjected to proof-of-market assessment, both with clinicians as well as patients, by MedTech research specialists Harvey Research, based in Cambridge.

Study 1 - Primary Care Medical Professionals - May 2015[36]

> *The objective of this project was to research the market for a monitoring device that can help patients to improve the management of their asthma, leading to a reduction in asthma attacks that lead to hospitalisations and increased mortality. The study sought to understand the issues surrounding patient monitoring of asthma, including compliance issues and to establish if device design can improve compliance.*
>
> *Sixteen healthcare professionals were recruited. Six respiratory nurses (primary or secondary care) and ten GPs (with a special interest in respiratory). Recruitment took place in two regions in the UK – Cambridgeshire and Stockport. All interviews were face-to-face and took place at the participants' place of work, or at home. The interviews lasted for 45 minutes.*

Study 1 - Harvey Medical's Conclusions

> *Asthma patient monitoring and diagnosis is an ongoing problem resulting in patients being poorly managed and ultimately hospitalised.*

[36] Harvey Medical. Healthcare Professional Asthma Monitoring Device Proof-of-Market Study Final Report. May 2015

*Asthma patient monitoring has hardly evolved at all, with the primitive peak flow meter being the most a GP or nurse can offer even their most vulnerable of patients. The forced expiration technique required to use peak flow can be difficult and in some cases impossible for patients to achieve. Diagnosis in the Under 5's is a particularly worrying area for healthcare professionals. Current devices seem to incur an excessive number of lengthy initial diagnosis appointment due to spirometry taking around 20 minutes.*

*Most healthcare professionals interviewed use the British Thoracic Society. Asthma management plans are often created for patients but there is a huge variation in quality and customisation of these.*

*As seen in all sectors of medicine patient compliance is very subjective to a patient's personality. The less well-controlled asthmatics are the most compliant as they are unwell. In general, patients who are feeling well are poorly compliant.*

*Healthcare professionals would suggest that poorly controlled or brittle asthmatics monitor their asthma around once per day.*

*Hospitalisations have not notably subsided in the last ten years with the majority of healthcare professionals thinking there has been an increase.*

*Redecol's device was very well-received by respondents for both asthma monitoring and diagnosis. However the cost of the device (for the NHS to purchase) would likely inhibit this being used as a monitoring tool for all patients. However, there is definitely a strong market need for the Anaxsys device for certain groups of patients where the research indicated that a health economic argument could be generated. These patient groups being those who are not well-managed, perhaps over using their reliever inhalers, those being hospitalised, and brittle asthmatics. The patient interviews should focus on these patient types.*

*There is also a definite market need for Redecol's device in diagnosing patients who have asthma. The HCPs thought that Redecol's device would be far easier for younger patients, and elderly patients, to use as the technique is much easier. On the whole participants thought that the cost of Redecol's device for diagnosis could be around £200 to £300.*

*The CAD concepts were very well received with 5/6 respondents preferring the tablet option. The traffic light concept and percentage readout proving to be very popular even with GPs for their own interpretation. The research indicated that a patient monitoring device would only need to display the traffic light display. For diagnosis the healthcare professionals should have the option of also seeing the graphical data.*

Study 2 – Patients with Asthma and B2C Potential– August 2015[37]

*The objective of this project was to research the market for a monitoring device that can help patients improve the management of their asthma, leading to a reduction in asthma attacks that lead to hospitalisations and increased mortality. The study aimed to understand the issues surrounding patient monitoring of asthma, including compliance issues. The patient interviews evaluated if patients might buy Redecol's device off-the-shelf to monitor their asthma.*

*Twenty-five participants were recruited, to give at least eight patients in each category. No drop-outs occurred so there was an additional participant in Group 2.*

- *Group 1: 8 x adult asthma patients who are overusing their reliever inhalers (over 3 times a week)*
- *Group 2: 9 x patients who have been hospitalised due to their asthma in the last 12 months or who have had an asthma attack in the last 3 months*
- *Group 3: 8 x paediatric asthma patients with parents*

*Recruitment took place across Cambridgeshire and Essex. Patients were under the following hospitals: Addenbrooke's, Radwinter Road and Herts and Essex.*

[37] Harvey Medical. Patient Asthma Monitoring Device Proof-of-Market Study Final Report. August 2015

*All interviews were face-to-face and most (23/25) took place in the participants' home. This enabled the moderator and observer to get a greater perception of each participant's lifestyle, which a viewing facility could not achieve. The interviews were scheduled for 1 hour each.*

Study 2 – Asthma Patients' Response to B2C

*Patients were asked if they "would be interested in buying something like this if it wasn't available on the NHS?" 23/25 respondents expressed an interest with the majority being very positive with comments such as:*

- *P4 "definitely, yes definitely"*
- *P5 "I think that would be great"*
- *P11 "definitely… I think it would be really useful, you could monitor it and then go back and see"*
- *P12 "that would be handy"*
- *P13 "I think it sounds like a really good idea"*
- *P14 "That would be fantastic I would definitely use something like that"*
- *P16 "Oh you know this would be so useful as I know tomorrow she [the respiratory nurse] is going to ask me for the breakdown on how I've been feeling, and I haven't been writing it down, most people don't have time to write things like that down so this would be useful to have actual documented proof and information there on how it has been fluctuating if it has been.. and also to track back in there has been any particular reasons why it has got worse"*
- *P17 "I think that's a brilliant idea…*
- *P25 "For me it would be really helpful"*

Study 2 - Harvey Medical's Conclusions

*Redecol's device concept was very well received from a variety of patients from those well-controlled to those who are frequently hospitalised, appealing to both males and females, parents of children, and adults with asthma.*

*The research suggests that there is a market need for Redecol's device for people with asthma to buy off-the-shelf or online. Participants liked the idea of purchasing a 'starter pack' contained the electronics and around 6 month's supply of mouthpieces, with the ability to reorder more mouthpieces online. This could be marketed for around £80 (£50 for the electronic tablet and £5 per mouthpiece).*

*Redecol's device should be endorsed by Healthcare Professionals and preferably also with Asthma UK in order for most patients to buy it.*

*The research indicated that Redecol's device would be much easier to use than the peak flow meter especially when people are very poorly with their asthma. Interestingly parents of the children interviewed all gave a consistent view on how old a child would need to be in order to use Redecol's device. They thought the device could be used from the age of 3, as tidal breathing, for 30 seconds through the mouthpiece, could be achieved by a child of this age. This is a marked improvement on the age children can use the peak flow, which is around 6. Further research should be conducted with working prototypes to validate these findings as his could be a remarkable improvement for the future of asthma diagnosis and monitoring.*

## Exploratory Clinical Research

In addition to the Imperial College prototype study, Redecol's Class I respiratory data collector device, together with the proof-of-concept analytical software, has already been assessed in three clinical studies with adults. Throughout its development we have engaged with patients, clinicians, respiratory nurses, parents and care-givers.

**Redecol's proof of concept device has already been used by 400 patients in four clinical studies**. It has been proven to be **quick and easy to use**. The results delivered from monitoring exhaled breath condensate have demonstrated **equivalence to the more difficult to monitor spirometry and peak-flow**.

First Clinical Study

**Prototype Study - Imperial College – Professor Martyn Partridge** – Published as a clinical poster[38].

> Proof-of-principle study of an early prototype with 61 patients. The study results demonstrated that an early sensor design was able to distinguish between different levels of asthma status, and also **correlated with a high degree of significance (p+>0.001) with asthma status derived from spirometry.**

Second Clinical Study

**Proof-of-Concept Study- EU and Asia- Professor M Hasan** – Published in the Indian Medical Gazette[39]

This was an initial proof-of-concept study using Redecol's Class I PoC device and assessed against spirometry in 215 patients. The study team concluded that Redecol's device …. "**shows a good correlation with severity of asthma judged clinically as well as using spirometry**."

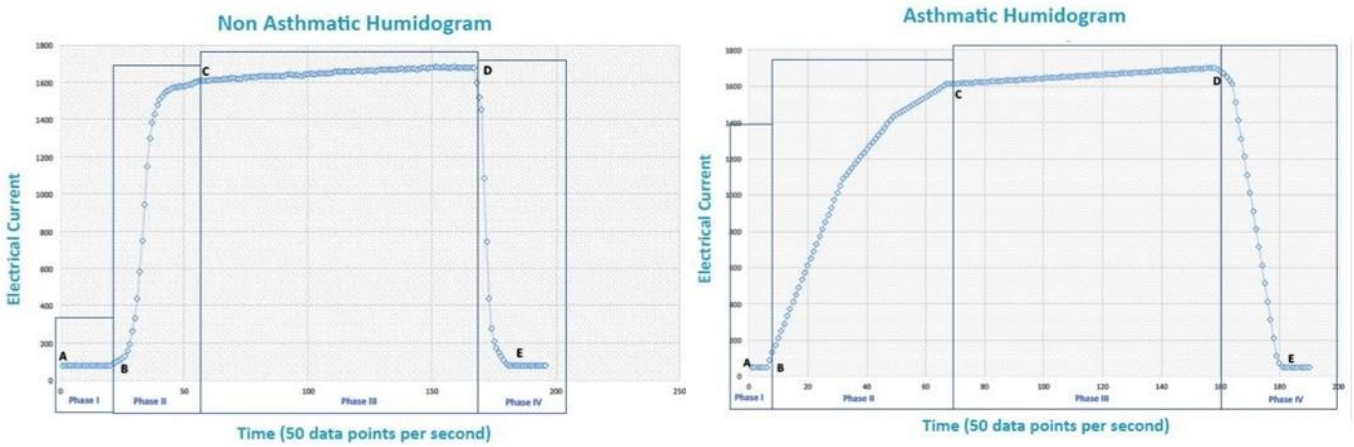



**Figure 12: Clear differences in humidograms from a person without asthma (left) and a person with asthma (right).**

Third Clinical Study

**challenge Study - Leicester - Professor Wardlaw** – Published as a poster at the EAACI congress[40]

A 20 patient methacholine challenge study compared Redecol's device to spirometry over a four hour period with each study participant. The primary objectives were to optimise the sensor performance in the device and to demonstrate that the device can detect changes in lung function. The researchers concluded that "**The device was able to detect changes in lung function tracked using FEV1**."

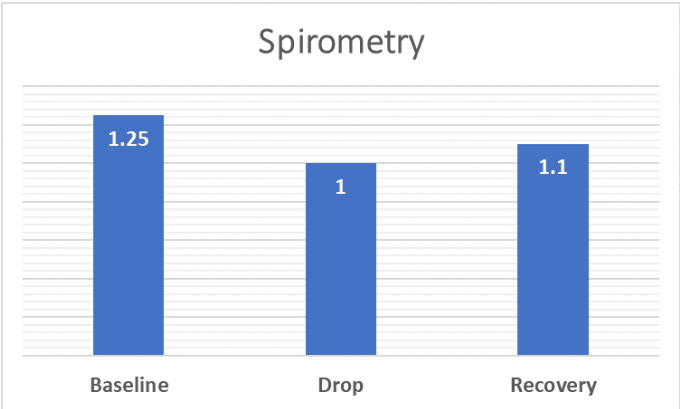



**Figure 13: Comparison of EBC concentrate with FEV1**

Figure 13 shows three breath profiles from the same study participant measured by Redecol's device during a methacholine challenge (Baseline, the Drop in lung function during an induced asthma attack

[38] Partridge MR, Lindsell A, et al; An Assessment of the Value of a New Capnographic Device in the Diagnosis and Clinical Assessment of Asthma and COPD.

[39] Hasan M; Brookes, L; Evaluation of Breathe Easyflow Humidogram As a Novel Diagnostic Tool for Asthma. Indian Medical Gazette, September 2016, p. 253

[40] Brooks LP, Wardlaw AJ, Bourne LM; A Novel Asthma Monitoring Device Methacholine Challenge Study; EAACI 2018 Poster

and the Recovery) showing the corresponding FEV1 results from spirometry tests conducted alongside EBC1.

Fourth Clinical Study

**Multi-centre Steroid Naïve Study - India** – Published as a poster at the British Thoracic Society[41]

The fourth study was 100 participants in a comparator study. The study was a multi-centre study of steriod naïve, symptomatic asthma sufferers. Each study participant was followed for a period of four weeks where the effects of steriod therapy was monitored both with peak flow and spirometry, as well as Redecol's PoC device.

Figure 14 shows the change in patient lung function when tracked by Redecol's device (EBC - green line), spirometry (FEV1 – blue line) and Peak flow (PEF – orange line).

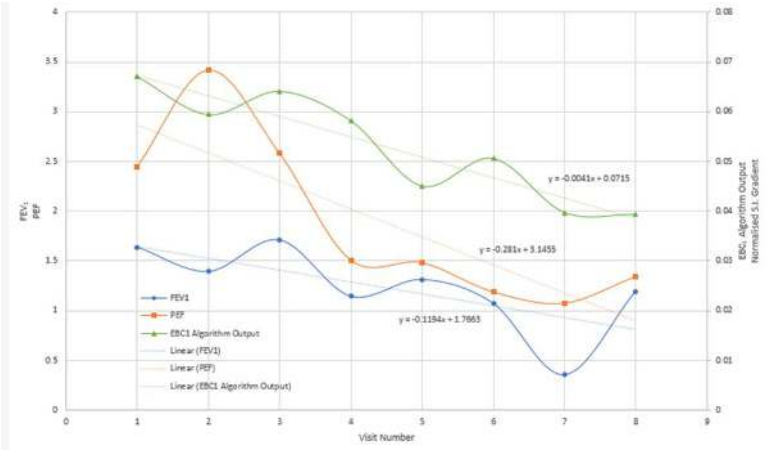



**Figure 14: Participant 1012 Symptomatic Asthma Monitoring Study. EBC Green; FEV1 Blue; PEF Orange**

The researchers concluded that "**The device (using EBC1) was equivalent to Peak Expiratory Flow in detecting changes to lung function tracked using FEV1. These data suggest that EBC1 could provide a viable alternative to peak flow meters and monitor lung function more effectively in the home, without the forced exhalation technique currently required for standard tests**."

All four clinical studies run by independent reseachers have concluded that Redecol's PoC device demonstrates equivalence to FEV1 when monitoring the impact of asthma.

## Expressions of Support for EBCRM

Professor Andrew Wardlaw, Head of Department and Professor of Respiratory Medicine, Leicester: "Accurate, user friendly and interactive day to day monitoring of asthma control is essential to prevent exacerbations and optimise treatment, particularly in children where current monitoring methods such as peak flow have limited effectiveness. The Redecol device uses a novel approach based on the exhaled breath condensate breath profile and preliminary data suggests it could add great value to the management of the asthma patient in the home."


Asthma UK: "Remote monitoring could help healthcare professionals to better support people with asthma, with technology potentially able in the future to detect when a person's asthma is worsening and respond appropriately to prevent an attack."

Dr John Blakey, Respiratory Lead for the NIHR Clinical Research Network: "Asthma outcomes in the UK remain disappointing. There are hundreds of preventable admissions due to asthma every week, and hundreds of thousands of people have poor asthma symptom control that could be addressed; for decades people with asthma and primary care clinicians have tried to manage the disease by informed

[41] LP Brooks, TP Kumar, S Miryala, D Pawar, M Bourne. Redecol Ltd, Keele UK; Srikara Hospitals, Hyderabad, India; Kamineni Hospitals, Hyderabad, India; Drug Research Laboratory, India; Respiratory Biomedical Research Centre, University Hospitals of Leicester, Leicester, UK; A Novel Asthma Monitoring Device Studying Symptomatic Asthmatics During the First month of Corticosteroid Treatment; BTS Winter 2018

guesswork. However, newer technologies currently in development such as EBC have tremendous potential to inform initial diagnosis and ongoing self-management, and support clinician decision making."

Redecol's technology is ready for commercialisation.

# Commercialisation

## Overview

With self-care in the community as our primary use for the EBCRM, due to the global nature of the opportunity, **Redecol intends to contract with strategic commercial partners with established respiratory reach**. The company has already had some positive early exploratory discussions with both respiratory MedTech companies and pharmaceutical companies.

From the outset, **Redecol's technology has been developed with commercialisation at the centre**. The same core devices and consumables can monitor different respiratory conditions with different price points by disease and country. **It will deliver long-term consistent revenues to the company, save costs for the healthcare payer and improve clinical outcomes for the users.**


In addition to the above route to market, there are three other opportunities which the team intends to develop concurrently. Importantly, the first two opportunities can be addressed once the company has secured Class I UKCA/CE status.

- **Direct to Consumer:** Once the Class I medical device license has been granted, the company could start developing a user-base through consumer purchase of the device as a lung function monitor. This could also be the primary commercialisation route in some markets, which the team will investigate during the development of the MVP.
- **Clinical Research:** Redecol intends to develop the research revenue stream itself, by forming partnerships with pharmaceutical companies and clinical research organisations. Building these initial relationships has already commenced, with early discussions with two global pharmaceutical companies. Once the Class I MVP device is specified and under development, the company will continue and expand the early discussions. Whilst a useful revenue stream, the potential is much smaller than the self-care market. IQVIA reported that one of the primary reason for participants not completing respiratory clinical studies was failure to meet the spirometry requirements.
- **Elite Sports:** This is a niche market with potentially significant benefits, especially with its impact on young people. Monitoring lung function is a critical element of elite sport performance.

## Strategic Commercial Partners

Redecol's innovative technology will be targeted to the high-volume self-care market for medical devices, which has been significantly expanded by Covid-19.

The size of the respiratory market, the number of respiratory and paediatric clinicians involved in providing care, the diversity of healthcare systems internationally and the support required for respiratory disease management systems all create barriers to successful commercialisation. This is why Redecol has committed to commercialising its technology through a "licensing model" through partnerships with established players with significant respiratory reach. Redecol has already made initial exploratory contacts with international MedTech and respiratory businesses.

Redecol intends to commercialise its technology through strategic commercial partners with established respiratory reach. Currently, the team's intention is to manufacture the breathing tubes, sensor and handsets and to be responsible for the commercial process for distribution to our commercialisation partners. In more detail:

- Redecol will develop the core technology, control the key clinical studies, manufacture the handsets and breathing tubes, secure marketing authorisations, specify the central database structure and train to commercial partners.
- The commercial partners will establish the local secure database, and promote, sell and support the self-care monitors in their market for their approved condition(s). (Each national database

will host the data in a consistent format but will comply with local data privacy and data ownership regulations.)

- Redecol will also have a right of access to the pseudonymised national central databases for algorithm enhancement. Additionally, it will receive a royalty from research data sales.

The UK is a particularly important market for the company to address, being the "home market" and, through its healthcare delivery structure, creates unique challenges. Redecol has drafted a framework commercialisation strategy to bring its digital health respiratory solution successfully to the UK market, followed by a roll-out in the first European countries (Denmark, Netherlands and Switzerland) and then the US.

Our framework strategy is based on the decision factors of the "Kotler model", which we have modified to maximise the impact and returns for our self-care monitors. This strategy entails five different aspects ("When?" "Where?" "To Whom?" "How?" "With Whom?") and has been developed to position Redecol to become a leading digital health company in the diagnosis and self-care monitoring of respiratory diseases in both adults and CYP. The team has identified the primary USPs of our innovative technology:

- ease-of-use/universal acceptability
- cost
- disease agnostic
- rich data set

Importantly, our technology has been developed throughout with commercialisation and manufacturing in mind.

## Exploratory Commercial Partner Discussions

In early 2020, Redecol initiated exploratory discussions with a number of potential commercial partners including Aptar, Trudell Medical, Astra Zeneca, Circassia, etc. Several companies expressed interest in continuing the discussions at a later stage. They indicated that, although Redecol's clinical studies had delivered interesting results, the technology was not sufficiently developed at that time and needed to be at the MVP level prior to any substantive discussions.

> Company A - "We recognise the need for asthma diagnostics and monitoring solutions and see a place for this product."
>
> Company B - "The move to a "home monitoring" diagnostic solution, to replace FEV1, is very, very interesting."
>
> Company C - "This is definitely in an area of interest and something we would appreciate being kept informed of in terms of future development."

## Designed for Commercialisation

From the outset Redecol has developed its EBCRM and digital health solution with commercialisation at its core. The focus has been to ensure that the device retains a low cost of goods and delivers long-term consistent revenue streams, whilst allowing for different prices by market and condition. This will ensure that the cost-benefit for the healthcare provider is delivered, Redecol's margins are maintained and increased, and the company's shareholders enjoy share value growth.

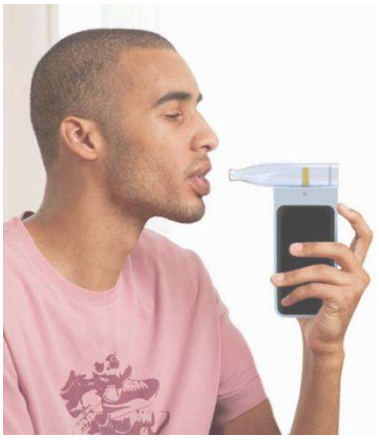


**Figure 18: Early MVP EBCRM concept**

The handset is low cost to manufacture and can be either prescribed by the healthcare provider or purchased by the user, generating a margin for Redecol. The long-term revenue streams are delivered by the breathing tubes which require regular replacement to ensure hygiene. The replacement will be managed through the feedback app, which will both remind the patient to replace the tubes and recognise the Q-code on the replacement packaging.

Differential pricing is facilitated through minor modifications to the breathing tube fitting, so that low-cost asthma tubes for the UK cannot be used to manage high-cost cystic fibrosis in the USA. In effect, the handsets and the breathing tubes are market and condition specific, protecting margins.

## First Target Market - Asthma

The first condition to be monitored will be asthma. The target users will be people with moderate-to-severe poorly controlled asthma (about 20% of the market). Our technology will also cost-effectively improve the self-care management of children and young people (CYP) with respiratory conditions. Poorly-controlled moderate-to-severe asthma sufferers and CYP use the largest amount of avoidable healthcare resource (cost). The initial target clinicians will be respiratory specialists (as well as paediatricians for CYP), who will over time influence the more general prescribers.

Initially, Redecol will focus on the top 10% of CYP with poorly-controlled moderate-to-severe chronic respiratory conditions (about 110,000 CYP in the UK), since these consume the highest healthcare resource and will derive the greatest benefit. We believe that our technology will decrease demand on hospitalisations, deliver better patient outcomes and reduce NHS costs by over £100m annually [Redecol Estimate]. We estimate a UK end-user price of £90 per year, including the replaceable breathing tubes. This compares favourably with digital peak-flow meters and spirometers which are currently being supplied to these patients. We forecast a cost of goods of 20%, which will provide attractive margins for the company and its commercialisation partners.

In addition There is significant global commercial opportunity, focused on CYP with moderate-to-severe poorly-controlled asthma (approximately 600,000 CYP in Europe and 700,000 in the USA).

## Competitive Advantage

Redecol's EBCRM will have significant competitive advantages over both existing devices used to home monitor chronic respiratory conditions:

| Competitor Product or Methodology | Suppliers | Advantages | Disadvantages | UK End-user price | Competitor Risk | Why Redecol is Better |
|---|---|---|---|---|---|---|
| **EBC Respiratory Monitor (EBCRM)** | **Redecol** | **Easy-to-use<br>Tidal breathing<br>Rich granular dataset<br>Connected for self-care<br>Low cost** | **Novel monitoring technique** | **£7.50 per month** | | **Easy-to-use<br>Tidal breathing<br>Lower cost<br>Rich dataset<br>First-in-class** |
| N-Tidal | CRI | Easy-to-use<br>Tidal breathing<br>Rich granular dataset<br>Connected for self-care | Novel monitoring technique<br>Significantly higher cost<br>(due to $CO_2$ sensor) | £15 per month | Medium | Healthcare purchasing is primarily price-based |
| Spirometers | Various | "Trusted" specialist diagnostic<br>Current Gold Standard lung function monitor<br>Digital versions can be connected for self-care | Forced expiratory manoeuvre<br>Very difficult technique, which young children can't master<br>Can cause coughing fits<br>Needs three matching results<br>Poor self-care adherence | £250 to £2,500 | Low | Technique is difficult to master for reliable results<br>Poor self-care adherence |
| Peak-flow Meters | Various | "Trusted" primary care diagnostic<br>Relatively inexpensive<br>Digital versions can be connected for self-care | Forced expiratory manoeuvre<br>Difficult technique, especially for children<br>Poor self-care adherence | £10 to £250 | Low | Basic measurement<br>Poor self-care adherence |
| FeNo Monitors | Aerocrine, NiOx, Circassia, etc | Identifies NO from inflammation of airways.<br>Asthma diagnostic | Only records level of inflammation Expensive<br>Not suitable for lung function monitoring or self-care | £1,500 to £4,000 | Low | Not suitable for self-care<br>Expensive |

## US Market Entry & Reimbursement

US market entry will require significant preparation, including seeking the FDA's advice through what is known as a 'pre-sub' once it has finalised its UK pivotal clinical study protocol. This advice will encompass the clinical evidence required for US market authorisation as well as potential reimbursement strategies. The team will work with our strategic partners to ensure that the EBCRM delivers the marketing claims required for successful US market entry.

Reimbursement Assessment

Redecol will commission a reimbursement assessment to optimise the way that the ECBRM self-care monitor accesses current payment methodologies such as DRGs, resource-based relative value scale (RBRVS), or bundled payments. This assessment will determine the prospects for coding, coverage, and payment, based on the specific clinical problem that the team choses to address with EBCRM. The reimbursement methodology is likely to differ by respiratory condition since there are several methods of being reimbursed, as exampled following:

Plans which have long-term health commitments

**Self-Insured Health Plans (or Self-Funded Health Insurance)**

Many large corporations have self-insured health plans (also known as self-funded health insurance). With these, the employer is responsible for the financial risk when it comes to health benefits coverage for its employees. It is possible that EBCRM self-care monitors would be attractive to these companies because they would benefit from both better outcomes and lower costs. The sale would be to the "benefits manager" at the company and could possibly be one of the "quick wins".

**Accountable Care Organizations**

An ACO is a **network of doctors** and hospitals that shares financial and medical responsibility for providing coordinated care to patients in hopes of **limiting unnecessary spending.** They tie provider reimbursements to quality metrics and reductions in the cost of **care.** They use alternative payment models, normally capitation. ACOs could be a route to securing reimbursement for EBCRM.

**Medicaid reimbursement**

The company will investigate whether **1915c Home & Community-based Service Waivers** could be a method of reimbursement for EBCRM for chronic moderate-to-severe poorly controlled asthma. This could work particularly well for populations which are quite remote, where the population density is low. These tend to have a greater acceptance of telehealth. However, we should be aware that this would probably have to be negotiated on a State-by-State basis, because Medicaid is not centrally-managed.

**Veterans' Association reimbursement**

The VA has a large telehealth service which could be applicable because of distance to VA hospitals. Significant number of veterans with respiratory conditions (often COPD due to culture of smoking in the armed forces). Traditionally, the VA is not thought to be a fast mover.

**Clinician reimbursement - Possible CPT Codes**

Clinician reimbursement is controlled by CPT codes and the rates at which they are allowed to charge. There are sometimes several codes for reimbursement which could be appropriate to a specific technology and the reimbursement assessment will provide guidance on the best approach for the company.

Potential CPT codes for the clinician to charge (2019/20 rates), where Redecol could provide the evidence for a partial fee, include:

- **99454:** $64.15 per month, based on a patient being monitored in the community for at least 16 out of 30 days.
- **99457:** $51.54 per month, based on spending 20 minutes of care by overseeing patient monitoring.

Monitoring post-acute care episodes - Affordable Care Act reimbursement

Hospitals - **30 Day Readmission Rates: 2015 Additions – COPD:** Monitoring patients post discharge using EBCRM to avoid readmission during the 30 days post discharge for an exacerbation. This is statistically one of the more likely times for an exacerbation event or relapse. This would likely be a sale hospital group by hospital group. Probably would need to be a specifically packaged product.

# Completing the Development of the EBCRM

## Redecol's Respiratory Digital Health Solution

Redecol's EBC Respiratory Monitor (EBCRM) is the unique source of lung function data which will drive the company's digital health self-care solution. It will deliver effective management of chronic respiratory conditions for personal and remote monitoring.

1. **EBCRM, the breath test device**: handset with the data capture device, matched with a replaceable breath pathway containing sensor. Lung function readings will be captured by this device and transmitted to the user's mobile phone app using Bluetooth connectivity.
2. **Feedback App**: Using the computing power of the user's mobile phone to analyse the 'humidogram' and deliver immediate patient feedback on their lung function.
3. **Secure Cloud Database**: Patient data is encrypted and stored securely on the cloud server. Here it can be augmented with third party sourced data (via API links) for analysis against known exacerbation triggers (e.g. air pollution, pollen count, weather conditions). The data store will also a valuable source for respiratory researcher and health care service providers.
4. **Clinician Review**: The prescribing clinician will have access to the patient's respiratory data periodic reviews of medication.
5. **Remote monitoring**: For more complex and concerning conditions, the central database could be used to alert the clinician to a deterioration in the patients' condition.

## Development Timeline

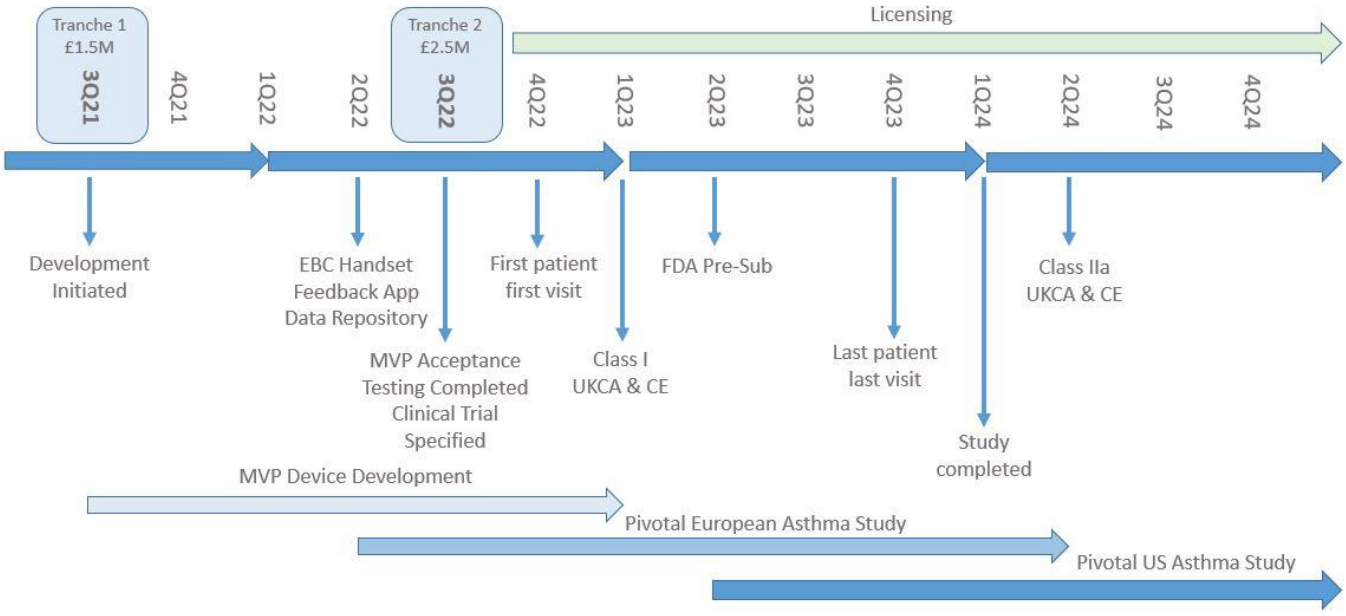



**Figure 15: Redecol's Development Timetable**

Please note that the dates in the Development Timeline assume that the first tranche of finance is secured by September 2021.

## Phase 1: Minimum Viable Product (MVP)

Redecol is developing a respiratory digital health self-care system, based on its unique low-cost EBC Nafion sensor technology. The most technically challenging work in developing the MVP has been completed. The sensor and breath pathway are fully developed. The team have focused on a plan to develop the minimum viable product which can then be enhanced, through embedded software, into a self-care monitor for any chronic respiratory condition.

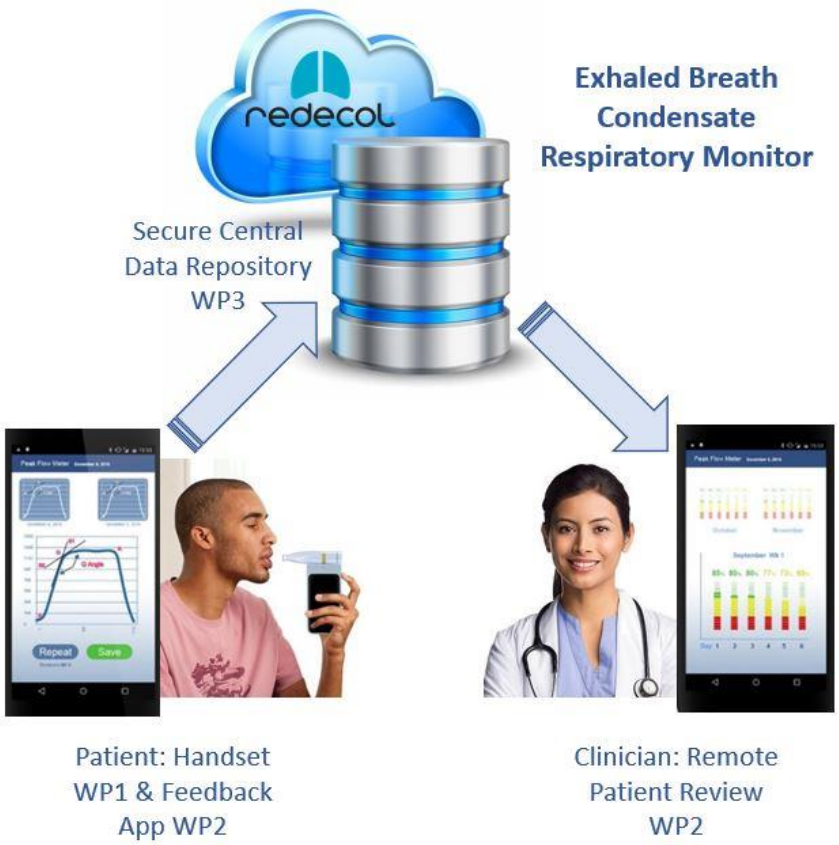



**Figure 16: MVP Schematic Overview**

The team has three primary deliverables for the MVP development project, which will position Redecol's innovative technology for the second development phase - a pivotal study for use in the monitoring of respiratory performance in asthma with both adults and children/young people (CYP). The three deliverables in Phase 1 are:

4. Develop the **user handset** from data-collector to pre-production respiratory monitor.
5. Develop a **feedback module** configurable to meet the needs of adults, CYP, parents/guardians/carers and clinical professions.
6. Develop a **secure central data repository** which can be used to provide access by the clinical team to the respiratory records of the EBCRM users.

The team has developed a detailed, fully costed MVP project plan which will take 12 months to complete. All development work will be completed to ISO 13485, ISO 62304 and ISO/IEC 27000 standards required for UKCA and CE-marking.

## Handset and Feedback App Design

Neither the handset nor the feedback app have currently been designed, since the User Requirements Specification and Design Specification are two of the first deliverables. Concepts have been developed as part of the development foundations (Figure 17). Importantly, the feedback app for patients will provide information on lung function as 'traffic lights' to the patient. This will ensure that the device is classified as a Class IIa medical device. However, all development work will be completed to the slightly higher documentation requirements of Class IIb.

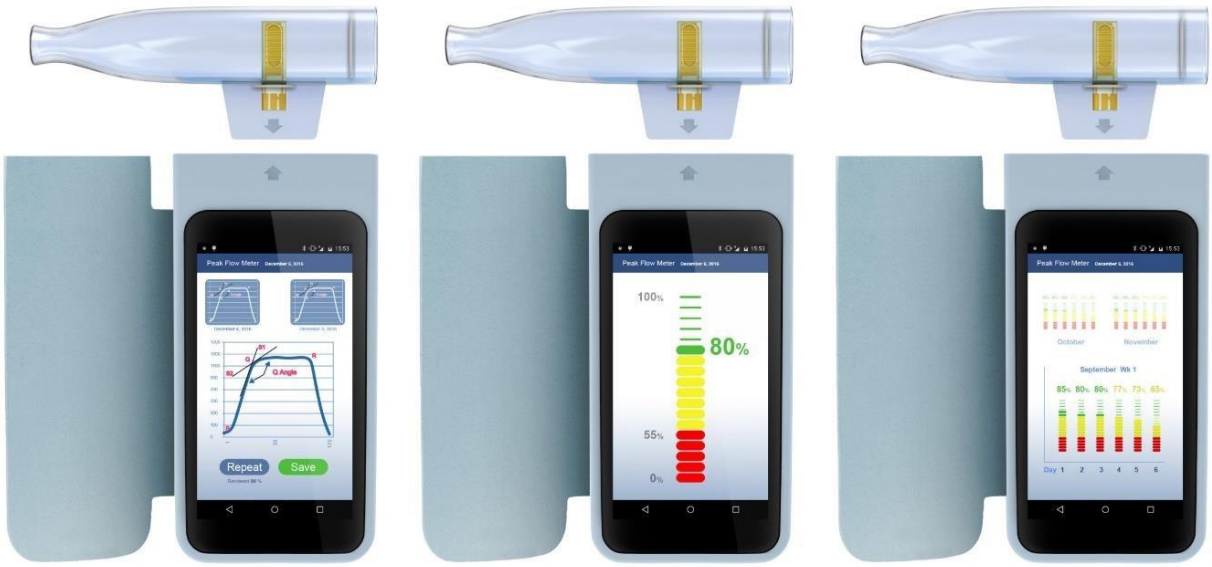



**Figure 17: Concepts for lung function feedback to patients and clinicians.**

## MVP Project Plan

The team have generated a comprehensive and detailed project plan, as well as a risk table. The principal sub-contractors for the development of the MVP will be Cambridge Medtech Solutions Limited (C-M-S) and Aseptika Limited (see Core Team – Subcontractors), with regulatory and governance consultancy provided by Compliance Solutions (Lifesciences) Limited (see Core Team – Consultants). The project plan, including project management, for developing the MVP follows:

| Work Package & Objective | Task & Duration | Key Tasks & Activities | Deliverables (D) & Milestones (MS) | Dependencies |
|---|---|---|---|---|
| **WP1: 'MVP' EBCRM Handset**<br><br>Develop a Minimum Viable Product TRL8 "connected" EBCRM handset | **WP1.1**: M1–M2 | **1.1: Detailed User Specification:** Define scope of the Minimum Viable Product for the EBCRM Handset with advice from Shallcross Partners. Expand to the Detailed User Requirements Specification (URS). Review and Approve. | **MS1.1**: **Detailed Handset URS (M2)** | **MS1.1:** No Dependencies |
| | **WP1.2**: M3-M4 | **1.2: Design Development:** Develop design options, review for manufacturing cost and user acceptability. Select design option. | **D1.2:** Design Review - option selected (M4) | **D1.2:** Dependent on MS1.1 |
| | **WP1.3**: M4-M8 | **1.3: Sensors and Breathing Tubes:** Build a set of sensors and breathing tubes to use for acceptance testing and validation. | **D1.3:** Sensors and breathing tubes delivered (M8) | **D1.3:** No Dependencies |
| | **WP1.4**: M5-M10 | **1.4: EBCRM Handset Development:** Overseeing the device development by Cambridge MedTech Solutions (C-M-S), review each stage and approve. | **MS1.4**: **10 EBCRM handsets delivered (M10)** | **MS1.4:** Dependent on D1.2 |
| | **WP1.5**: M7-M12 | **1.5: EBCRM Handset Documentation:** Working closely with C-M-S and Compliance Solutions, develop device documentation for the Technical File, to ISO13485 standards | **D1.5:** Device documentation completed (M12) | **D1.5:** Dependent on MS1.4 |
| | **WP1.6**: M11-M12 | **1.6: Acceptance Testing:** Develop an acceptance testing protocol and complete the acceptance testing of the handset | **MS1.6: MVP Handset tested and accepted (M12)** | **MS1.6:** Dependent on D1.3, MS1.4 and D1.5 |

| Work Package & Objective | Task & Duration | Key Tasks & Activities | Deliverables (D) & Milestones (MS) | Dependencies |
|---|---|---|---|---|
| **WP2: User & Clinician Feedback App**<br><br>Develop a feedback app to meet the needs of both users and clinicians | **WP2.1**: M3–M4 | **2.1: Detailed User Specification:** Advised by Shallcross Partners and our clinical adviser, develop a Detailed URS. Review and Approve. Recruit new software hire. | **MS2.1**: **Detailed Feedback App URS (M4)** | **MS2.1:** Dependent on MS1.1 |
| | **WP2.2**: M5-M6 | **2.2: Design Development:** In collaboration with subcontractor Aseptika and our clinical adviser, develop various feedback options. Assess by UX/UI. Select design option. | **D2.2:** Design Review - option selected (M6) | **D2.2:** Dependent on MS2.1 |
| | **WP2.3**: M7-M10 | **2.3: Feedback App Development:** Overseeing the feedback app development by subcontractor Aseptika. Prototyping and reviewing, refining and delivering. Development completed to ISO62304 and ISO27000 standards. | **MS2.3**: **MVP Feedback App developed (M10)** | **MS2.3:** Dependant on D2.2 |
| | **WP2.4**: M9-M12 | **2.4: Feedback App Documentation:** Working closely with C-M-S and Compliance Solutions, develop feedback app documentation for the Technical File, again to ISO62304 and ISO27000 standards | **D2.4:** App documentation completed (M12) | **D2.4:** Dependant on MS2.3 |
| | **WP2.5**: M11-M12 | **2.5: Acceptance Testing:** Develop an acceptance testing protocol and complete the acceptance testing of the feedback app | **MS2.5: Feedback App tested and accepted (M12)** | **MS2.5**: Dependant on MS1.4 and MS2.3 |
| **WP3: Central Data Repository**<br><br>Develop a secure cloud-based central data repository, to retain EBCRM data and allow access by authorised clinicians. | **WP3.1**: M5-M6 | **3.1: Detailed User Specification:** Develop a Detailed User Requirements Specification, based on requirements for the handset and the feedback app. Review and Approve. | **MS3.1**: **Detailed Repository URS (M6)** | **MS3.1:** Dependent on MS1.1 and MS2.1 |
| | **WP3.2**: M7-M8 | **3.2: Storage:** Overseeing and reviewing Aseptika develop the storage protocols & structure for the EBC data and user feedback. | **D3.2:** Storage system delivered and tested (M8) | **D3.2**: Dependent on MS3.1 |
| | **WP3.3:** M8-M9 | **3.3: Security:** Overseeing Aseptika develop and test the data security protocols for the EBC data and user feedback. | **MS3.3: Secure data storage delivered and tested (M9)** | **MS3.3:** Dependant on MS3.1 and D3.2 |
| | **WP3.4**: M8-M12 | **3.4: Central Data Repository Documentation:** Working closely with Aseptika and Compliance Solutions, develop central data repository documentation for the Technical File, to ISO62304 and ISO27000 standards | **D3.4:** Repository documentation completed (M12) | **D3.4**: Dependant on MS3.2 and MS3.3 |
| | **WP3.5**: M11-M12 | **3.5: Acceptance Testing:** Develop an acceptance testing protocol and complete the acceptance testing of the data repository | **MS3.5: Data repository tested and accepted (M12)** | **MS3.5**: Dependant on MS1.4, MS2.3 and MS3.3 |
| **WP4: Project Management**<br><br>Project completed on time and on budget. | **WP4.1**: M1-M12 | **4.1: Project Coordination, Monitoring, and Sustainability:**<br>1) Supervision of task implementation, including time and budget management<br>2) Conduct meetings and communicate with subcontractors<br>3) Manage quality control measures and monthly dynamic risk analysis<br>4) Conduct budget/resource evaluation | **D4.1:** Project management, climate impact, sustainability, and EDI reports | D4.1: No Dependencies |

| Work Package & Objective | Task & Duration | Key Tasks & Activities | Deliverables (D) & Milestones (MS) | Dependencies |
|---|---|---|---|---|
| | | 5) Climate, Sustainability and EDI monitoring and reports.<br>6) Reviewing disclosures for IP protection | | |
| | **WP4.2**: M1-M12 | **4.2: Milestone Review** Coordinate and document milestone reviews, identifying next action. | **D4.2:** Hit milestones | **D4.2:** No Dependencies |
| | **WP4.3**: M1-M12 | **4.3: Project Reporting** Organisation of update reports for the Board. | **D4.3:** Board reports completed (M3, M6, M9, M12) | **D4.3:** No Dependencies |

On completion of the MVP development the company will have the device accredited under ISO 13485 as a Class I medical device, with a UKCA marketing authorisation and a CE-mark for marketing in Europe.

## MVP Risks Have Been Mitigated

As with all development projects, the team has developed a detailed risk register and identified the methods to mitigate all primary risks to ensure that the development can be completed on time to budget.

The primary risks in the development of the MVP, and their mitigation, are as follows:

| Work Package | Risk | Likelihood (L/M/H) | Impact (L/M/H) | Mitigation |
|---|---|---|---|---|
| WP2, WP3 | **Technical Risk 1**: Data integrity and security in the transmission from the handset to the app and the central data repository, resulting in failure on Information Governance and GDPR grounds. | L | H | Redecol has made data integrity, provenance and permissions a key task within the development of the digital health system and central data repository. It has chosen data development partner Aseptika, with a proven record in this area, specifically to minimise the implementation risk. **After mitigation, impact: Low.** |
| WP2, WP3 | **Technical Risk 2**: Increasing national and international trend towards the patient 'owning' their own healthcare data, compromising the business model. | L | M | Redecol is designing the defaults to the central data repository based on pseudonymised data records, with the patient providing active permissions for other data to be supplied to the database or to their clinician, complying with GDPR and international healthcare information ownership trends. **After mitigation, impact: Low.** |
| WP1, WP2, WP3 | **Technical Risk 3:** Although clearly demonstrated, the relationship between tidal breathing parameters and those commonly used as 'Gold Standard', i.e. FEV1, peak flow and FVC, is not proven. The relationship might not be sufficiently strong. | L | H | Redecol has demonstrated the relationship in three clinical studies between parameters in the 'humidogram', FEV1 and peak flow. It has also demonstrated the relationship between parameters in the 'humidogram' and the overall respiratory function of the user. Equivalence can only be proven through a pivotal study and it believes that it has sufficient clinical evidence to feel confident that this will be successfully completed. The 'humidogram' has a wealth of parameters so we will be assessing multiple parameters for equivalence. **After mitigation, impact: Low** |
| WP2 | **Technical Risk 4:** Due to temporal variations in asthma and other respiratory conditions, it may not be possible to identify key parameters which identify the severity of the condition. | M | M | The relationship between key parameters in the tidal breathing 'humidogram', peak flow and FEV1 has been demonstrated. The larger pivotal study is required to be able to identify parameters within the waveform which may discriminate between controlled |

| Work Package | Risk | Likelihood (L/M/H) | Impact (L/M/H) | Mitigation |
|---|---|---|---|---|
| | | | | and un-controlled respiratory conditions. Redecol's EBCRM and its 'humidogram' should provide a more convenient, accessible diagnostic solution than either peak flow or spirometry. **After mitigation, impact: Low.** |
| All | **Technical Risk 5:** Scale up of production of the Nafion sensor could cause production difficulties or not result in the expected economies of scale. | L | L | Redecol's Nafion sensor has been produced in moderate size batches without quality or manufacturing issues. The team has in depth expertise in scale up of sensors. The budget envisages costs for production scale-up in due course. **After mitigation, impact: Low** |
| All | **Regulatory Risk 1:** The regulatory authorities have never previously approved a Class IIa respiratory monitor or diagnostic device based on parameters generated through tidal breathing measurements. | M | H | Redecol's EBC sensor has already been approved in a Class II device for use in monitoring respiratory rate in high risk post-operative patient recovery. Additionally, it is recognised that many patients find difficulty using the existing respiratory diagnostic devices. Redecol is supported by Compliance Solutions (Life Sciences) to facilitate regulatory approval. The company intends to have early discussions with MHRA (UK Conformity Assessment) and EMA (CE approval) about requirements for a pivotal study. It will then approach the FDA with a pre-sub to clarify the requirements for the USA. **After mitigation, impact: Low** |
| All | **Commercial Risk 1:** Clinicians have never used tidal breathing analysis previously to monitor respiratory conditions. They have relied on peak-flow meters and spirometers. They could be very sceptical of the technique. | M | M | Adoption of new monitoring and diagnostic devices is generally slow, although the importance of improving the diagnosis and management of respiratory conditions is well documented and accepted. Redecol will form an international clinical advisory group to undertake market support studies. Clinical studies will be published and an aggressive approach taken to develop opinion leader interest. Influential congresses will be attended and, specifically, asthma and lung disease charities approached to gain support. **After mitigation, impact: Low.** |
| All | **Commercial Risk 2:** Competitors could find other ways of monitoring respiratory condition using tidal breathing, based on a direct measure of respiratory performance, securing intellectual property and limiting the company's ability to exploit its technology. | L | H | Redecol has already been granted three patents for its sensor and its usage. The company has a clear and established freedom to operate. Capnography has created additional freedom to operate. The team regularly reviews the capabilities of its potential competitors to ensure that we understand their development direction. **After mitigation, impact: Low.** |
| All | **Commercial Risk 3:** There is no guarantee that healthcare payers will reimburse the costs of the EBCRM | M | H | Redecol will be completing health economics evaluations after the EBCRM has received marketing approval. The pivotal clinical study should deliver the required evidence of the detection of asthma, which should enable superior self-care management. This will in turn deliver the financial benefits to the healthcare payers. Early desk research for reimbursement in the USA indicates that there are multiple routes to monetise the technology. A reimbursement assessmment will be required. **After mitigation, impact: Low** |

| Work Package | Risk | Likelihood (L/M/H) | Impact (L/M/H) | Mitigation |
|---|---|---|---|---|
| All | **Managerial Risk 1:** Loss of a key sub-contractor. | L | L | Whilst the sub-contractors have been chosen for the quality of their work and experience, there are alternatives that could be used. Loss of a key sub-contractor could cause a slight delay and possibly a cost over-run, however it would not impact the success of the development programme. **After mitigation, impact: Low.** |
| All | **Managerial Risk 2:** Failure to meet the timelines and operate within the project budget. | L | M | The Redecol management team are experienced in managing development projects. The plan will be closely monitored. Detailed specifications and acceptance criteria will be provided for outsourced work. Frequent project meetings will be held with all sub-contractors to monitor progress and identify potential issues. **After mitigation, impact: Low** |
| All | **Managerial Risk 3:** Loss of key personnel. | L | H | All senior personnel hold equity in the company, ensuring that they are focused on delivering a successful outcome to the project. New key appointments will be incentivised with option grants. **After mitigation, impact: Low.** |
| WP1 | **Environmental Risk 1:** The use of the device could cause impact on the environment due to waste products. | M | M | The amounts of gold used in the sensor are extremely low. The team will look at medical-grade biodegradable materials for the manufacture of the breathing assembly to minimise the impact on landfill. **After mitigation, impact: Low.** |

## Phase 2: Pivotal Asthma Self-Care Management Clinical Studies

The team envisages two pivotal clinical studies; the first in the UK and the second in the USA. Once the study protocol is developed for the UK pivotal study, the company will approach the FDA with a 'pre-sub' to ensure that they are collecting the appropriate data for the US market. This will mean that the US study will follow the UK study by about 12 months.

Each pivotal clinical study will evaluate the EBCRM in comparison to the 'current standard of care', as detailed above. This clinical study will generate the data and the algorithm to upgrade the MVP so that it can be used as a self-care asthma monitor. The study will take 21 months to complete, however the preparatory work for the UK study will commence before the MVP is completed. Redecol will use their Class I device as the data collector device through the study, with each study participant using the device at least once per day for a period of at least six months.

The study project plan, when detailed fully by the research team, will contain the following primary elements:

- Protocol development (Months 1-2)
- Patient facing documentation development (Months 2-3)
- IRAS submission for approval (Month 3)
- Other study documentation development (Months 4-5)
- Study approvals granted (Month 6)
- First participant first visit (Month 7)
- Last participant first visit (Month 12)
- First participant last visit (Month 13)
- Last participant last visit (Month 18)
- Study documentation and technical file completed (Month 21)

It should be noted that the final study protocol will be developed in collaboration with the Chief Investigator, who will be a respected NHS respiratory consultant with a significant research background. The study will be multi-centre, with each research site being under the leadership of a Principal Investigator, who will also be respiratory specialists with a significant research background. Management believes that between 150 and 200 participants will be recruited for the study. The actual number of

study participants will be determined by a 'power calculation' completed by a statistician to ensure that the results from the study are statistically meaningful and acceptable to the regulatory authorities.

Participation in the study is likely to be open to people who meet the following criteria:

1. Male or Female (the minimum age has yet to be determined but Redecol is keen to include CYP in the study, as they are a key target area with asthma).
2. A confirmed clinician diagnosis of asthma for ≥ 6months.
3. At least 1 asthma exacerbation in the last 6 months.
4. Moderate or Severe asthma defined as BTS stage 3-5
5. Participant or parent/legal guardian able to provide written informed consent for participation in the study.

People with the following criteria would be excluded from the study:

1. Known other lung, chest wall, neuromuscular, cardiac or other comorbidity or abnormality that would affect spirometry and/or other measures of lung function or EBC1 waveform shape measurements.
2. In the opinion of the clinical investigator, a participant who would have difficulty completing the study procedures consistently over the course of 6 months.

The study protocol is likely to have objectives similar to these:

**Primary Objective**

To determine whether the EBC1 waveform shape as captured by Redecol's EBCRM device can distinguish an asthma exacerbation from stable disease state.

**Secondary Objectives**

1. To describe the relationship between characteristics of the EBC waveform shape ('humidogram') and the severity of asthma, as measured by:
    a. Spirometry (% predicted FEV1)
    b. Peak Expiratory Flow (PEF)
    c. Fractional exhaled Nitric Oxide (FeNO in ppb)
    d. Airway resistance (Airway Oscillometry)
    e. British Thoracic Stage (BTS) Stage
    f. Disease control (Asthma Control Questionnaire)
    g. Quality of Life (Asthma Quality of Life Questionnaire)
2. To determine whether the EBC1 waveform shape ('humidogram') as captured by Redecol's EBCRM device can predict asthma exacerbations.
3. To explore the feasibility of monitoring asthma control at home using Redecol's EBCRM device in all participants.
4. To assess the usability and acceptability of Redecol's device to study participants and their family/carers, gathering ideas for improved use and further development.
5. Assess the adherence to use of the device by patients and explore barriers and facilitators to adherence.
6. Evaluate healthcare resource use, costs and quality-of-life measures over a 6-month period.

This study will be run by research specialists in the NHS and the total third-party costs are expected to be about £350,000.

## Current Standard of Care

The clinical utility of any digital health self-care asthma monitor will be determined by comparison with currently available devices. The current standard of care for respiratory self-care for both adults and CYP involves respiratory diagnostic and monitoring devices that:

- Measure respiratory proxies, whereas Redecol's measures a direct respiratory output, EBC.
- Are difficult or impossible for people with really compromised lung function, as well as young children, to use because they are technique dependent and require "forced expiratory manoeuvres". Redecol's technology is based on monitoring lung function during tidal breathing. It is not technique dependent and it is easy for any person to use. The primary respiratory diagnostic devices used by medical professionals are peak-flow meters (developed in the 1950s)

and spirometers (developed in the 1860s to assess TB), both requiring "forced expiratory manoeuvres". Their measurements are effort and technique dependent and the results are only reliable when supervised by a suitably trained healthcare professional. Young children cannot be taught the usage techniques, so cannot even use the devices when supervised. These devices can cause severe respiratory distress (often lasting several hours) to patients with significantly compromised lung function. Results from patients' home-usage, without supervision, are quite variable. Redecol's technology will, over time, replace these devices.

FeNO devices measure inflammation levels during an asthma flare-up, making them unsuitable for most self-care respiratory monitoring.

## Expected EBCRM Marketing Claims

Although the pivotal clinical study will determine the actual marketing claims that the company can make, these claims are likely to include all of the following, although diagnosis of respiratory conditions will come at a later stage:

1. **Ease-of-Use/Universal Acceptability:** Redecol's technology is based on tidal breathing and can be used by all ages of people (from paediatric respiratory assessment through young people to adults) with all respiratory conditions. It doesn't cause distress or require a recovery time.
2. **Equivalence:** In clinical studies with adults, Redecol has already demonstrated that parameters within the humidogram are equivalent to standard measurements of lung function, specifically the most used metric from spirometry, FEV1.
3. **Cost:** Our novel sensor has a low manufacturing cost, delivering a technology with significant cost advantages over the other tidal breathing respiratory monitor.
4. **Independent of Treatment and Clinical Pathway:** Redecol's technology measures respiratory function and can be included in current treatment pathways. It is not linked to any specific treatment regime.
5. **Disease Management and Diagnosis:** The company intends to use the rich data set delivered from the monitor to develop algorithms to both manage a range of chronic respiratory diseases and, in time, to diagnose respiratory conditions.

There is a critical need to improve the diagnosis and monitoring of children and young people with chronic respiratory conditions. Redecol's novel technology meets this need and is ready for final development for industrialisation and commercialisation.

# Redecol's Core Team

## Management Team

**Experienced in MedTech and Digital Health**

Jeremy Walsh – CEO: Jeremy has 30+ years' experience in healthcare information systems, MedTech and Digital Health. He has been a life-long innovator, holding leadership positions in both publicly-quoted companies and emerging SMEs. Jeremy joined Redecol in mid-2020 and authored its development strategy, before being appointed as CEO at the start of 2021. He also currently provides consultancy services to SMEs on Digital Health and MedTech, and has supported Innovate UK as a Digital Health expert to assess opportunities in South Korea and Japan.

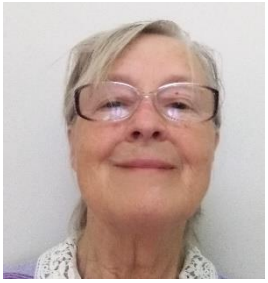
Previously Jeremy spent six years developing tidal breathing respiratory monitors as CEO of Cambridge Respiratory Innovations, taking the technology through several clinical studies towards regulatory approval, all primarily financed through non-dilutive grant funding. Although he never worked for Anaxsys, Jeremy was one of the co-founders of the company and a co-inventor of its original patent. Additionally, in 1999 and in partnership with Sky, he co-founded and launched the UK's first CPE medical television channel, The Medical Channel.

Jeremy spent over twenty years developing an international syndicated healthcare information company which he and his partners split in two, completing two successful NASDAQ healthcare IPOs (PMRX and WSHI). Both businesses ultimately became part of IQVIA, having been acquired by Quintiles and IMS respectively, and continue to deliver some of IQVIA's core services.

Jeremy was awarded his degree in Aeronautical Engineering from the University of Bristol before flying jets in the Royal Air Force as a commissioned officer, reaching the rank of Flight Lieutenant. He has been granted two patents and is co-inventor on four other patent applications.

Zia Mursaleen – Financial director: Zia is a chartered accountant and corporate financier, having qualified and worked with Deloitte for 10 years. As well as bringing his financial expertise to Redecol, Zia has been 'hands on' during the technical and clinical development of its technology.

In 1995 Zia founded VA Corporate Finance Ltd, which provides corporate finance and financial consultancy services to SMEs. In 1999 he was appointed as Finance Director of Anson Medical Limited, an early-stage medical devices company, which was sold in 2001 to Lombard Medical plc, an AIM listed company.



Margaret McQueen – Quality Assurance Manager: Margaret has a BSc Hons in Applied Biology. She spent 17 years in the pharmaceutical sector with Fisons in respiratory development, then Rhone-Poulenc and Aventis, with her final position being Pilot Manufacturing Technologist producing Clinical Supplies for Sanofi Aventis. In September 2008 Margaret joined Anaxsys as the Quality Assurance Manager, developing and implementing the quality system and gaining ISO 13485 accreditation. When Redecol acquired Anaxsys in 2017, Margaret transferred to Redecol in the same role.

## Redecol's Board

**Technology, Healthcare and MedTech**

Dr Graham Hine – Chairman: Graham has broad leadership experience across a range of medical equipment, nanotechnology and sensor companies including listed and VC backed entities. He currently chairs several companies including Redecol, Nalia, Pronec, and Nanolyse.

Graham worked internationally for Philips Semiconductors (now NXP) and then as a director of Hitachi Europe. He then had a successful career as a serial CEO

spinning out, running and exiting companies from universities including Capteur Sensors (UCL), Microsaic (Imperial College), P2i (MOD, Porton Down) and Hardide (Moscow).

Graham was awarded a PhD in Physics from Cambridge University.

Barbara Lead – Non-Executive director: Barbara is the CEO at Oval Medical, a drug delivery device company. She has more than thirty years wide and varied experience in pharmaceutical and medical device industries at a VP and board level.

Having joined Oval in 2013 she sold the company in 2016 to a SMC Ltd, a US Medical Device Company. Before joining Oval Barbara had a successful career in the Pharmaceutical Industry holding Vice President Positions in Akela Pharma a US Company and Orion Pharma in Finland. She has proven ability to take responsibility for and provide leadership in major change management programmes and organisational development and demonstrates considerable experience in business planning and strategy development in the international arena.

Barbara has successfully managed strategic alliances and major projects across different cultures in Europe, USA and Japan. As well as working on assignments in pharma, biotech and healthcare for Pharma Ops Consulting, Barbara has also worked for Rhone Poulenc Rorer and Fisons.

Tim Coutts – Non-Executive director: Tim has over thirty years of leadership experience in the MedTech sector, with senior roles in both multi-national (Boston Scientific) and SME organisations (including the "launch" CEO for Redecol). Tim brings real focus on the whole product life cycle - how to develop disruptive solutions, through to full commercial exploitation and adoption in different markets.

Tim spent the earlier part of his career with US Surgical/Tyco Healthcare in various roles including UK GM, head of European Marketing and European M&A lead. He then joined Boston Scientific, working as Vice President of Northern Europe then Healthcare Partnerships. During this time he was also a Board member at ABHI.

Since leaving in 2013, Tim has founded Carecube Solutions Ltd, where he is the CEO, as well as co-founding Access Strategy Partners Inc. in Boston, Mass, for whom he is the European MD. He also assisted Redecol by being part-time CEO after its formation. Tim has a degree in Economics.

## Adding Breadth and Depth

### Key New Positions in the Development Plan

The company intends to run a lean, agile organisation but build and retain all key core competencies in house. Historically, during its development phase, most expertise was 'brought in', as and when required. One of the uses of funds will be in hiring the core team responsible for commercialising and delivering Redecol's EBCRM digital health solution. The key senior positions are likely to be awarded share options by the Board, ensuring that they are focused on delivering shareholder returns.

The five key positions, which will be filled within the first two years, are:

Partnership Lead/Director: Another early key appointment will be the Partnership Lead, who should become part of the Management Board, responsible for forming the strategic relationships with commercial partners. This person will also be involved in recruiting the clinical advisory group of clinical opinion and thought leaders. An early focus will be on securing contracts to use the Class I MVP to support clinical studies, driving initial revenue prior to the approval of the asthma management device. As partnerships and commercialisation develops, this person will recruit, train and manage the partner support team.

Digital Lead/Director: The company will be looking to appoint a person to lead the company's digital and data development. This person will need to be skilled at signal processing, data analysis and technical implementations, as well as understanding the requirements of ISO27000. The successful candidate should become part of the Management Board, developing the technical and data analysis

infrastructure from the MVP system. This person will recruit and manage the team who will analyse new respiratory data sets as well as advise on the implementation of national central data repositories.

Clinical/Regulatory Manager: This will be an experienced individual who understands clinical studies, in the UK, Europe and the USA, technical files, and the regulatory and marketing approval process. The successful candidate will work closely with the company's regulatory consultants to ensure that clinical studies deliver marketing approvals to manage additional respiratory conditions.

U/X App Developer: Working for the Digital Lead/Director, the U/X app developer will be responsible for developing and maintaining the core user feedback app so that it operates on both iOS and Android platforms, as well as on pc and Mac. The app will also need to be customised to specific market requirements, by both language and data-specific requirements.

Supply Chain Manager: The company intends to continue to outsource the manufacture of the breath pathways, sensors and handsets. The successful candidate for this position will have experience in managing relationships with third-party suppliers, including production processes, supply chains, quality controls and cross-border transportation. This person will be responsible for ensuring that strategic partners receive the appropriate volumes of EBCRM handsets and condition-specific breath pathways to meet their requirements.

## Specialist Consultants

**Accelerating, Catalysing and Securing**

The company will continue to require the services of specialist consultants to assist with the delivery of its development and clinical plan, as well as securing shareholder value.

International Clinical Advisory Group: Management will recruit an international clinical advisory group comprising of respiratory opinion and thought leaders to advise and assist in the clinical development of the EBCRM for respiratory self-care. These clinical specialists will be from Europe, the USA and Asia. The primary recruitment method will be at international respiratory congresses. There are two main international congresses each year: The American Thoracic Society Congress in the late spring and the European Respiratory Society Congress in late summer.

Compliance Solutions (Life Sciences) Limited: Edwin Lindsay, the founder and lead regulatory and quality consultant, will advise the company on regulatory issues to ensure that marketing approval is delivered without delay. Edwin has years of experience in securing marketing approvals for medical devices and associated digital technology in the UK, Europe and the USA. Edwin can arrange for EU representation ensuring that the company can hold its marketing approvals (CE-marks) and that they are not held by strategic partners.

Shallcross Partners: Christopher Hall, lead partner in Shallcross Partners, will provide commercialisation consultancy and strategic partner advice. Chris has held leadership and senior positions in the respiratory device market, most recently with Aptar, a leading European respiratory device manufacturer. He was responsible for their digital strategy and strategic partnerships. (Chris is a minor shareholder in Redecol.)

Eastern Academic Health Science Network: EAHSN specialises in supporting innovative healthcare SMEs in gaining market traction within the NHS and also in facilitating introductions to pharmaceutical companies. Jeremy has developed a strong relationship with EAHSN and will use this to accelerate discussions with pharmaceutical companies to use the Class I EBCRM to supplement the participant data in their respiratory clinical research.

Patent Attorneys: Redecol uses HGF (www.hgf.com), a leading patent and trademark firm based in London. The partner responsible for Redecol's patents and trademark is Dr Claire Irvine.

Accountants: Redecol uses Thompson Wright (www.thompsonwright.co.uk), a Newcastle based local accounting firm, to provide the Company with Accounting and Taxation services.

Legal Advice: Redecol uses Berry Smith (www.berrysmith.com), a Cardiff based law firm, for corporate legal matters. They also provide company secretarial services.

## Specialist Subcontractors

### Delivering the Technology

The company will continue to require the services of specialist subcontractors to develop the handset and initial versions of the app and central data repository. It should be recognised that, should either subcontractor become unavailable, alternates can be appointed without impacting either the delivery timetable or budget.

Cambridge MedTech Solutions: C-M-S, based near Cambridge, will be the primary subcontractor for WP1, to design and develop the updated handset, manufacturing ten for acceptance testing and a further 200 for the initial clinical study. C-M-S is ISO13485 accredited.

C-M-S is an independent technical and strategic consultancy for the design, development and industrialisation of commercially successful medical devices and enabling technology. In addition to adding value throughout the product lifecycle, C-M-S work internationally with all sizes of company, from virtual start-ups through to multinational corporations. C-M-S is based just outside Cambridge.

www.c-m-s.com

C-M-S draws on an extensive skill base in engineering, product design and the sciences to offer a wide range of services across the entire innovation, development and industrialisation lifecycle, including:

- Due diligence
- Concept Generation
- Prototype Development
- Detailed Design
- Pilot Production
- Industrialisation
- Design Verification
- Risk Management and Assessment
- Cost Reduction
- Reliability Improvements.

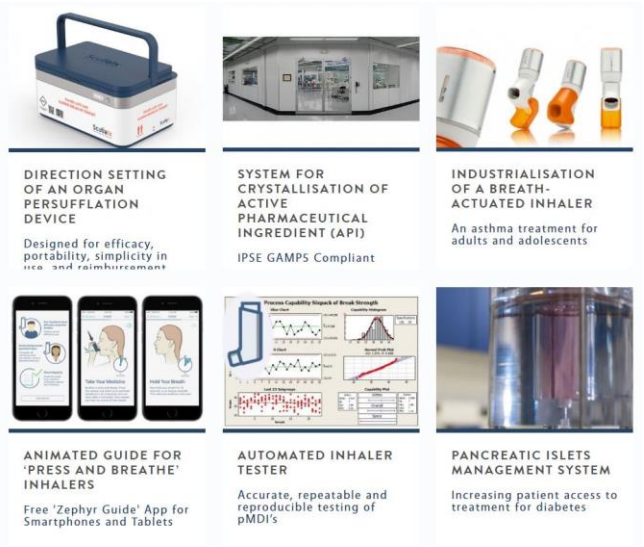



**Figure 18: Examples of other C-M-S development projects**

Aseptika: Aseptika, based in St. Ives, near Cambridge, will be the primary subcontractor for the development of the feedback and analysis app for users and clinicians, as well as the central data repository. Jeremy Walsh has worked previously with Aseptika, which has previously successfully completed major development projects, both internally funded and grant funded.

This company has developed a platform to integrate information from a range of remote-monitoring cardio-respiratory sensors. The feedback information is provided by a range of user and clinician feedback app. Since EBCRM is not competing with any of their technology, they will act as subcontractor to develop the user feedback apps and the central data repository. Various concepts have been discussed using the currently PC-based EBC data analysis package created for the proof-of-concept devices.

Aseptika has an internal team of app developers who develop only MedTech and Digital health applications. The company is ISO13485 and ISO62304 accredited. The company is also accredited to NHS information governance standards.

# Company and Financials

## About Redecol

Redecol Limited was formed in February 2017 to research, develop and commercialise unique sensor technology for the monitoring and managing Asthma and COPD. Redecol obtained a perpetual field of use licence for Asthma and COPD from Anaxsys Technology Limited (Anaxsys), which had developed the sensor technology over a number of years previously. In September 2019 Redecol acquired Anaxsys, and as a result now owns all the patents and IP relating to sensor technology. Anaxsys R&D staff transferred to Redecol and brought with them considerable know-how and process required to manufacture the sensors.

## Forecast Financials

The management team has developed detailed financial forecasts for the company which are based on assumptions which the team believe are realistic and achievable. The dates assume that funding is secured by September 2021. Although the funds could be invested in two tranches, the financial model shows a single investment on closing.

Costs: The forecasts include estimated costs for:

- the development of the MVP
- building the core management, development and partner support team
- recruiting the international clinical advisory group
- scaling-up production
- the European and US asthma pivotal clinical studies
- costs of goods for handsets (replaced every two years) and breath pathways (based on six per user per year)
- regulatory and marketing approvals
- the revenue share with strategic commercial partners
- completing further clinical studies in areas other than asthma

Sales: The forecasts include estimated revenues based on:

- Average sale price in Europe for the asthma self-care monitor of £7.50 per month
- Average sale price in the USA for the asthma self-care monitor of £15.00 per month
- Market adoption rates based on moderate-to-severe poorly controlled asthma as the primary initial target group
- Users being reimbursed for the cost of the EBCRM either through prescriptions or by reclaim (i.e. the technology is supported and financed by the healthcare provider)
- Redecol having competition in the market but its asthma solution, EBCRM, being the 'low-cost self-care asthma monitor'

## Forecast Summary Profit and Loss

**Redecol Ltd**

| **Summary - Financials** | | Forecast | Forecast | Forecast | Forecast | Forecast | Forecast |
|---|---|---|---|---|---|---|---|
| Y/E 31 JANUARY | | 2021 | 2022 | 2023 | 2024 | 2025 | 2026 |
| Patients | UK/EU | | | 38,250 | 156,443 | 361,669 | 661,445 |
| Patients | USA | | | - | 19,931 | 61,585 | 211,443 |
| Installed patients | TOTAL | | | 38,250 | 176,373 | 423,254 | 872,887 |
| No of EBCRM Handsets supplied | | | | 38,250 | 138,123 | 285,131 | 626,006 |
| No of Sensor/Breath Pathways sold | | | | 229,500 | 1,058,238 | 2,539,526 | 5,237,324 |

| Summary Profit and Loss | £ | £ | £ | £ | £ | £ |
|---|---|---|---|---|---|---|
| | 2021 | 2022 | 2023 | 2024 | 2025 | 2026 |
| Sales (net of commercial partner margin) | - | - | 2,295,000 | 10,232,100 | 23,515,673 | 53,007,959 |
| Cost of Sales | - | - | 1,032,750 | 4,188,321 | 9,356,021 | 19,864,738 |
| Gross Profit | - | - | 1,262,250 | 6,043,779 | 14,159,652 | 33,143,221 |
| GP% | | | 55.00% | 59.07% | 60.21% | 62.52% |
| Payroll costs | (88,406) | (192,720) | (775,127) | (1,067,203) | (1,485,994) | (1,829,146) |
| Product Research and Development | (317,000) | (137,000) | 0 | 0 | (200,000) | (200,000) |
| Manufacturing set up and scale up costs | 0 | (100,000) | 0 | 0 | (75,000) | (75,000) |
| Clinical Trial Costs | 0 | (550,000) | (1,000,000) | (375,000) | (300,000) | (300,000) |
| Overheads | (104,492) | (224,690) | (438,700) | (518,600) | (1,910,000) | (2,875,000) |
| EBIT | (509,898) | (1,204,410) | (951,577) | 4,082,976 | 10,188,658 | 27,864,076 |
| Other income/costs | (173,600) | (4,400) | (4,800) | (4,800) | (4,800) | (4,800) |
| Profit before tax | (683,498) | (1,208,810) | (956,377) | 4,078,176 | 10,183,858 | 27,859,276 |
| Corporation tax | 20,000 | 30,000 | 0 | 0 | (2,545,964) | (6,964,819) |
| Profit after tax | (663,498) | (1,178,810) | (956,377) | 4,078,176 | 7,637,893 | 20,894,457 |

## Forecast Summary Cash Flow

| Summary Cash Flow | 2021<br>£ | 2022<br>£ | 2023<br>£ | 2024<br>£ | 2025<br>£ | 2026<br>£ |
|---|---|---|---|---|---|---|
| Receipts | 0 | 0 | 2,524,500 | 9,292,455 | 26,945,755 | 59,192,221 |
| Payments | (601,566) | (1,331,900) | (3,288,727) | (5,504,040) | (10,294,850) | (19,804,976) |
| Operational cash flow | (601,566) | (1,331,900) | (764,227) | 3,788,415 | 16,650,905 | 39,387,245 |
| Exceptional items | - | - | - | - | - | - |
| Taxation | 80,027 | 133,050 | (180,783) | (1,862,703) | (5,875,853) | (13,192,949) |
| New Funds raised (Net) | 3,846,400 | (4,800) | (4,800) | (4,800) | (4,800) | (4,800) |
| Net cash flow | 3,324,861 | (1,203,650) | (949,809) | 1,920,912 | 10,770,252 | 26,189,496 |
| Balance b/f | 30,456 | 3,355,317 | 2,151,667 | 1,201,858 | 3,122,770 | 13,893,022 |
| Balance c/f | 3,355,317 | 2,151,667 | 1,201,858 | 3,122,770 | 13,893,022 | 40,082,517 |

Forecast Summary Balance Sheet

| Summary Balance Sheet | 2021 £ | 2022 £ | 2023 £ | 2024 | 2025 | 2026 |
|---|---|---|---|---|---|---|
| Fixed Assets | 280,608 | 280,608 | 280,608 | 280,608 | 280,608 | 280,608 |
| Current Assets | 3,365,335 | 2,161,685 | 1,544,651 | 4,478,800 | 17,457,706 | 48,777,953 |
| Current Liabilities | - 1,050 | - 25,890 | 313,453 | 1,162,477 | 6,503,489 | 16,929,280 |
| Net Current Assets | 3,366,385 | 2,187,575 | 1,231,198 | 3,316,323 | 10,954,217 | 31,848,673 |
| Long term Liabilities | - | - | - | - | - | - |
| Net Assets | 3,646,993 | 2,468,183 | 1,511,806 | 3,596,931 | 11,234,825 | 32,129,281 |
| Share Capital | 4,509,620 | 4,509,620 | 4,509,620 | 4,509,620 | 4,509,620 | 4,509,620 |
| Share Premium | 867,297 | 867,297 | 867,297 | 867,297 | 867,297 | 867,297 |
| Profit & Loss | - 1,729,924 | - 2,908,734 | - 3,865,111 | - 1,779,985 | 5,857,908 | 26,752,365 |
| Shareholders Funds | 3,646,993 | 2,468,183 | 1,511,806 | 3,596,932 | 11,234,825 | 32,129,282 |

## Use of Funds

Earmarked use of funds for the investment in Redecol.

| Outline Use | Cost | % of Raise |
|---|---|---|
| Developing the Minimum Viable Product | £750,000 | 18.75% |
| European pivotal clinical study with asthma | £750,000 | 18.75% |
| Commercialisation | £600,000 | 15.00% |
| Algorithm development | £500,000 | 12.50% |
| US pivotal clinical study asthma | £1,000,000 | 25.00% |
| Scale up and recruitment costs | £400,000 | 10.00% |

## Key Investment Facts

Redecol Limited is a company registered in England, registration number 10606405.

Redecol's funding to date totals £1,076,265.

Redecol Limited acquired 100% of Anaxsys Limited in late 2019. Anaxsys invested £8m in sensor and technology development. Redecol benefits from a £8m corporation tax loss carry-forward.

Shareholding: Redecol's shareholding consists entirely of Ordinary shares, including an EMI Share Option Plan. The fully diluted share capital is 5,760,234 shares, held as follows:

- 26.46% Syndicate Room Nominees Limited
- 12.52% CriSeren Investments Limited
- 8.91% Peter Simpson
- 30.07% Other shareholders
- 22.05% Management & Board

Redecol is raising £4m of new equity funds, equating to 2,880,117 Ordinary Shares at £1.39 each. The issue of the Ordinary shares will attract EIS. If the investment is to be made in two tranches, the first tranche should be £1.5m and the trigger event for the following £2.5m tranche could be the award of Class I UKCA and CE mark for the MVP.

Independent of the above offering, Redecol is in the process of raising £100,000 from existing shareholders at a discount of 25% on the new investor price. These funds will be used to extend the Company's cash runway whilst securing the £4m investment.

## Potential Shareholder Exits

Redecol's technology will be an attractive acquisition to three groups of companies, each of which are also potential commercial partners:

- **MedTech Companies**, such as Trudel Medical, Aptar, ResMed and Philips
- **Pharma Companies**, such as GSK, AstraZeneca, Circassia and Chiesi
- **Healthcare Data Companies**, such as IQVIA, Amazon and Google

Redecol has already had early-stage exploratory discussions with many of these companies with respect to commercial partnerships. Although the Board believes that the best shareholder value will be delivered by completing the development of the technology through to commercialisation, they also envisage that the company will attract offers of increasing value as soon as UKCA and CE marking as a Class I device are granted.

- **Mid-2022:** UKCA and CE-marked Class I EBCRM. Exit catalysed before the second tranche investment at a target value of £15m or more.
- **Early 2024:** Completion of the pivotal asthma selfcare clinical study with UKCA and CE-mark for Class IIa selfcare monitor for asthma, at a target value of between £25m and £40m.
- **Late 2024:** With FDA marketing approval for asthma selfcare in the USA, at a target value in excess of £75m or more.

## Recent Respiratory MedTech/Digital Health M&A Activity

| Date | Company | | Technology | Acquirer | Value | Link |
|---|---|---|---|---|---|---|
| Apr14 | Inspiro Medical | Israel | Smart Inhaler | Opko Health | >$10m | https://www.mobihealthnews.com/32207/pharma-company-opko-acquires-smart-inhaler-startup-for-at-least-10m/ |
| Sep15 | Gecko Health | USA | Smart Inhaler | Teva Pharma | N/A | https://www.mobihealthnews.com/47039/teva-pharmaceuticals-buys-smart-inhaler-company-gecko-health-innovations |
| Jul19 | Propeller Health | USA | Smart Inhaler & Apps | ResMed | $225m | https://investors.resmed.com/investor-relations/events-and-presentations/press-releases/press-release-details/2019/ResMed-Completes-225-Million-Acquisition-of-Propeller-Health/default.aspx |
| Nov20 | Cohero Health | USA | Smart Spirometer | Aptar | N/A | https://www.aptar.com/news-events/aptar-pharma-acquires-the-assets-of-cohero-health-a-digital-respiratory-health-company |

# Contact Details

## Redecol Limited

Graham Hine, Chairman - +44 (0)7774 257333 - graham@grahamhine.net

Jeremy Walsh, CEO – +44 (0)7785 574641 – Jeremy.walsh@redecol.co.uk

Zia Mursaleen, Finance Director – +44 (0)7768 123388 – zia.mursaleen@redecol.co.uk