



## TPE 2023 – Case Study Part 1

### Derma

#### History

Examination November 2018. 2½ hrs am, 3 hrs pm. Pass rate 88.1%

FA 2021

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A large graphic in the bottom right corner consisting of two concentric circles. The outer circle is a bright green, and the inner circle is a darker teal. The lowercase letters 'tpe' are written in white, bold, sans-serif font across the teal circle.



## Background Notes

It is early November Yr 38 and you are Alex, a newly-qualified chartered accountant working for a medium-sized firm, Clifton LLP ('Clifton'). You have recently joined their Bristol office and you have been assigned to work on their pharmaceutical sector team. The partner in charge, Husain, has asked to meet you first thing on Tuesday morning to discuss a new assignment. As you approach Husain's desk, you can see that he is zipping up his laptop bag in preparation to leave the office.

Husain points to a chair beside his desk. "Hi Alex, have a seat. I think you are going to enjoy this assignment. It's a new client and they're doing some really fascinating work. We've worked with them for a few months now and it's great to have the opportunity to help them."

You smile at Husain as you sit down and say, "That sounds intriguing!"

"Yes," laughs Husain. "Let me tell you more. The client is Derma Ltd ('Derma') – have you heard of them?" You shake your head and Husain continues, "Well, you'll soon know all about them." He pats a file on his desk and says, "I'll give you this file (Sections 1 to 4) in a minute. It will give you lots of helpful information. But I'll give you some key details now, so you'll want to take some notes".

"Derma is a private biopharma company specialising in skin products. I know that you are fairly new to our pharmaceutical team and might not be aware of biopharma yet. But don't worry about it, we have plenty of relevant information on file. In simple terms, biopharma is a rapidly developing subsector within the larger pharmaceutical sector. The distinguishing feature is that biopharma develops drugs that are wholly or partially manufactured in, or extracted from, biological sources such as plants. It's an exciting area to be involved in from a scientific point of view, but from our perspective, the key business issues are the same as for any other business: cash flow and good governance.

"Derma is very much the brainchild of Tanya Silvertree, who set it up five years ago. She is the CEO and usually comes along to our board member events. I made a point of calling Tanya now and then to see how Derma was doing. I think that personal approach made a difference when we tendered for the account. Apparently, their previous firm never even visited their labs!"

"Tanya was a research scientist at the University of Bristol when she set the company up to commercialise her work on a chemical compound found in seaweed – 'RetinX6' I think it's called. Wait 'til you meet her, she is so enthusiastic about her work and you'll end up knowing more about the chemicals in seaweed than you ever thought possible! Apparently RetinX6 can help skin cells regenerate and Derma believes that it has potential as a medicine – helping burns' victims, operations where skin needs help to heal – and as an anti-ageing cream. I could do with some of that myself, haha!"

"Seriously though," says Husain, stroking his chin, "what that means is that while Derma is going through the lengthy and rigorous process to develop RetinX6 into a medicine, they are also able to use a modified form of RetinX6 for cosmetic purposes. The timescales for developing cosmetics are much shorter than those for medicines and the testing requirements are much less too. All going well, Derma should be in the fortunate

position of generating some revenue from the cosmetic use of RetinX6 while they are still investing in the development of the medical version.”

“So that means that the one chemical compound can be used to make two products?” you ask.

“Exactly,” nods Husain. “Let me tell you a little more about Derma before I explain what I would like you to do. Originally the company was working in collaboration with the University of Bristol but they now have diversified and have a number of different projects underway to develop a range of products. You’ll find some information about them in the file (Section 1).”

“Things have really taken off for them and they now have a number of projects including the anti-ageing cream – ‘Peau’ they’re calling it – at a stage where critical investment is required. Tanya phoned me last night. She sounded a bit stressed. She’s been working on this RetinX6 for decades now and just when she’s close to bringing it to market, Derma is having funding issues.”

“When she set up the company, Tanya invested a lot of her own money from an inheritance. She originally owned most of the company and two former colleagues came on board as non-executive directors (NEDs). When it looked as if some big players were interested in what they were doing, they needed to invest more in development and they brought in another investor, Hywell Jones, who now owns 20% of the shares. Hywell isn’t a board member but he obviously has a lot of clout. He wants a rights issue to raise around £500,000 in funds but Tanya would prefer to borrow. She’s even willing to put up her own home as security. The truth is, Tanya and the NEDs couldn’t afford to buy any more shares themselves but Hywell could afford to increase his stake. The NEDs are unsure: they want Tanya to retain control of the company but they don’t know the first thing about rights issues. And one of the NEDs has even asked about the AIM market as an option.”

“So that’s the first issue, the board needs some advice on the pros and cons of the different funding options. Pull together a brief evaluation of the potential funding options and recommend the best option for them to pursue.”

You are just about to say, “Well that sounds straightforward enough to explain,” when Husain continues:

“I mentioned ‘big players’ – well they don’t come much bigger than Medsanta. Tanya was presenting a paper on RetinX6 at a conference in Seoul, South Korea in Yr 34 and she met one of Medsanta’s senior project managers there. Small world – you go to Seoul to meet someone who works around the corner from you in Bristol!”

“Anyway, that led to an agreement with Medsanta in Yr 37 that they will part-fund some of the research into the medical application of the RetinX6 chemical compound in return for an exclusive licence. Derma keeps the intellectual property (‘IP’) rights but there are conditions attached to the licence agreement and Derma could lose the IP rights if the conditions are breached. The one condition that they are really worried about relates to the deadlines for delivery of clinical testing. Tanya thinks she has found a good option to outsource the testing to a company in the US called Chemtest. It is not a company I’ve come across before but they are offering to do the testing at a discount in return for ordinary shares. The shares would be treated as nil paid initially and instalments would be credited at key stages, with the final stage conferring voting rights.

I think the Board needs to think through the control and other implications carefully. You'll see more information about this in the file (Section 2)."

"And the final thing is Peau, the cosmetic application of the modified form of RetinX6. Because clinical testing is not required for cosmetics, it's now at the stage where it can be brought to market. Derma has had an approach from Skindeep PLC. Have you seen their advert with the song "Skin" as the soundtrack? How does it go again?" Husain coughs and without waiting for a reply, hums a few bars of the song, tapping on the desk with the fingers of his left hand. "OK, that's enough music for this morning! Skindeep are very interested in Peau. They have a range of brands that are only available in specialist shops, airports and large pharmacists and they think that Peau would suit their target customer of women over 40 years old who are willing to pay a premium for anti-ageing products. The price point would be around £50."

"They are offering to buy the rights to sell Peau outright from Derma or to market it under licence (Section 3). Hywell is keen that Derma should bring Peau to market since that is where the big money is to be made – I did some work with a large cosmetic company a few years ago, the margins on face creams can be as high as 80%! So, if Derma can keep costs at £10 a unit, they could be making £40 profit on each one. But the rest of the board is unsure whether they have the capacity to do this.

"We can help them think through the financial and non-financial implications of the three options for marketing Peau:

- selling the rights to Skindeep;
- entering into a licencing agreement with Skindeep; and
- marketing Peau themselves.

I'm not sure if all of the board members have the same awareness of the business risks they face – they are so focussed on the science."

"Could Hywell think that we are trying to steer the board in a particular direction if we only focus on risks?" you ask.

"Good point, Alex," says Husain. "I don't want the board to think that we are only focussed on the risks or Hywell to think that we are encouraging the board members to oppose him. We need to be seen to be objective. Let's make sure that we don't ignore the potential benefits of the marketing options but be realistic and make a clear recommendation based on your analysis. This should be a familiar approach for Hywell and should help the board decide what to do."

"Derma has a board meeting next week and I promised we would get a briefing paper to Tanya by close of play today so that she can decide what information should go to the board. Just to be clear, cover the pros and cons of the different funding options for Derma and the control and other implications of Chemtest's proposal. Also, include an appraisal of the financial and non-financial implications of the three proposals for marketing the cream including their respective benefits and risks and make a clear recommendation."

You stop typing and say, “This sounds fine. I’ll make a start straight away. Do you want to see a draft of the paper?”

“Normally, I would work with you closely on this myself,” says Husain, “but I’ve got another client who is coming up to financial close on a big acquisition and I need to go to Cardiff right after our chat. I’ll be away for the rest of the week, but I’m sure you’ll be fine: I’ve heard good things about you from your manager. Have a word with her if you have any problems but otherwise, email me through your draft paper by lunchtime and I’ll get back to you with any comments.”

At that moment, Husain’s phone rings. He looks at the caller display before answering and at the same time he hands you the file. As you leave to return to your desk, Husain gives you a smile and a thumbs up.

In preparation for answering the case study question this afternoon, you will find it useful to undertake the following tasks during the morning session:

- read all the information carefully and note down any points you feel are significant; and
- prepare the briefing paper for Tanya as requested by Husain.

## Section 1

### Summary of the background information on Derma Ltd held by Clifton LLP.

#### *History*

Derma was set up in Yr 33 by Dr Tanya Silvertree, a former research scientist at the University of Bristol. She originally set up the company to commercialise her discovery that a particularly potent form of retinoic acid can be used to aid the regeneration of skin cells in mammals. Two former colleagues joined the board as non-executive directors. After a couple of years, the company began to struggle for resources just when it looked as if RetinX6 had the potential to move into clinical testing. Through the local business incubator, Tanya was introduced to Hywell Jones, a Cardiff-based entrepreneur who made a substantial fortune, around 15-20 years ago, by investing in call centre technology to sell double glazing and insulation to homeowners in Cardiff and the surrounding areas. He has since handed over control of the business to his daughters and he concentrates on his charitable trust and on his investment portfolio. Before investing in Derma, Hywell had a portfolio of AIM investments in biopharma and he was particularly interested in Derma because both of his daughters suffered from severe eczema when they were young.

The company received a grant from the Local Enterprise Company ('LEC') to set up laboratories in the Innovation Park in Bristol. The LEC also supports Derma with subsidised rent for its accommodation. Derma employs eight staff: seven are employed in research and development and there is an office manager who deals with the administration and payroll. Accounting services are outsourced to a local firm of accountants who specialise in providing these services to small businesses.

#### *Board members*

Dr Tanya Silvertree, CEO, is a renowned biopharmacist who has spent 25 years investigating the biochemistry of marine algae. She has a Bachelor of Science degree in molecular biology from the University of Aberdeen and a Doctor of Philosophy from the University of Bristol. Her website lists her extensive academic publications and conference papers. Her Yr 21 paper on retinyl palmitate and its inhibitory effect on human low-density lipoprotein is frequently cited by other scientists working in the same field and in Yr 34 she was invited to give the keynote address to the International Society of Dermatology in Seoul, South Korea.

Professor Gilbert Gendron, NED, was Tanya's supervisor at the University of Bristol. He is also her co-author on a number of academic papers and a highly respected researcher in his own right. He spends nine months of the year in Bristol and three months in Australia where he is an associate professor at Monash University.

Dr Adina Stasinakis, NED, is also a biopharmacist. She is based at the University of the West of England where she specialises in quantitative research methods and data analytics. She is currently leading a bid for a large Economic and Social Research Council ('ESRC') funded project which if successful, will displace all other teaching and research work for three years.

## Ownership structure

Derma has a share capital of 1,500,000 ordinary shares of £1 each, all of which are issued and fully paid. The owners of the shares are:

	No. of shares
Dr Tanya Silvertree	800,000
Professor Gilbert Gendron	200,000
Dr Adina Stasinakis	200,000
Hywell Jones	300,000

## Research & Development (R&D)

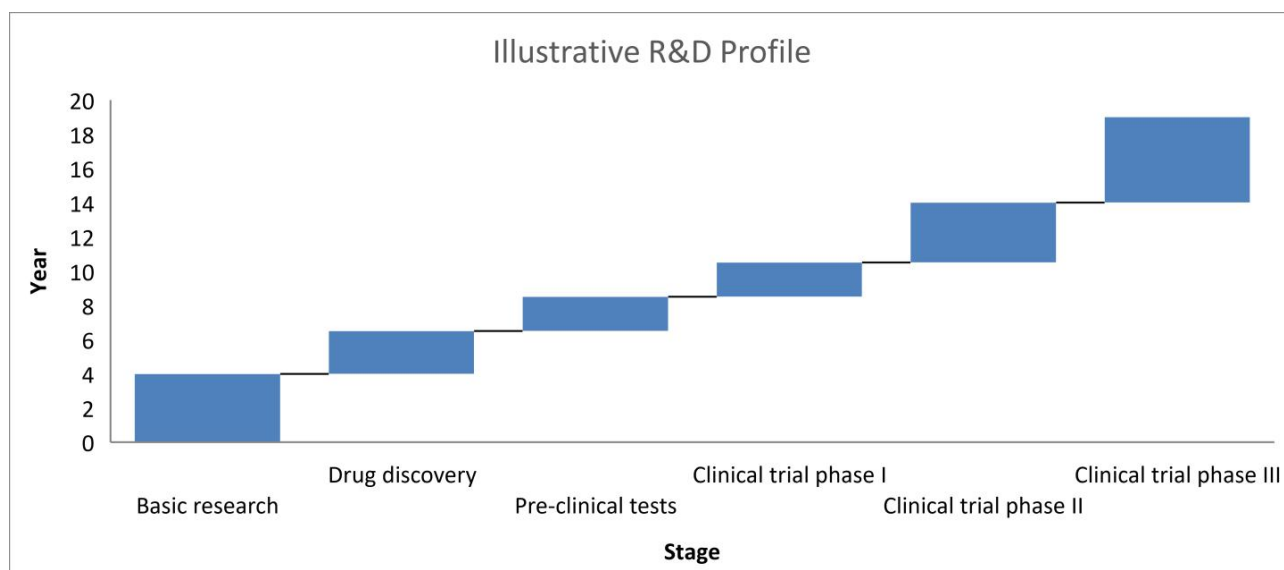
### Medicines

All medicines in the UK must be approved by the Medicines and Healthcare Products Regulatory Agency (MHRA). All new medicines must be tested for safety, quality and effectiveness. There are clear stages for the research and development of a new drug for medical use:

- Pre-clinical stage – the drug is tested using tissue culture, computer modelling and possibly animal testing
- Clinical trials - the drug is tested on human volunteers under strictly controlled conditions. Phase I involves tens of people; phase II involves hundreds of people and phase III involves thousands of people.

Only a small percentage of drugs that start pre-clinical tests actually become approved medicines. It takes 10-15 years to discover and develop a new medicine.

A similar process is followed in the USA where new drugs are regulated by the US Food & Drugs Administration (FDA). Recent research suggests that the percentage of drugs passing all of the clinical trials is as low as 12% in the USA.





The long timescales and high development costs involved present major challenges for small biopharma companies who are typically resource-constrained. But, increasingly, many larger companies will enter into partnership arrangements with smaller companies to benefit from their scientific discoveries in exchange for their expertise in bringing the discoveries to market.

## Cosmetics

All cosmetic products intended for sale in Europe must comply with relevant European regulations. These regulations aim to ensure that the product is safe to be used but they do not cover any claims for the cosmetic benefits that are made by the companies which sell the products.

This means that chemical compounds used in cosmetics do not have to go through the same rigorous testing as those that are included in medicines. Consequently, compared to developing a new drug, the time to produce a new cosmetic is significantly less and the development costs are significantly lower.

## Derma's current products under development

Product	Purpose/ Status	Drug/ Cosmetic
<b>RetinX6</b>	Development of an active ingredient for medical use to regenerate skin cells. Pre-clinical trials have been completed and it is now ready to go to clinical trials.	Drug
<b>Peau</b>	Development of an anti-ageing cosmetic cream using a modified form of RetinX6. The scientific development process will complete in Yr 38/39.	Cosmetic
<b>HA156</b>	Development of a topical anti-inflammatory cream. Still at the pre-clinical stage.	Drug
<b>BU39</b>	Development of a drug to inhibit epidermal skin cell production. In the drug discovery stage.	Drug

## Section 2

### Email from Shawnee Knope, Vice-President of Chemtest, Boston, 14 September Yr 38 as provided by Tanya Silvertree

Hi Tanya,

Hope this finds you well. We're delighted that you have decided to go with Chemtest for the clinical trials of RetinX6 and that you are happy with the thorough approach we take. Karl and I appreciate how tough it is for you guys to keep your investors happy while you go through these tests. It might reassure them to know that we have a track record of bringing the tests in ahead of the industry average timescales and more importantly, 15% of the drugs we test make it through to FDA/ MHRA approval – way ahead of the industry average of 12%.

So just to be clear, here is what we've discussed: 300,000 new ordinary shares at par, to be credited as paid in instalments at the end of each phase.

- Phase 1 - completion by June, Yr 38; 30% paid
- Phase 2 - completion by June, Yr 40; 30% paid
- Phase 3 - completion by June, Yr 42; 40% paid and full voting rights.

We only need two weeks' notice to start Phase 1 and if this is how you want to proceed, please send me confirmation and I'll get my team to draw up the contracts for you.

You mentioned that you were hoping to be over in Boston for a conference. Karl and I would love to catch up with you and so please let me know your plans nearer the time.

Best wishes,

*Shawnee*

## Section 3

### Letter from Simon Carter, Regional Director of Skindeep, 30 October Yr 38 as provided by Tanya Silvertree

Dear Tanya,

Thank you for your time last Thursday. I appreciated meeting your team and viewing your laboratory. The facilities you have in Bristol are very good and I think you will be impressed by our labs here in Cardiff when you visit next month.

You asked me for some figures so that you could discuss our offer with your Board and that is the purpose of this letter.

In essence, Skindeep would be willing to purchase the rights to Peau outright for a one-off payment of £1.2 million. This is based on our assumption of sales over a 10-year period.

Alternatively, we would be willing to pay an annual licence fee of £15 per unit sold for the exclusive marketing of the Peau skin cream. As a gesture of goodwill, we are willing to guarantee a minimum annual payment of £45,000. The licence fee arrangement would be for a fixed period of five years with the option to renew at the end of the period.

We believe that this is a generous offer and it remains open until 30 November Yr 38. Please do not hesitate to contact me if you or your board members have any queries.

Best wishes,

*Simon,*

Regional Director (New Developments)

## Section 4

### Financial statements for the year ended 30 June Yr 38

#### Derma Ltd, Statement of Profit or Loss for the year ended 30 June Yr 38

		Yr 38 £'000	Yr 37 £'000
<b>Revenue</b>	<b>Note</b>		
	1	300	350
Research and development expenses		(450)	(430)
Gross loss		(150)	(80)
Administration expenses		(49)	(47)
Depreciation		(1)	(1)
Operating loss		(200)	(128)
Finance income		2	3
Finance costs		(1)	(1)
Loss before taxation		(199)	(126)
Taxation	2	114	99
<b>Loss for the year</b>		<b>(85)</b>	<b>(27)</b>

#### 1. Revenue

Signing and interim payments for HA156 £nil (Yr 37: £100,000)  
Development services for RetinX6 £ 300,000 (Yr 37: £250,000)

#### 2. Taxation

Research and Development Credit £114,000 (Yr 37: £99,000)

# Derma Ltd, Statement of Financial Position as at 30 June Yr 38

		Yr 38 £'000	Yr 37 £'000
<b>ASSETS</b>			
<b>Non-current assets</b>	<b>Note</b>		
Property, plant & equipment		29	30
Intangible assets		<u>1,216</u>	<u>1,216</u>
		1,245	1,246
<b>Current assets</b>			
Inventories		10	5
Trade and other receivables		16	7
R&D tax credits		114	99
Cash and cash equivalents		<u>10</u>	<u>15</u>
		150	126
<b>Total assets</b>		<u>1,395</u>	<u>1,372</u>
<b>EQUITY AND LIABILITIES</b>			
Share capital		1,500	1,500
Retained losses		<u>(227)</u>	<u>(142)</u>
<b>Total equity</b>		<u>1,273</u>	<u>1,358</u>
<b>Non-current liabilities</b>			
Deferred income	1	100	0
<b>Current liabilities</b>			
Trade and other payables		22	14
<b>Total liabilities</b>		<u>122</u>	<u>14</u>
<b>Total equity and liabilities</b>		<u>1,395</u>	<u>1,372</u>

## Note

### 1. Deferred income

Deferred income relates to a research grant from the University of Bristol in support of project BU39.

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