Interim Report and Financial Statements
For the 6 Month Period Ended 31 December 2018

SkinBioTherapeutics plc

Company Registration Number: 09632164

SkinBioTherapeutics

Chairman and Chief Executive's Statement

During the first half of the financial year SkinBioTherapeutics continued to deliver on its stated objectives.

Of particular note was the commencement of its human studies and during the period the Company reported successful safety and irritancy data. Furthermore, the Company completed testing on 60 of the total 120 volunteers in its efficacy study, with no compliance or safety concerns. The final 60 volunteers are currently being treated and the Company expects to complete the study during Q1 2019.

Since the IPO, the Company has been in a scientific growth phase; where the focus has been on developing SkinBiotix® technology, working on formulation, manufacturing and scale-up and being in a position to commence human studies. The current study will generate efficacy data which will be of relevance to ongoing discussions with potential partners interested in commercialising the technology.

During the course of 2018 the Company has achieved a number of important product development milestones which have reduced investor risk and reinforced the Board's confidence in the potential of SkinBiotix® to deliver a wide range of cosmetic and dermatological applications. These applications are designed to address unmet needs in the large Cosmetic Skin Care (forecast to reach $180bn by 2024) and Dermatology (forecast to reach $14.2bn by 2021) markets.

Science continues to be a primary driver for the business and having commenced its efficacy clinical study the Company is considering how best to address other applications for its SkinBiotix® technology, for example in the oral cavity or on the scalp. In addition, the Company is assessing how it can apply its microbiome and dermatological expertise to other skin conditions, for example psoriasis where the Company is in discussions with a third party for a potential joint development agreement.

As the Company continues to develop, both broadening its scientific focus and its intentions to extend commercial discussions following the completion of the human studies, the Board considers this is an appropriate time to split the currently combined role of Chief Executive and Chief Scientific Officer. With these combined roles Dr. O'Neill has been responsible for the considerable success of the Company to date, delivering on all the key objectives outlined at the IPO and commencing the various commercial negotiations.

The Board has commenced a search process for a commercially experienced individual to succeed Dr. O'Neill as Chief Executive and expects this, together with a managed transition, to be completed during the course of 2019. During this time, Dr. O'Neill will continue to lead the scientific developments of the Company as well as the ongoing commercial discussions.

The Board and Dr O'Neill intend to retain a strong ongoing relationship; either in a direct Company role or as part of her role as Professor of Translational Dermatology at the University of Manchester, the Company's key partner for research and development activities.

Financial review

R&D expenditure in the period was £392k (H1 2017: £125k) and combined with other operating expenditure of £240k (H1 2017: £261k) resulted in a loss from operations of £632k (H1 2017: £386k).

Cash burn during the period was £666k (H1 2017: £273k) and in line with management's expectations. The Company finished the six-month period with a cash balance of £2.5m (H1 2017: £3.6m).

Operational review

For the past six months the Company has been busy driving the clinical programmes forward, especially the human study for the cosmetic application. The Company commenced the human study in September 2018 with three elements: a skin irritation study, a moisturisation potential study and an efficacy study. The other clinical programmes have also progressed during the period.

Skin Irritation Study

24-72 hours test - involved applying a cream containing SkinBiotix® to 30 healthy subjects in a series of five doses of increasing concentration. The area of skin treated was then covered to drive absorption of the cream into the skin. At 24, 48 and 72 hours following application, subjects were assessed for any signs of irritation. There were no instances of irritation in any of the subjects - even at 20 times the standard use dose of SkinBiotix®.
Repetitive, longer term test - involved repeated application of the cream at five doses to the skin of 31 healthy subjects. The product was in contact with the skin for 12 days, using an exaggerated exposure method to provide a more rigorous test of skin tolerance. The volunteers were regularly monitored for signs of irritation for up to 15 days following the initial application. While one volunteer experienced irritation in response to the cream (which occasionally happens in tests using prolonged exposure under exaggerated test conditions), no irritation was observed in the remaining 30 volunteers, even at concentrations of SkinBiotix® well above that of therapeutic use (up to 20 times the standard dose).

Moisturisation Potential Study

The moisturisation effect of the SkinBiotix® technology was tested in a 12-hour study - an industry standard test - using 21 healthy subjects. In this study, the cream containing SkinBiotix® was applied to an area of skin and the moisture content of the skin was measured for up to 12 hours. The moisturising effect of the cream without the technology was also measured as a control for comparison. As in-house laboratory tests have indicated that SkinBiotix® requires at least 24 hours to produce its effects, no difference was anticipated when compared against the control.

The cream containing SkinBiotix® provided good moisturisation which was generally higher than that provided by the control cream, but the difference was not significant.

No irritation was observed in this study in any volunteer.

Efficacy Study

The final phase of the human study commenced in November 2018 and is assessing whether the SkinBiotix® technology retains the same beneficial property to improve skin health when in a cream formulation. By the end of 2018 the Company had completed testing on 60 of the total 120 volunteers in this study with no compliance or safety concerns. The remaining 60 subjects are currently being treated and the Company expects to complete the study during Q1 2019.

The study is double-blinded, meaning neither the volunteers nor the experimenters know who is receiving a particular treatment, to prevent any bias. For this reason, SkinBioTherapeutics will need the full dataset before it can be 'unblinded' for statistical analysis. The data will then be assessed to determine effectiveness - whether the SkinBiotix® technology retains the same beneficial property of improving skin health when in a cream formulation.

The Company has continued to progress discussions with third parties interested in commercialising the SkinBiotix® technology and once available, will share the data of the various elements of the human study to further the discussions.

Eczema Programme

The Company is working with its regulatory advisors to prepare the medical device dossier for the eczema programme for submission to the notified body. Subject to the eczema programme following the medical device pathway, the Company anticipates seeking approval in the second half of 2019 for the commencement of a clinical trial.

Outlook

The Company has made significant progress over a relatively short period of time – manufacture of its lysate and volume scale-up, production of a cream formulation incorporating the SkinBiotix® technology and completion of its human safety studies. This progress has culminated in the efficacy study for the cosmetic application which will complete in the first quarter of 2019. This will be a key milestone, bringing the total number of people treated with the cosmetic formulation close to 200 and placing the Company in a strong position to both commercialise the technology with suitable industry partners and continue exploring other avenues for its core technology.

The splitting of the CEO/CSO role during the course of 2019 will result in the expansion of the executive team which will provide additional resources to support the parallel scientific and commercial growth of the Company. On behalf of the Board, we would like to thank everyone for their endeavours to drive the programmes further, especially Cath for her considerable contribution to the business so far.

Martin Hunt (Non-executive chairman)
Dr. Catherine O'Neill (Chief Executive Officer)

Statement of Comprehensive Income

For the 6 months ended 31 December 2018

	Notes	6 months to 31 Dec 2018 *Unaudited*	6 months to 31 Dec 2017 *Unaudited*	12 months to 30 Jun 2018 *Audited*
		£	£	£
Continuing operations				
Research and development		(391,907)	(125,283)	(415,902)
Operating expenses		(240,372)	(261,240)	(525,549)
Loss from operations		(632,279)	(386,523)	(941,451)
Loss before taxation		(632,279)	(386,523)	(941,451)
Taxation	4	99,546	43,479	97,033
Loss for the period		(532,733)	(343,044)	(844,418)
Total comprehensive loss for the period		(532,733)	(343,044)	(844,418)
Basic and diluted loss per share (pence)	6	(0.45)	(0.29)	(0.71)

Statement of Financial Position

As at 31 December 2018

	Note	As at 31 Dec 2018 *Unaudited*	As at 31 Dec 2017 *Unaudited*	As at 30 Jun 2018 *Audited*
		£	£	£
ASSETS				
Non-current assets				
Property, plant & equipment		9,350	-	-
Intangible assets		308,104	242,745	287,672
Total non-current assets		317,454	242,745	287,672
Current assets				
Other receivables		26,227	35,812	93,421
Corporation tax receivable		185,818	86,164	86,272
Cash and cash equivalents		2,516,876	3,649,476	3,182,898
Total current assets		2,728,921	3,771,452	3,362,591
Total assets		3,046,375	4,014,197	3,650,263
EQUITY AND LIABILITIES				
Equity				
Capital and reserves				
Called up share capital	5	1,187,085	1,187,085	1,187,085
Share premium		3,577,640	3,577,640	3,577,640
Other reserves		205,166	134,709	170,418
Accumulated deficit		(2,026,906)	(992,799)	(1,494,173)
Total equity		2,942,985	3,906,635	3,440,970
Liabilities				
Current liabilities				
Trade and other payables		103,390	107,562	209,293
Total current liabilities		103,390	107,562	209,293
Total liabilities		103,390	107,562	209,293
Total equity and liabilities		3,046,375	4,014,197	3,650,263

Statement of Cash Flows

For the 6 months ended 31 December 2018

	6 months to 31 Dec 2018 *Unaudited*	6 months to 31 Dec 2017 *Unaudited*	12 months to 30 Jun 2018 *Audited*
	£	£	£
Cash flows from operating activities			
Loss before tax for the period	(632,279)	(386,523)	(941,451)
Depreciation	850	-	-
Share option expenses	34,748	36,150	71,859
	(596,681)	(350,373)	(869,592)
Changes in working capital			
Decrease in trade and other receivables	67,194	115,377	57,768
Increase / (decrease) in trade and other payables	(105,903)	(11,098)	90,633
Cash generated by / (used in) operations	(38,709)	104,279	148,401
Taxation received	-	-	53,446
Net cash used in operating activities	(635,390)	(246,094)	(667,745)
Cash flows from investing activities			
Purchase of property, plant & equipment	(10,200)	-	-
Payments for intangible assets	(20,432)	(27,333)	(72,260)
Net cash used in investing activities	(30,632)	(27,333)	(72,260)
Net decrease in cash and cash equivalents	(666,022)	(273,427)	(740,005)
Cash and cash equivalents at the beginning of the period	3,182,898	3,922,903	3,922,903
Cash and cash equivalents at the end of the period	2,516,876	3,649,476	3,182,898

Statement of Changes in Equity

For the 6 months ended 31 December 2018

	Share capital £	Share premium £	Other reserves £	Retained earnings £	Total £
As at 1 Jul 2017	1,187,085	3,577,640	98,559	(649,755)	4,213,529
Loss for the period	-	-	-	(343,044)	(343,044)
Share-based payments	-	-	36,150	-	36,150
As at 31 Dec 2017	1,187,085	3,577,640	134,709	(992,799)	3,906,635
As at 1 Jan 2018	1,187,085	3,577,640	134,709	(992,799)	3,906,635
Loss for the period	-	-	-	(501,374)	(501,374)
Share-based payments	-	-	35,709	-	35,709
As at 30 Jun 2018	1,187,085	3,577,640	170,418	(1,494,173)	3,440,970
As at 1 Jul 2018	1,187,085	3,577,640	170,418	(1,494,173)	3,440,970
Loss for the period	-	-	-	(532,733)	(532,733)
Share-based payments	-	-	34,748	-	34,748
As at 31 Dec 2018	**1,187,085**	**3,577,640**	**205,166**	**(2,026,906)**	**2,942,985**

Share capital is the amount subscribed for shares at nominal value.

Share premium is the amount subscribed for share capital in excess of nominal value.

Other reserves arise from the equity element of a convertible loan issued and converted in the period to 30 June 2017, and from share options granted on 5 April 2017.

Retained earnings represents accumulated profit or losses to date.

Notes to the half yearly report

1. General information

SkinBioTherapeutics plc is a public limited company incorporated in England under the Companies Act and quoted on the AIM market of the London Stock Exchange (AIM: SBTX). The address of its registered office is 15 Silk House, Park Green, Macclesfield, SK11 7QJ.

The principal activity of the Company is that of research and development into the effects of lysates derived from the human microbiome on skin.

The financial information set out in this half yearly report does not constitute statutory accounts as defined in Section 434 of the Companies Act 2006. The statutory financial statements for the year ended 30 June 2018, prepared under International Financial Reporting Standards ("IFRS"), have been filed with the Registrar of Companies. The auditor's report on those financial statements was unqualified and did not contain statements under Sections 498(2) and 498 (3) of the Companies Act 2006.

Copies of the annual statutory accounts and the half yearly report can be found on the Company's website at http://www.skinbiotherapeutics.com/.

2. Significant accounting policies and basis of preparation

2.1 Statement of compliance

This half yearly report has been prepared using the historical cost convention, on a going concern basis and in accordance with International Financial Reporting Standards ("IFRS") as adopted by the European Union, IFRS Interpretations Committee (IFRIC) and the Companies Act 2006 applicable to companies reporting under IFRS, using accounting policies which are consistent with those set out in the financial statements for the year ended 30 June 2018.

2.2 Application of new and revised International Financial Reporting Standards (IFRSs)

There are no IFRSs or IFRIC interpretations that are effective for the first time in this financial period that would be expected to have a material impact on the Company.

3. Segmental reporting

The Company has one reportable segment, namely the research and development of the SkinBiotix® technology, all within the United Kingdom.

Notes to the half yearly report (continued)

4. Taxation

Income taxes recognised in profit or loss	6 months to 31 Dec 2018 £	6 months to 31 Dec 2017 £	12 months to 30 Jun 2018 £
Current tax			
R&D tax credit	97,509	43,479	86,272
R&D tax credit – prior year	2,037	-	10,761
Tax credit for the period	99,546	43,479	97,033

5. Share capital

Issued share capital comprises	31 Dec 2018 £	31 Dec 2017 £	30 Jun 2018 £
118,708,494 ordinary shares of £0.01 each	1,187,085	1,187,085	1,187,085

6. Loss per share

	6 months to 31 Dec 2018 £	6 months to 31 Dec 2017 £	12 months to 30 Jun 2018 £
Basic and diluted loss per share			
Loss after tax (£)	(532,733)	(343,044)	(844,418)
Weighted average number of shares	118,708,494	118,708,494	118,708,494
Basic and diluted loss per share (pence)	(0.45)	(0.29)	(0.71)

As the Company is reporting a loss from continuing operations for the period then, in accordance with IAS 33, the share options are not considered dilutive because the exercise of the share options would have an anti-dilutive effect. The basic and diluted earnings per share as presented on the face of the income statement are therefore identical.

7. Events after the reporting date

The Company has evaluated all events and transactions that occurred after 31 December 2018 up to the date of signing of the financial statements.

No material subsequent events have occurred that would require adjustment to or disclosure in the financial statements.