Tissue Therapies Limited
ABN 45 101 955 088

Appendix 4D
ASX Half-Year Report
31 December 2015

Lodged with the ASX under Listing Rule 4.2A

Contents

RESULTS FOR ANNOUNCEMENT TO THE MARKET

Summary of Financial Information

Extracts from this report for announcement to the market:

	Half-year Ended 31-Dec-15 $	Half-year Ended 31-Dec-14 $	Movement $	Movement %
Revenue from continuing operations	208,720	268,321	(59,601)	(22.2%)
Profit/(Loss) after income tax for the half-year attributable to members	(9,581,073)	(5,030,939)	4,550,134	90.4%
Total comprehensive income for the half- year attributable to members	(9,596,798)	(5,058,571)	4,538,227	89.7%

NTA backing

	31-Dec-15 Cents	31-Dec-14 Cents
Net tangible asset backing per ordinary security	1.06	4.41

Dividends

No dividends were paid or declared since the start of the financial period. No recommendation for payment of dividends has been made.

Highlights of Results

Refer to the Directors' Report.

DIRECTORS' REPORT

Your Directors present their report on Tissue Therapies Limited ("the Company") and controlled entities ("the Group") for the half-year ended 31 December 2015.

Directors

The names of Directors who held office during or since the end of the half-year:

Dr Cherrell Hirst – Chairman, non-Executive Director
Mr Tim Hughes – non-Executive Director
Dr Christian Behrenbruch – Executive Director (appointed 12 October 2015)
Dr Mel Bridges – non-Executive Director (resigned 25 November 2015)
Mr Iain Ross – non-Executive Director (resigned 17 September 2015)

Operating Results

- Tissue Therapies recorded an after-tax loss of $9,581,073. This loss included an impairment of the inventory of $7,485,691.
- Revenue of $208,720 arose from interest earned on funds on deposit and R&D claim incentive.

Review of Operations

- The Company has revised the regulatory strategy to focus on US-centric product development as a pharmaceutical company. The pharmaceutical pathway is the strongest development option for the Company (Please see **ASX: TIS** Change in Strategy, 28 July 2015). A greater market opportunity, superior price potential and access to patients in community care are obtained by virtue of the pharmaceutical strategy.
- Product development transitioned from an EMA to an FDA-focused process. In making this shift the Company has effectively re-engaged with the FDA by virtue of a substantial submission reporting extensive manufacturing process development activity that the Company has pursued since December 2013 (Please see **ASX: TIS** FDA Regulatory Progress Update, 17 December 2015). The FDA has indicated that no additional process development is required for Phase II material manufacturing at this time. This outcome de-risks the manufacturing control process for the US jurisdiction and the Company is now well placed to prepare and certify final material and commence Phase II studies, subject to FDA approval.
- Following strategic re-evaluation of the key application areas of the Company's technology, a pipeline was re-established in order to create additional value and market opportunities for under-served wound conditions (Please see **ASX: TIS** Investor Update, 23 November 2015). Business development activities have recommenced for the lead program (VF001) and the company's new ocular wound care program (VF003/4).
- Assignment of all intellectual property (five patent families) by Queensland University of Technology (QUT) was accomplished in order to provide the market with more certainty around the Company's assets and commercialisation potential (Please see **ASX: TIS**, QUT Transfers Ownership of IP to Tissue Therapies, 13 July 2015).
- Subsequent to the changed IP arrangement a new commercial research agreement was negotiated with QUT (Please see **ASX: TIS**, TIS Signs New Commercial Research Agreement with QUT, 26 August 2015). The revised arrangement is now non-exclusive and provides considerably more flexible terms for the Company in-line with the focus to reduce expenditure and overheads.

Financial Review

- Impairment of $7,485,691 was made against the work-in-progress of component inventory. This impairment is in line with the change of strategy of the Company outlined above whereby product development of VF-001 would be pursued as a pharmaceutical with a United States focus.
- Cash and cash equivalents were $2,736,521 at 31 December 2015.
- The Company's contributed equity at 31 December 2015 was $66,028,808.
- Research and development expenditure of $91,633 was incurred in pursuing the Company's key research and business priorities.

- Option expense of $38,700 was recorded during the period related to options issued to key Tissue Therapies' staff in September 2015 and Directors in December 2015 under the Company's Equity Option Plan.

Future Developments, Prospects and Business Strategies

- Preparation and execution of Phase II clinical development of the lead program (VF-001) will commence during the first half of CY2016. The Phase II program is designed to deliver clinically and statistically significant proof of efficacy in the initial indication of venous leg ulcers.

- The Company has disclosed that it intends to raise A$15 million for investment in three main areas:
    - A multi-centre Phase II efficacy study of VF001;
    - Further bioprocess development to meet the needs of Phase III and beyond in accordance with the transition to a pharmaceutical development pathway;
    - Pipeline development to further expand the core technology into new indication areas and capture future value; and
    - Provide working capital.

Auditor's Declaration

The auditor's independence declaration under section 307C of the Corporations Act 2001 is attached to this Directors' Report for the half-year ended 31 December 2015.

Signed in accordance with a resolution of the Board of Directors.

Cherrell Hirst
Chairman

Brisbane, 27 January 2016

Auditor's Independence Declaration

under Section 307C of the *Corporations Act 2001*
to the Directors of Tissue Therapies Limited

I declare that, to the best of my knowledge and belief, during the half-year ended 31 December 2015 there have been:

a) no contravention of the auditor independence requirements as set out in the *Corporations Act 2001* in relation to the review; and

b) no contravention of any applicable code of professional conduct in relation to the review.

PKF Hacketts

PKF Hacketts Audit

Brisbane, 27 January 2016

Shaun Lindemann
Partner

PKF Hacketts Audit
ABN 33 873 151 348

Level 6, 10 Eagle Street, Brisbane QLD 4000
GPO Box 1568, Brisbane QLD 4001
p +61 7 3839 9733
f +61 7 3832 1407

8 East Street, PO Box 862
Rockhampton QLD 4700
p +61 7 4927 2744
f +61 7 4927 4317

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HALF-YEAR FINANCIAL STATEMENTS

Consolidated Statement of Comprehensive Income

	Note	CONSOLIDATED 31-Dec-15 $	31-Dec-14 $
Continuing operations			
Other income	2	208,720	268,321
		208,720	**268,321**
Research & development		(91,633)	(312,682)
Manufacturing development costs		(514,918)	-
Impairment of inventory	5(a)	(7,485,691)	(1,407,603)
Amortisation of non-current inventory		(33,950)	(33,950)
Clinical trials expenses		-	(225,911)
Occupancy expenses		(101,259)	(133,298)
Marketing and business development		-	(205,875)
Regulatory expenses		(253,230)	(613,117)
Intellectual property		(181,146)	(129,371)
Sales and distribution		-	(35,302)
Transport and logistics		(53,014)	(79,032)
Employment expenses		(648,281)	(1,033,208)
Consultants		(25,739)	(452,791)
Administration expenses		(189,507)	(411,987)
Option expenses		(38,700)	(81,966)
Depreciation		(23,889)	(42,810)
Finance costs		(5,518)	(8,793)
Loss on foreign exchange		(20,380)	(14,086)
Other expenses		(122,673)	(70,800)
Loss before income tax expense		**(9,580,808)**	**(5,024,261)**
Income tax benefit / (expense)		(265)	(6,678)
Net loss after tax		**(9,581,073)**	**(5,030,939)**
Other comprehensive income items			
Other comprehensive income:			
Foreign exchange translation reserve		(15,725)	(27,632)
Income tax relating to components of other comprehensive income		**-**	**-**
Other comprehensive income after tax		**(15,725)**	**(27,632)**
Total comprehensive income for the period		**(9,596,798)**	**(5,058,571)**
Loss attributable to members of the Company		**(9,581,073)**	**(5,030,939)**
Total comprehensive income attributable to members of the Company		**(9,596,798)**	**(5,058,571)**
Earnings per share		**Cents**	**Cents**
Basic earnings per share	10	(3.16)	(1.91)
Diluted earnings per share	10	(3.16)	(1.91)

The accompanying notes form part of these financial statements.

Consolidated Statement of Financial Position

	Note	CONSOLIDATED 31-Dec-15 $	30-Jun-15 $
Current assets			
Cash and cash equivalents	4	2,736,521	5,578,730
Trade and other receivables		61,647	120,426
Incentive – R&D claim		83,858	355,122
Inventories	5(a)	351,615	648,611
Other assets	6	67,290	111,327
Total current assets		**3,300,931**	**6,814,216**
Non-current assets			
Inventories	5(b)	715,903	7,882,188
Property, plant and equipment		99,155	165,864
Intangible assets	7	557,250	342,250
Other assets		-	1,525
Total non-current assets		**1,372,308**	**8,391,827**
Total assets		**4,673,239**	**15,206,043**
Current liabilities			
Trade and other payables		673,356	1,618,590
Current tax liabilities		12,065	11,804
Provisions		130,808	145,435
Other liabilities		29,964	29,964
Total current liabilities		**846,193**	**1,805,793**
Non-current liabilities			
Other liabilities		59,930	75,036
Total non-current liabilities		**59,930**	**75,036**
Total liabilities		**906,123**	**1,880,829**
Net assets		**3,767,116**	**13,325,214**
Equity			
Contributed equity	8	66,028,808	66,028,808
Reserves		(32,910)	(55,885)
Accumulated losses		(62,228,782)	(52,647,709)
Total equity		**3,767,116**	**13,325,214**

The accompanying notes form part of these financial statements.

Consolidated Statement of Changes in Equity

	Share Capital	Reserves: Option Reserve	Reserves: Foreign Exchange Translation Reserve	Accumulated Losses	Total
	$	$	$	$	$
Total equity at 1 July 2014	58,308,941	435,169	(20,003)	(41,864,364)	16,859,743
Total comprehensive income	-	-	(27,632)	(5,030,939)	(5,058,571)
Transactions with owners in their capacity as owners:					
- Share based payments	76,960	-	-	-	76,960
- Transaction costs	(1,614)	-	-	-	(1,614)
- Employee share options	-	81,966	-	-	81,966
- Option reserve lapsed/expired	-	(418,705)	-	418,705	-
Total transactions with owners	75,346	(336,739)	-	418,705	157,312
Total equity at 31 December 2014	58,384,287	98,430	(47,635)	(46,476,598)	11,958,484
Total equity at 1 July 2015	66,028,808	-	(55,885)	(52,647,709)	13,325,214
Total comprehensive income	-	-	(15,725)	(9,581,073)	(9,596,798)
Transactions with owners in their capacity as owners:					
- Share based payments	-	-	-	-	-
- Transaction costs	-	-	-	-	-
- Employee share options	-	38,700	-	-	38,700
- Option reserve lapsed/expired	-	-	-	-	-
Total transactions with owners	-	38,700	-	-	38,700
Total equity at 31 December 2015	66,028,808	38,700	(71,610)	(62,228,782)	3,767,116

The accompanying notes form part of these financial statements.

Consolidated Statement of Cash Flows

	Note	CONSOLIDATED 31-Dec-15 $	31-Dec-14 $
Cash flows related to operating activities			
Payments to suppliers and employees		(2,413,074)	(4,031,934)
Payments for research & development, clinical trials and regulatory		(920,019)	(756,766)
Interest received		85,311	162,065
Income tax rebate received		426,816	404,979
Interest and other costs of finance paid		(5,518)	(8,793)
Net cash provided by (used in) operating activities		**(2,826,484)**	**(4,230,449)**
Cash flows related to investing activities			
Payment for property, plant and equipment		-	(3,950)
Net cash provided by (used in) investing activities		**-**	**(3,950)**
Cash flows related to financing activities			
Proceeds from issues of shares and other equity securities		-	-
Cost of share issue		-	(1,614)
Net cash provided by (used in) financing activities		**-**	**(1,614)**
Net increase (decrease) in cash held		**(2,826,484)**	**(4,236,013)**
Cash and cash equivalents at beginning of period		5,578,730	7,077,387
Foreign currency movement		(15,725)	(27,632)
Cash and cash equivalents at end of period	4	**2,736,521**	**2,813,742**

The accompanying notes form part of these financial statements.

Condensed Notes to the Financial Statements

Note 1 Summary of Significant Accounting Policies

These consolidated interim financial statements and notes represent those of Tissue Therapies Limited ("the Company") and controlled entities ("the Group).

Tissue Therapies Limited is a public company incorporated and domiciled in Australia.

The financial statements were authorised for issue on 27 January 2016 by the Directors of the Company.

Basis of Preparation

These general purpose interim financial statements for the half-year reporting period ended 31 December 2015 have been prepared in accordance with requirements of the Corporations Act 2001 and Australian Accounting Standards including AASB 134 *Interim Financial Reporting*. The Group is a for profit entity for financial reporting purposes under Australian Accounting Standards.

This half-year financial report is intended to provide users with an update on the latest annual financial statements of the Group. As such, it does not contain information that represents relatively insignificant changes occurring during the half-year within the Group. It is therefore recommended that this half-year financial report be read in conjunction with the annual financial statements of the Group for the year ended 30 June 2015, together with any public announcements made during the half-year.

Accounting Policies

The same accounting policies and methods of computation have been followed in this half-year financial report as were applied in the most recent annual financial statements, except in relation to the matter discussed below.

Significant Uncertainty regarding the Recoverability of VF-001 Inventory and Impairment considerations due to the change in Regulatory Strategy

As at 30 June 2015, the Group recorded VF-001 (previously communicated as VitroGro® ECM) inventory at a total value of $8,530,799, net of impairment adjustments to that point. Previous impairment adjustments were made due to delays and subsequent withdrawal from the EMA process.

On 28 July 2015, the Company announced a change in strategy whereby product development of VF-001 would be pursued as a pharmaceutical with emphasis on the United States market.

The Directors and management are of the view that the Company will not likely be in a position to file a New Drug Application (NDA) for approval until at least the second half of the calendar year 2018. Hence, a market approval is considered a matter of 'years' away and during this time it will not be possible to place current inventory of VF-001 on market for the purpose of sale.

The Board remain of the view that existing product development and manufacturing experience will remain useful for Phase III and beyond. Moreover, the current inventory of VF-001 continues to have internal utility and is expected to be consumed during future development for NDA. However, given that clinical development has been rolled back to Phase II as a result of the significant change in circumstances outlined above, the Board have conservatively elected to impair all VF-001 inventory held as at 1 July 2015.

Inventory carried at balance date reflects the concentrated VF-001 protein, production cells and reference protein, syringes and stoppers carried at cost.

Costs incurred on clinical development from 1 July 2015 in line with the revised strategy of the Company have been determined to be research and feasibility costs in nature, and accordingly have been expensed as incurred in accordance with the provisions of AASB 138 'Intangible Assets'.

In accordance with the Company's accounting policy regarding 'Research and Development Expenditure', development costs will only be capitalised when technical feasibility studies identify that the project will deliver future economic benefits and these benefits can be measured reliably.

Condensed Notes to the Financial Statements

NOTE 1 Summary of Significant Accounting Policies (continued)

New and Revised Accounting Requirements applicable to the current half-year reporting period

A number of new and revised accounting standard requirements become mandatory for the first time during the half-year reporting period to 31 December 2015.

The Group has adopted all of the new and revised standards and interpretations that are relevant to their operations and effective for the current half-year. Adoption has not resulted in any material changes to the Group's accounting policies and has no effect on the amounts reported for the current or prior half-year.

Critical Accounting Estimates and Judgments

Aside from the impairment considerations outlined above, all other critical estimates and judgments are consistent with those applied and disclosed in the 30 June 2015 annual report.

Going Concern

The Directors have prepared the financial statements on a going concern basis. However, due to a number of factors, including:

- the net loss recorded by the Group for the period of $9,596,798 (2014: $5,058,571);
- operating cash outflows for the period of $2,826,484 (2014: $4,230,449);
- likely significant funding which will be required over the coming years to achieve the revised Group strategy, as announced to the market; and
- the expected further delay to the generation of sales due to the revised Group strategy.

The appropriateness of the going concern basis of the Group must be considered. The Directors believe the ongoing appropriateness of the going concern assumption is dependent upon the ability of the Group to achieve the following:

- further capital raising from either existing or new shareholders – the Group has disclosed that it intends to raise A$15 million for investment in three main areas (Please see **ASX: TIS** 'Investor Update', 23 November 2015 and 'AGM Presentation', 25 November 2015);
- obtaining other sources of funding, through partnering or other strategic arrangements; and
- the continued support of major creditors, if required.

Should these initiatives not succeed, the going concern assumption may not be appropriate, and assets may not be recoverable for the amounts currently stated.

NOTE 2 Revenue

	31-Dec-15 $	31-Dec-14 $
Other income		
Interest revenue	53,169	79,489
Incentive – R&D claim	155,551	188,832
Total other income	**208,720**	**268,321**

Condensed Notes to the Financial Statements

NOTE 3 Segment Information

Operating segments are identified, and segment information disclosed, on the basis of internal reports that are regularly provided to, or reviewed by, the Company's chief operating decision maker, which, for the Company, is the Board of Directors. In this regard, the Board of Directors confirms that the Company continues to operate in one operating segment, being biotechnology.

NOTE 4 Cash and cash equivalents

	31-Dec-15 $	30-Jun-15 $
Cash at bank	495,944	668,953
Short term bank deposits – at call	2,237,577	4,909,777
Total cash and cash equivalents at end of period	**2,736,521**	**5,578,730**

Note 5 Inventories - non-current

a) Current

	31-Dec-15 $	30-Jun-15 $
VF-001– at cost	-	102,392
Syringes and stoppers	135,614	135,614
	135,614	238,006
VF-001– Work-in-progress – at cost	216,001	3,094,833
Less: Provision for impairment	-	(2,684,228)
	216,001	410,605
Total Inventories - Current	**351,615**	**648,611**

b) Non-current

	31-Dec-15 $	30-Jun-15 $
VF-001 – Work-in-progress – at cost	715,903	7,882,188

VF-001 (previously communicated as VitroGro® ECM) work-in-progress includes concentrated protein, production cells and reference protein. The manufacturing development and quality management cost included at 30 June 2015 have been impaired during the period in-line with the change of strategy of the Company as outlined in Note 1.

Note 6 Other assets – current

	31-Dec-15 $	30-Jun-15 $
Prepayments	67,290	111,327

Condensed Notes to the Financial Statements

Note 7 Intangible assets

	31-Dec-15 $	30-Jun-15 $
Opening balance	342,250	342,250
Additions[(1)]	215,000	-
Closing balance	**557,250**	**342,250**

(1) The increase in recorded intangible assets relates to the execution of a Deed of Assignment of Intellectual Property with the Queensland University of Technology (QUT) during the period.

Note 8 Issued and quoted securities at end of current period

Category of Securities	Number	Issue Price per Security Cents	Amount Paid Up per Security Cents	$
Balance at 1 July 2015	302,878,835			66,028,808
Nil movement	-	-	-	-
Balance at 31 December 2015	**302,878,835**			**66,028,808**

Note 9 Contingent assets or contingent liabilities

Directors are not aware of any contingent assets or liabilities that are likely to have a material effect on the results of the Company as disclosed in these financial statements.

Note 10 Earnings per security ("EPS")

	31-Dec-15 $	31-Dec-14 $
Loss after income tax benefit attributable to the Company	(9,581,073)	(5,030,939)
Weighted average number of shares used as the denominator	**No.**	**No.**
Weighted average number of ordinary shares outstanding during the year used in calculation of Basic EPS	302,878,835	263,160,501
Weighted average number of options outstanding which are considered potentially dilutive	-	-
Weighted average number of potential ordinary shares outstanding during the year used in calculation of Dilutive EPS	302,878,835	263,160,501

The diluted EPS calculation includes that portion of these options considered to be potentially dilutive, weighted with reference to the date of conversion.

	Cents	Cents
Basic earnings per share	(3.16)	(1.91)
Diluted earnings per share	(3.16)	(1.91)

Condensed Notes to the Financial Statements

Note 11 Events occurring after the balance sheet date

On 4 January 2016, the Company announced that it has re-branded itself as "Factor Therapeutics". The Company has registered the new Business Name with the Australian Securities and Investments Commission (ASIC), and also made a trademark application to IP Australia. The Company anticipated that shareholder approval will be sought for renaming itself as "Factor Therapeutics Limited" at a future shareholder meeting.

No other matter or circumstance has arisen since 31 December 2015 that has significantly affected, or may significantly affect the Group's operations, the results of those operations, or the Group's state of affairs in future financial years.

Note 12 Dividends

No dividend has been paid for the half-year ended 31 December 2015. As at 31 December 2015 and up until the date of this report, the Directors have made no recommendation concerning dividends for the half-year, or any period thereafter.

DIRECTORS' DECLARATION

The Directors of the Company declare that:

1. The financial statements and notes, as set out on pages 6 to 14 are in accordance with the Corporations Act 2001, including:

    a. complying with Accounting Standard AASB 134 *Interim Financial Reporting*; and

    b. giving a true and fair view of the consolidated entity's financial position as at 31 December 2015 and of its performance for the half-year ended on that date.

2. In the Directors' opinion there are reasonable grounds to believe that the Company will be able to pay its debts as and when they become due and payable.

This declaration is made in accordance with a resolution of the Board of Directors.

TISSUE THERAPIES LIMITED

Cherrell Hirst
CHAIRMAN

Brisbane, 27 January 2016

INDEPENDENT AUDITOR'S REVIEW REPORT
TO THE MEMBERS OF TISSUE THERAPIES LIMITED

Report on the Half-Year Financial Report

We have reviewed the accompanying half-year financial report of Tissue Therapies Limited ("the Company") and its controlled entities ("the consolidated entity"), which comprises the consolidated statement of financial position as at 31 December 2015, the consolidated statement of comprehensive income, consolidated statement of changes in equity and consolidated statement of cash flows for the half-year ended on that date, condensed notes comprising a summary of significant accounting policies and other explanatory information, and the Directors' declaration.

Directors' Responsibility for the Half-Year Financial Report

The Directors of the Company are responsible for the preparation of the half-year financial report that gives a true and fair view in accordance with Australian Accounting Standards and the *Corporations Act 2001* and for such internal control as the Directors determine is necessary to enable the preparation of the half-year financial report that is free from material misstatement, whether due to fraud or error.

Auditor's Responsibility

Our responsibility is to express a conclusion on the half-year financial report based on our review. We conducted our review in accordance with Auditing Standard on Review Engagements ASRE 2410 *Review of a Financial Report Performed by the Independent Auditor of the Entity,* in order to state whether, on the basis of the procedures described, we have become aware of any matter that makes us believe that the half-year financial report is not in accordance with the *Corporations Act 2001* including: giving a true and fair view of the consolidated entity's financial position as at 31 December 2015 and its performance for the half-year ended on that date; and complying with Accounting Standard AASB 134 *Interim Financial Reporting* and the *Corporations Regulations 2001*. As the auditor of Tissue Therapies Limited and its controlled entities, ASRE 2410 requires that we comply with the ethical requirements relevant to the audit of the annual financial report.

A review of a half-year financial report consists of making enquiries, primarily of persons responsible for financial and accounting matters, and applying analytical and other review procedures. A review is substantially less in scope than an audit conducted in accordance with Australian Auditing Standards and, consequently, does not enable us to obtain assurance that we would become aware of all significant matters that might be identified in an audit. Accordingly, we do not express an audit opinion.

Independence

In conducting our review, we have complied with the independence requirements of the Corporations Act 2001.

Conclusion

Based on our review, which is not an audit, we have not become aware of any matter that makes us believe that the half-year financial report of Tissue Therapies Limited and its controlled entities is not in accordance with the *Corporations Act 2001* including:

(a) giving a true and fair view of the Consolidated Entity's financial position as at 31 December 2015 and of its performance for the half-year ended on that date; and

(b) complying with Accounting Standard AASB 134 *Interim Financial Reporting* and *Corporations Regulations 2001*.

Emphasis of matter

Without modifying our opinion, we draw attention to Note 1 in the financial report, which indicates that the Group incurred a net loss of $9,596,798 and experienced net cash outflows from operating activities of $2,826,484 for the period ended 31 December 2015. These conditions, along with other matters as set forth in Note 1, indicate the existence of a material uncertainty that may cast significant doubt about the Group's ability to continue as a going concern and therefore, the Group may be unable to realise its assets and discharge its liabilities in the normal course of business.

PKF Hacketts

PKF Hacketts Audit

Shaun Lindemann
Partner

Brisbane, 27 January 2016

PKF Hacketts Audit
ABN 33 873 151 348

Level 6, 10 Eagle Street, Brisbane QLD 4000
GPO Box 1568, Brisbane QLD 4001
p +61 7 3839 9733
f +61 7 3832 1407

8 East Street, PO Box 862
Rockhampton QLD 4700
p +61 7 4927 2744
f +61 7 4927 4317

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