CLEO DIAGNOSTICS

ASX:COV

Cleo Diagnostics Limited

ABN 13 655 717 169

Appendix 4E and Preliminary Financial Report

30 June 2023

Cleo Diagnostics Limited
Appendix 4E
Preliminary final report

1. Company details

Name of entity:	Cleo Diagnostics Limited
ABN:	13 655 717 169
Reporting period:	For the year ended 30 June 2023
Previous period:	For the period ended 30 June 2022

2. Results for announcement to the market

				2023 $
Other income from ordinary activities	up	100%	to	110,080
Loss from ordinary activities after tax attributable to the owners of Cleo Diagnostics Limited	up	3,836%	to	1,729,500
Loss for the year attributable to the owners of Cleo Diagnostics Limited	up	3,836%	to	1,729,500

Dividends
There were no dividends paid, declared or recommended during the financial year.

About Cleo
Cleo has developed a blood test for the detection of ovarian cancer, with potential to substantially improve existing standard of care. It has IP protection in place in the USA and Australia, with patents pending in Europe, China, India, Japan, Korea, Israel, New Zealand and Singapore. The company intends to secure the remaining patents and develop the technology with the aim of commercialising the technology across multiple jurisdictions.

Review of operations
The loss for the company after providing for income tax amounted to $1,729,500 (30 June 2022: $43,931).

During the year the company secured seed funding of $1,600,000 in the form of convertible notes, with further convertible notes to the value of $3,500 issued in relation to founder convertible notes. The founder notes were converted to equity in December 2022. Funds were used to pay the licence fees in accordance with a licence agreement with the Hudson Institute of Medical Research. Completion of the licence agreement occurred on 29 August 2022.

The company also repaid loan funds of $200,000 that had been received during the June 2022 period to pay a deposit on an agreement with the Hudson Institute of Medical Research ("Hudson") to secure licencing of pharmaceutical goods for commercialisation.

Events after balance date
Subsequent to the year-end the company lodged its prospectus with the ASX. On 22 August 2023, the company was admitted to the Official List of the ASX, its IPO raising $12,000,000 before costs and issuing 60 million ordinary shares. In addition 16 million shares were issued on conversion of the convertible notes outstanding at 30 June 2023. A further 7,500,000 ordinary shares were issued to Hudson pursuant to the licence agreement, providing a total of 128,500,001 ordinary shares on the market.

A total of 13,500,000 listed options were also on issue at the date of listing on the ASX. These included 7 million KMP options, and the 1.5 million consultant options noted in note 6, plus 5 million options issued to the lead broker on completion of the IPO. In addition, 500,000 unlisted shares were issued as part of the employee share option scheme.

On 22 August 2023 the Company announced that it had been granted a US patent covering proprietary biomarkers and antibody formulations, which comprise the core technology of the company's ovarian cancer diagnostic blood test, securing the company's IP protection in the USA.

Business development
Cleo is a medical diagnostics/devices entity focused on the development of non-invasive blood based IVD tests to detect the presence, and recurrence, of ovarian cancer. The Company has developed a three-phased product development strategy that will deliver three related tests for ovarian cancer detection:

(a) **Triage Test** – a pre-surgical test to determine the likelihood that a pre-surgical ovarian mass in a patient not yet referred to an oncologist, is malignant.

(b) **Recurrence Test** – a post-surgical test to identify whether a cancer is recurring following surgical removal and chemotherapy of cancerous tissue.

(c) **Screening Test** – a screening test to identify early-stage ovarian cancer in patients who do not present any symptoms consistent with ovarian cancer.

Each of the three tests are non-invasive and are performed using a sample of the patient's blood. They are specifically designed to be low-cost and fit within existing pathology lab infrastructure.

The Company's primary focus is to bring the Triage Test to market which has to date produced strong results to accurately differentiate patients with malignant ovarian cancer from those with benign gynaecological conditions.

The key dependencies of the Company's business model include (amongst others):

(a) sufficient market awareness and industry adoption;
(b) being able to continue to maintain the Hudson Licence Agreement and to maintain, protect and develop the Technology licensed under the Hudson Licence Agreement;
(c) further product development to increase the functionality and performance of the Technology;
(d) sufficient funding to ensure the Company is able to complete development;
(e) future access to additional capital, should it be required to fund potential future growth;
(f) the ability to continually protect and advance the Company's existing knowledge and intellectual property
rights and trade secrets; and
(g) attracting and retaining key staff and personnel.

Key risks – additional capital requirements
The Company currently has no operating revenue and is unlikely to generate any operating revenue unless and until the Triage Test is successfully developed and commercialised. The future capital requirements of the Company will depend on many factors including its business development activities. The Company has budgeted to fund its activities and objectives for the two-year period following Admission. Subsequent to that period of time the Company may seek further capital as required.

Key risks – Intellectual property
The Company's success, in part, depends on its ability to obtain patents, maintain trade secret protection, and operate without infringing the intellectual proprietary rights of third parties. If patents are not granted, or granted only for limited claims, the Company's intellectual property may not be adequately protected and may be able to be copied, reproduced or otherwise circumvented by third parties. The Company's existing intellectual property includes the Company's licencing rights under the Hudson Licence Agreement. The Company has, under the Hudson Licence Agreement, acquired (amongst other things) the rights to various patent applications pending in a number of countries based on international (PCT) application no PCT/AU2020/051403.

The Company has engaged FB Rice to develop and implement an intellectual property strategy to seek to establish patent protection in its proposed key markets as a means of enabling the Company to guard its exclusivity, maintain an advantage over competitors and provide it with a basis for enforcement in the event of infringement (or potential infringement) of the Company's intellectual property rights by third parties.

Key risk – the uncertainty of research
The development and commercialisation of medical diagnostic products is subject to an inherent and high risk of failure. The key steps in the Company's development strategy for the Triage Test include:

(a) (**antibody development**): the successful in-house development of protein reagents and monoclonal antibodies for each of the target biomarker proteins which is anticipated to reduce reliance on commercial assays;

(b) (**test performance evaluation**): test evaluation to ensure that the product is robust, scalable, meets the performance expectations of patients, clinicians, and testing laboratories, as well as demonstrating safety and efficacy to the relevant regulatory bodies; and

(c) (**regulatory submissions**): subject to the foregoing, the initial FDA 510(k) application and subsequent Australian and European regulatory approvals.

Each research step carries an inherent uncertainty in relation to the outcome impacting the next step. Cleo's management has many years of experience in the field of research, and has been engaged in research activities upon the licenced technology and is confident that it has the best team available to ensure its research is thorough and effective, providing the best chance of positive research outcomes.

Key risks – Regulatory Approval
Product commercialisation and development involves lengthy processes that are dependent on the evaluation by external groups such as the FDA (in the US), 'CE marking' (in the European Union) and approval from the TGA (in Australia). The process may require the Company to conduct further clinical studies. Again, the experience of the Company's management and its engagement of FB Rice is intended to mitigate this risk as much as possible.

Key risks – Product risks and liability
As with all new public health products, even if the Company was successful in development of its products and obtains regulatory approvals, there is no assurance unforeseen adverse events or manufacturing defects will not arise. Adverse events could expose the Company to product liability claims in litigation, potentially resulting in any regulatory approval (when/if obtained) being removed and damages being awarded against the Company. In such event, the Company's liability may exceed the Company's insurance coverage (if any). The efficacy and results of trials relating to future products will rely on the proper implementation of use/testing protocols which may include requirements for clinicians and diagnostic labs to adhere to standard operating procedures for collection and processing of blood samples. While none of the anticipated requirements of the proposed Cleo products are expected to be onerous or unusual, a failure to adhere to these requirements may adversely affect the efficacy and reliability of test results.

3. Net tangible assets

	Reporting period *Cents*	Previous period *$*
Net tangible liabilities per ordinary security	3.12*	242,276

* During the prior year only one share was on issue. Therefore NTA is shown using dollars in 2022, and cents in 2023.

4. Control gained over entities

Not applicable

5. Loss of control over entities

Not applicable

6. Details of associates and joint venture entities

Not applicable

7. Audit qualification or review

Details of audit/review dispute or qualification (if any):

The audit of the financial statements has not yet been completed, however an unmodified opinion is expected to be issued.

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8. Attachments

Details of attachments (if any):

The Statement of profit or loss and other comprehensive income, Statement of financial position, Statement of changes in equity, Statement of cash flows and selected notes to the financial accounts of Cleo Diagnostics Limited for the year ended 30 June 2023 is attached.

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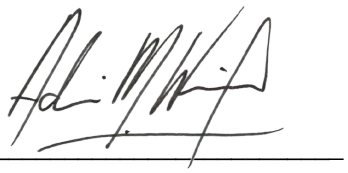
9. Signed



Signed _____ Date: 31 August 2023

Adrien Wing
Chairman
Melbourne

Cleo Diagnostics Limited
Statement of profit or loss and other comprehensive income
For the year ended 30 June 2023

	Note	30 June 2023	30 November 2021 to 30 June 2022
		$	$
Other income		110,080	-
Expenses			
Employee benefits expense		(1,097,275)	-
Professional fees		(271,596)	(19,791)
Compliance costs		(25,400)	-
Research and development expenditure		(247,755)	(23,306)
Depreciation and amortisation		(43,821)	-
Finance expense		(110,776)	(834)
Other expenses		(42,957)	-
Loss before income tax expense		(1,729,500)	(43,931)
Income tax expense		-	-
Loss after income tax expense for the year attributable to the company		(1,729,500)	(43,931)
Other comprehensive income			
Other comprehensive income for the year, net of tax		-	-
Total comprehensive income for the year attributable to the company		(1,729,500)	(43,931)
		$	**$**
Loss per share from continuing operations attributable to the owners of Cleo Diagnostics Limited			
Basic loss per share		(0.0659)	(43,931)
Diluted loss per share		(0.0659)	(43,931)

The above statement of profit or loss and other comprehensive income should be read in conjunction with the accompanying notes

Cleo Diagnostics Limited
Statement of financial position
As at 30 June 2023

	Note	30 June 2023 $	30 June 2022 $
Assets			
Current assets			
Cash and cash equivalents		239,774	42,751
Trade and other receivables		31,919	859
Prepayments	2	308,519	-
Total current assets		580,212	43,610
Non-current assets			
Intangible assets	3	458,333	200,000
Property plant and equipment		38,084	-
Total non-current assets		496,417	200,000
Total assets		1,076,629	243,610
Liabilities			
Current liabilities			
Trade and other payables		417,368	45,206
Borrowings		-	200,000
Convertible loan note	4	1,600,000	40,680
Employee benefits		2,676	-
Total current liabilities		2,020,044	285,886
Total liabilities		2,020,044	285,886
Net liabilities		(943,415)	(42,276)
Equity			
Issued capital	5	46,531	1
Reserves	6	783,485	1,654
Accumulated losses		(1,773,431)	(43,931)
Total equity		(943,415)	(42,276)

The above statement of financial position should be read in conjunction with the accompanying notes

Cleo Diagnostics Limited
Statement of changes in equity
For the year ended 30 June 2023

Consolidated	Issued capital	Reserves	Accumulated losses	Total equity
	$	$	$	$
Balance at 30 November 2021	-	-	-	-
Loss after income tax expense for the year	-	-	(43,931)	(43,931)
Other comprehensive income for the year, net of tax	-	-	-	-
Total comprehensive income for the year	-	-	(43,931)	(43,931)
Transactions with owners in their capacity as owners:				
Contributions of equity, net of transaction costs	1	-	-	1
Issue of convertible notes	-	1,654	-	1,654
Balance at 30 June 2022	1	1,654	(43,931)	(42,276)

Consolidated	Issued capital	Reserve	Accumulated losses	Total equity
	$	$	$	$
Balance at 1 July 2022	1	1,654	(43,931)	(42,276)
Loss after income tax expense for the year	-	-	(1,729,500)	(1,729,500)
Other comprehensive income for the year, net of tax	-	-	-	-
Total comprehensive income for the year	-	-	(1,729,500)	(1,729,500)
Transactions with owners in their capacity as owners:				
Conversion of convertible notes	46,530	(1,654)	-	44,876
Share based payments	-	783,485	-	783,485
Balance at 30 June 2023	46,531	783,485	(1,773,431)	(943,415)

The above statement of changes in equity should be read in conjunction with the accompanying notes

Cleo Diagnostics Limited
Statement of cash flows
For the year ended 30 June 2023

	Note	30 June 2023 $	30 November 2021 to 30 June 2022 $
Cash flows from operating activities			
Payments to suppliers and employees (inclusive of GST)		(684,465)	-
Net cash used in operating activities	8	(684,465)	-
Cash flows from investing activities			
Payments for intangible asset		(300,000)	(200,000)
Payments for property plant and equipment		(40,239)	-
Net cash used in investing activities		(340,239)	(200,000)
Cash flows from financing activities			
Proceeds from issue of shares		-	1
Payment of listing fees		(181,523)	-
Net (Repayment of) / Proceeds from borrowings		(200,000)	200,000
Issue of convertible notes		1,603,250	41,500
Sundry loans		-	1,250
Net cash from financing activities		1,221,727	242,751
Net increase in cash and cash equivalents		197,023	42,751
Cash and cash equivalents at the beginning of the financial year		42,751	-
Cash and cash equivalents at the end of the financial year		239,774	42,751

The above statement of cash flows should be read in conjunction with the accompanying notes

Note 1. Significant accounting policies

The principal accounting policies adopted in the preparation of the financial statements are set out below.

New or amended Accounting Standards and Interpretations adopted
The company has adopted all of the new or amended Accounting Standards and Interpretations issued by the Australian Accounting Standards Board ('AASB') that are mandatory for the current reporting year.

Any new or amended Accounting Standards or Interpretations that are not yet mandatory have not been early adopted.

Basis of preparation
These financial statements have been prepared for management in accordance with Australian Accounting Standards and Interpretations issued by the Australian Accounting Standards Board ('AASB'), as appropriate for for-profit oriented entities and represent the year from 1 July 2022 to 30 June 2023. The comparative figures represent the period from incorporation on 30 November 2021 to 30 June 2022.

Historical cost convention
The financial statements have been prepared under the historical cost convention, except for, where applicable, the revaluation of financial assets and liabilities at fair value through profit or loss, financial assets at fair value through other comprehensive income and derivative financial instruments.

Going concern
During the year the company incurred losses of $1,729,500. As at 30 June 2023 the Company has cash assets of $239,774 and net current liabilities of $1,439,832. During the year the Company has entered into a licence agreement and has committed to developing the licenced technology upon completion of the agreement. The Company will therefore require additional cash resources to meet its obligations within the next 12 months.

After the year end the Company lodged its prospectus for an Initial Public Offering ("IPO") on the ASX and was admitted to the Official List of ASX on 22 August. The IPO raised $12 million in capital funds, before costs. These funds will be used to meet its statutory obligations and to develop the licenced technology and secure patents in multiple jurisdictions enabling further development and commercialisation of the technology.

The directors have prepared cash flow forecasts that incorporate the recent capital raising of $12 million which demonstrates the company has sufficient funding to meeting its obligations for a period at least 12 months from the date of issue of this preliminary financial report. Accordingly the financial statements have been prepared on a going concern basis.

Current and non-current classification
Assets and liabilities are presented in the statement of financial position based on current and non-current classification.

An asset is classified as current when: it is either expected to be realised or intended to be sold or consumed in the company's normal operating cycle; it is held primarily for the purpose of trading; it is expected to be realised within 12 months after the reporting period; or the asset is cash or cash equivalent unless restricted from being exchanged or used to settle a liability for at least 12 months after the reporting period. All other assets are classified as non-current.

A liability is classified as current when: it is either expected to be settled in the company's normal operating cycle; it is held primarily for the purpose of trading; it is due to be settled within 12 months after the reporting period; or there is no unconditional right to defer the settlement of the liability for at least 12 months after the reporting period. All other liabilities are classified as non-current.

Deferred tax assets and liabilities are always classified as non-current.

Note 2. Current assets - prepayments

	30 June 2023 $	30 June 2022 $
Prepayments	308,519	-

Prepayments relate largely to costs incurred in relation to preparing the company's prospectus for the capital raising completed after the balance date (see note 7). Subsequent to the year end the company was admitted to the Official List of the ASX.

Note 3. Non-current assets – intangible assets

	30 June 2023 $	30 June 2022 $
Deposit paid on licence agreement	-	200,000
Licence acquired	500,000	-
Licence – accumulated amortisation	(41,667)	-
	458,333	200,000

The company entered into a licence agreement with Hudson Institute of Medical Research that was signed on 29 August 2022.

The licence agreement gave the company exclusive rights to commercialise the licenced technology. In the period ended 30 June 2022 the company had paid a deposit pursuant to the licence agreement, paying the remaining $300,000 upon signing of the agreement. The agreement also provides for the company to issue shares to the value of $1,500,000 to be issued on the lodgement of a prospectus to list the company (the shares will be cancelled by way of a selective buy back if the listing is insufficient) as well as a payment of $1,500,000 in cash upon achievement of the first regulatory approval for the first product in the USA (FDA), Australia (TGA), Europe (CE) or Japan (PMDA). The agreement also included a royalty of 3% on net sales, plus levies on any sub-licencing agreements entered into by the company.

Estimated Useful Lives of Other Intangible Assets
The company determines the estimated useful lives and related amortisation charges for its finite life intangible assets. The useful lives could change significantly as a result of technical innovations or other event. The amortisation charge will increase where the useful lives are less than previously estimated lives, or technically obsolete or non-strategic assets that have been abandoned or sold will be written off or written down.

The company's acquired licence will be amortised over its useful life from the commencement of the licence agreement with Hudson, in accordance with the terms of the licence agreement, with the amortisation period commencing from 1 January 2023.The useful life is estimated based on the sales life cycle and patent period of the licenced technology. No sales have yet been made, or patents secured. The current estimated useful life of the licenced technology is 10 years and will be reassessed as the licenced technology is developed.

Note 4. Current liabilities – convertible notes

	30 June 2023 $	30 June 2022 $
Convertible loan notes	1,600,000	40,680

The initial convertible note funding in place at 30 June 2022 formed the Founder convertible notes, which were converted to issued shares during the year to 30 June 2023.

During the current year the company issued 1.6 million convertible loan notes at an issue price of $1 per note. The notes are convertible into ordinary shares at the earlier of a change in control of the company or completion of an Initial Public Offer ("IPO") or Reverse Takeover ("RTO"). On issue, the loan notes will mature 12 months from issue with the company being able to extend for 12 months whereby conversion terms change. The convertible note is a non-derivative financial instrument accounted for at amortised cost.

The interest expensed for the year is calculated by applying an effective interest rate of 15 per cent to the liability component since the loan notes were issued. The liability component is measured at amortised cost. The difference between the carrying amount of the liability component at the date of issue and the amount reported in the reporting at 30 June 2023 represents the effective interest rate less interest paid to that date.

The net proceeds received from the issue of the convertible loan notes have been split between the financial liability element and an equity component, representing the fair value of the embedded option to convert the financial liability into equity of the company, as follows:

	30 June 2023 $	30 June 2022 $
Liability component brought forward	40,680	-
Proceeds from issue of convertible notes (Foundation notes)	3,500	41,500
Proceeds from issue of convertible notes (Seed capital notes)	1,600,000	-
Equity component	(76)	(1,654)
Discount received on convertible notes	(110,080)	-
Interest charged (using effective interest rate)	110,776	834
Converted to equity	(44,800)	-
Liability component of convertible loan notes	1,600,000	40,680

Note 5. Equity - issued capital

	30 June 2023 $	30 June 2022 $
Ordinary shares - fully paid	46,531	1

Movements in ordinary share capital

Details	Date	Shares	Issue price	$
Issued on incorporation	30 November 2021	1	$1.00	1
Balance as at 30 June 2022		1		1
Conversion of convertible notes (liability portion)	30 November 2022	45,000,000		46,530
Balance	30 June 2023	45,000,001		46,531

Ordinary shares
Ordinary shares entitle the holder to participate in dividends and the proceeds on the winding up of the company in proportion to the number of and amounts paid on the shares held. The fully paid ordinary shares have no par value and the company does not have a limited amount of authorised capital.

On a show of hands every member present at a meeting in person or by proxy shall have one vote and upon a poll each share shall have one vote.

Note 6. Equity – reserves

	30 June 2023 $	30 June 2022 $
Convertible note reserve (a)	-	1,654
Share based payments reserve (b)	783,485	-
	783,485	1,654

(a) Convertible note reserve

This reserve represents the equity component of convertible debt instruments (see note 4). During the year the reserve was transferred to issued capital.

(b) Share based payments reserve

The reserve is used to record the value of equity instruments issued to employees, directors and service providers as part of their remuneration, and other parties as part of compensation for their services.

Movement in reserve	30 June 2023 $	30 June 2022 $
Opening balance	-	-
Share based payments – services received	783,485	-
Closing balance	783,485	-

During the year the company employed executives and employees and included long-term incentives in the terms and conditions, with share options provided. The options vest over periods stipulated within the contracts and only have service conditions attached to them.

Option valuation inputs

The options issued during the current year were valued using the following inputs:

Input	*KMP options 1*	*KMP Options 2*	*KMP Options 3*
Number of options	2,500,000	1,500,000	3,000,000
Grant date	30 August 2022	13 September 2022	19 April 2023
Expiry date	22 August 2026	22 August 2026	22 August 2026
Share price at grant date [1]	$0.20	$0.20	$0.20
Exercise price	$0.30	$0.30	$0.30
Risk free rate	3.29%	3.19%	3.18%
Volatility [2]	80%	80%	80%
Fair value at grant date $/option	$0.0872	$0.0870	$0.0870
Expense recorded in year	$217,954	$130,548	$261,054

Input	*Employee options*	*Consultant options*
Number of options	500,000	1,500,000
Grant date	12 September 2022	22 April 2023
Expiry date	22 August 2026	22 August 2026
Share price at grant date [1]	$0.20	$0.20
Exercise price	$0.30	$0.30
Risk free rate	3.18%	3.13%
Volatility [2]	80%	80%
Fair value at grant date $/option	$0.0870	0.0869
Expense recorded in year	$43,509	$130,420

[1] Share price taken as IPO price as this is the price shares will next be offered at.

[2] Volatility is estimated based on volatility of a number of listed companies in the from the same sector of a comparable size

Movements in share-based payment options during the year

2022	KMP Share options	Employee Share options	Consultant options	Total
At 1 July 2022	-	-	-	-
Granted	7,000,000	500,000	1,500,000	9,000,000
Expired	-	-	-	-
Outstanding at 30 June 2023	7,000,000	500,000	1,500,000	9,000,000
Exercisable at 30 June 2023	7,000,000	500,000	1,500,000	9,000,000

Note 7. Events after the reporting date

Subsequent to the year-end the company lodged its prospectus with the ASX. On 22 August 2023 the Company was admitted to the Official List of the ASX, its IPO rising $12,000,000 before costs and issuing 60 million ordinary shares. In addition 16 million shares were issued on conversion of the convertible notes outstanding at 30 June 2023 (see note 4). A further 7,500,000 ordinary shares were issued to Hudson Institute of Research ("Hudson") pursuant to the licence agreement, providing a total of 128,500,001 ordinary shares on the market.

A total of 13,500,000 listed options were also on issue at the date of listing on the ASX. These included 7 million KMP options, and the 1.5 million consultant options noted in note 6, plus 5 million options issued to the lead broker on completion of the IPO. In addition, 500,000 unlisted shares were issued as part of the employee share option scheme.

On 22 August 2023 the company announced that it had been granted a US patent covering proprietary biomarkers and antibody formulations, which comprise the core technology of the company's ovarian cancer diagnostic blood test, securing the company's IP protection in the USA.

No other matter or circumstance has arisen since 30 June 2023 that has significantly affected, or may significantly affect the company's operations, the results of those operations, or the company's state of affairs in future financial years.

Note 8. Reconciliation of loss after income tax to net cash used in operating activities

	30 June 2023 $	30 June 2022 $
Loss after income tax expense for the year	(1,729,500)	(43,931)
Non-cash interest	696	834
Share based payment	783,485	-
Depreciation and amortisation	43,821	-
Change in operating assets and liabilities:		
(Increase) in trade and other receivables	(31,060)	(859)
(Increase) in prepayments	(126,996)	-
Increase in trade and other payables	372,413	43,956
Increase in employee benefits	2,676	-
Net cash used in operating activities	(684,465)	-