

December 2024 Quarterly Activities Report

Key milestones accomplished to accelerate clinical trial pathway advancing innovative psychedelic therapies

- Rapid clinical advancement of TRP-8803 underway following successful completion Phase 1b study
- TRP-8803 is an innovative and commercial psilocin-based IV-infusion with potential neuroplastic benefits
- Pharmaceuticals that achieve a change in neuroplasticity may cause adaptive structural and functional changes within the brain that are thought to be responsible for clinical improvements
- Key milestones achieved for the advancement of TRP-8803 in the quarter included:
 - Safety Review Council (SRC) determined TRP-8803 was safe and well-tolerated in human volunteers
 - Phase 1b study met all key objectives for safety and optimal dosage rates, enabling advancement to Phase 2 clinical trials in specific clinical indications
 - The Phase 1b study was extended to an obese patient population who were safely administered TRP-8803
 - Safe dosing of TRP-8803 in obese patients provided valuable, cost-effective human pharmacokinetic data to support dose selection for future Phase 2 trials
- Receipt of positive results from an interim analysis of Phase 2a Clinical Study in patients with Irritable Bowel Syndrome (IBS), undertaken at Massachusetts General Hospital (MGH) using TRP-8802 found 75% of treated patients achieved a reduction in abdominal pain and GI-associated anxiety
- These interim Phase 2a IBS results support IBS as a viable clinical target for TRP-8803
- \$6m raised from new and existing sophisticated and institutional investors through the issue of 300m new fully paid ordinary shares at an issue price of \$0.02 per share
- Placement was corner-stoned by the Merchant Biotech Fund and distinguished biotech investor Dr Daniel Tillett, with strong support from major existing shareholders
- Cash at bank of \$2.8m as of 31 December 2024 with an additional \$3.25m binding commitments and approximately \$1.1m ATO R&D tax refund expected in Q1 2025

Melbourne, Australia – Tryptamine Therapeutics Limited ('**Tryp**' or the '**Company**') (**ASX: TYP**), a clinical-stage biopharmaceutical company focused on the development of TRP-8803 (a proprietary IV-infused psilocin formulation with neuroplastic benefits), is pleased to provide an update of commercial and clinical activities undertaken during the quarter ended 31 December 2024 (the 'quarter').

Tryp completed a strongly supported capital raise with key strategic investors and made significant clinical advancements with both TRP-8802 (oral psilocybin) and TRP-8803 (IV psilocin). TRP-8803 is an innovative and commercially scalable psilocin-based IV-infusion with potential neuroplastic benefits. Pharmaceuticals that achieve a change in neuroplasticity are known to cause adaptive structural and functional changes within the brain that are thought to be responsible for clinical improvements.

Initiatives undertaken during the quarter leave the Company exceptionally well positioned to advance its next phase of clinical development pathway in 2025.

World-first Phase 1b trial for psilocin-based IV-infusion formulation, TRP-8803:



Following completion of patient dosing for the initial trial cohort in the previous quarter, Tryp achieved several milestones in connection with its Phase 1b study with TRP-8803.

Completion of Safety Review Council Assessment:

In October 2024, Tryp received a formal assessment from the designated Safety Review Council ('SRC') in connection with its Healthy Human Volunteer Study Phase 1b trial (refer ASX Announcement 18 October 2024). The SRC deemed TRP-8803 as generally safe and well-tolerated in healthy volunteers, at doses that achieve plasma levels of psilocin associated with beneficial effects in various patient populations previously treated with oral psilocybin.

The SRC assessment is a critical milestone to advance TRP-8803 into Phase 2 patient studies and is a key derisking event that validated Tryp's approach to achieve more precise blood levels psilocin.

Data analysis from Phase 1b trial determines optimal use of TRP-8803:

Analysis on the results of the Phase 1b study showed that the trial successfully met all key objectives, enabling advancement to Phase 2 clinical trials utilising the innovative and scalable formulation, TRP-8803 for specific therapeutic indications.

The study has established key safety parameters for TRP-8803 across low, mid and high dosage levels, demonstrating the ability to achieve a desired pharmacokinetic (PK) profile in humans, and identified refined loading and maintenance dosing levels required to achieve target psilocin blood levels and treatment duration in volunteers.

Patients infused with TRP-8803 achieved consistent blood levels of psilocin within the therapeutic zone reported in medical literature for oral psilocybin. IV dosing provides greater control and avoids the high interpatient variability inherent with oral psilocybin dosing.

Importantly, during the study the opportunity to demonstrate the rapidly reversible nature of TRP-8803 infusion occurred. One participant experienced a minor heart rate increase outside of the tightly designed study criteria of 100 beats per minute. Once infusion was paused, the participant's heart rate decreased to acceptable levels. This reversibility would not have been possible with oral psilocybin dosing. The results further strengthened the Company's IP portfolio and provided it with the relevant data necessary to proceed to Phase 2 clinical studies.

Successful completion of Phase 1b study of TRP-8803 in obese subjects:

Following completion of the Phase 1b trial on the initial cohorts, Tryp initiated an extension of the Healthy Human Volunteer Study to include three participants from an obese population.

The open label study was undertaken at CMAX Clinical Research in Adelaide using TRP-8803 to determine if there are any differences in pharmacokinetic parameters compared to the previously studied non-obese subjects.

The trial commenced on Thursday, 21 November 2024 and treated three subjects with TRP-8803 over a period of 140 minutes each. Tryp subsequently confirmed that each subject progressed through the treatment well and were safely discharged shortly after study completion.

Key objectives from Phase 1b trial extension achieved:

The primary objective of the Phase 1b trial extension was to confirm pharmacokinetic parameters of TRP-8803 in healthy obese volunteers was consistent with non-obese healthy human volunteers. Prior to the end of the quarter, Tryp confirmed that the key study objectives for the extension had been met.

In addition, obese volunteers infused with TRP-8803 also achieved and maintained controlled psilocin blood levels within the desired therapeutic zone. Oral dosing studies were not able to achieve this important outcome.

This highlights the ability of IV-infused psilocin to consistently deliver dosage control and avoid the high interpatient variability of oral psilocybin dosing with the aim of maximising neuroplastic treatment benefits for patients with neuropsychiatric conditions while minimising side effects.

Tryp both achieved its key objectives and obtained a valuable dataset in connection with the optimal pharmacokinetic profile of TRP-8803. The results provide defined pathway for the Company to proceed to Phase 2 clinical studies, which are anticipated to commence in the coming months.

Positive interim results in Phase 2a TRP-8802 (oral psilocybin) IBS trial:

Alongside its Phase 1b Healthy Human Volunteer Study for TRP-8803, Tryp also received positive interim data from its investigator-initiated Phase 2a Clinical Study for the application of TRP-8802 in patients with Irritable Bowel Syndrome (IBS), being undertaken at Massachusetts General Hospital ('MGH').

This study evaluated the safety and efficacy of TRP-8802 in conjunction with therapist support, based on clinical rationale involving the 'gut-brain axis' which primarily includes the neurotransmitter, serotonin. The study was designed to assess the capacity for psilocin, the active metabolite of psilocybin, to bind to serotonin receptors (5HT2A) in the brain and the gastrointestinal (GI) system, potentially resulting in a viable pathway to positively impact abdominal pain and visceral tenderness – both hallmarks of IBS.

Four, of up to 10 patients, were successfully administered treatment marking the first time MGH had administered psilocybin in a clinical setting. Strong interim results were observed across the preliminary cohort, with 75% of patients reporting a clinically meaningful decrease in abdominal pain and GI-related anxiety associated with gastrointestinal inflammation.

Along with the potential to achieve improved patient health outcomes, results from the Phase 2a trials with TRP-8802 provide an important proprietary dataset to advance the clinical development pathway for TRP-8803, the Company's lead asset.

The positive preliminary data from the Phase 2a IBS study for TRP-8802 will be incorporated into clinical design program for TRP-8803, including its application for patients suffering from IBS symptoms. IBS is estimated to affect up to 20% of Australiansⁱ and up to 15% of the total US populationⁱⁱ and is a leading cause of work absenteeismⁱⁱⁱ.

Corporate:

\$6m funding raised to fast track the TRP-8803 (IV-infused psilocin) clinical trial strategy:

On the success of its clinical strategy, TYP completed a placement to new and existing sophisticated and institutional investors to raise \$6m through the issue of 300 million (300,000,000) new fully paid ordinary shares at an issue price of \$0.02 per share (the 'Placement').

The Placement was corner-stoned by the Merchant Biotech Fund and distinguished biotech investor Dr Daniel Tillett. It was supported by existing major shareholders, Dr Bill Garner, Mr Herwig Janssen and Mr Ludwig Criel, as well as TYP CEO Mr Jason Carroll and Director Mr Chris Ntoumenopoulos (subject to shareholder approval at an upcoming general meeting).

Funds from the Placement will be deployed toward new clinical trials utilising TRP-8803 in specific indications. These trials are anticipated to provide pivotal clinical support of TRP-8803 in Australia and internationally.

Board Transitions:

The Company appointed Dr Daniel Tillett as a Non-Executive Director in the quarter and received resignation of two Non-Executive Directors, Mr Peter Molloy and Mr Clarke Barlow. The company thanks both Mr Molloy and Mr Barlow for their contribution and support and wishes them well in their future commercial endeavours.

Commentary on cash flow:

As of 31 December 2024, the Company held \$2.8m of cash and cash equivalents. Net operating cash outflows for the period was \$2.4m (\$2.3m net operating cash outflows in the prior quarter), predominately related to expenses associated with the Company's Phase 1b study of TRP-8803.

The company raised approximately \$2.75m in the quarter via a two-tranche placement. The Company expects to receive an additional \$3.25m (before costs) from firm commitments via the second tranche in Q1 2025 (subject to shareholder approval).

Further, the Company anticipates an ATO R&D tax refund in the coming months of approximately \$1.1m. In combination with the tranche 2 funds, TYP is well funded to undertake all announced Phase 2 clinical trial initiatives.

In accordance with Listing Rule 4.7C, payments made to related parties and their associates included in item 6.1 of the Appendix 4C incorporates gross salaries, superannuation, fees and benefits to executive and non-executive directors.

Management commentary:

Chief Executive Officer, Mr Jason Carroll said: *"During the quarter, Tryp made considerable progress on the stated clinical development strategy for our lead drug candidate. This was primarily underpinned by the Company's flagship Phase 1b study utilising TRP-8803 and very pleasing progress in our TRP-8802 trials, both of which provided the Company with valuable proprietary data as we seek to advance the use of TRP-8803 in patient specific indications.*

"Among the highlights of our clinical trial program during the period, the Phase 1b study showed that TRP-8803 was deemed safe and well tolerated in healthy human volunteers, for both an obese and non-obese patient population. Dosing for the obese patient population was initiated following strong results for the non-obese cohort and was completed in the span of a fortnight, allowing Tryp to undertake a detailed data review which showed that pharmacokinetic parameters for both volunteer groups were consistent. This was an important milestone for the broader application of the treatment, enabling further optimisation of the delivery method as part of the design framework for detailed Phase 2 trials which will seek to validate TRP-8803 on specific neuropsychiatric conditions.

"From a corporate standpoint, the Company received strong support from several strategic investors who participated in the \$6m placement, marking a validation of both our clinical trial strategy and the potential of Tryp's lead drug candidates to achieve improved health outcomes. I'd like to take this opportunity to again thank existing shareholders who participated in the placement, and to welcome new shareholders to the register. Funds from this initiative will provide the Company with important balance sheet strength to advance the clinical development of TRP-8803.

"Activities undertaken during the period have left Tryp very well placed to capitalise on a number of near-term opportunities. We look forward to providing further details on our broader Phase 2 trial strategy over the coming weeks."

Use of funds:

In accordance with ASX Listing Rule 4.7C2, the Company provides the following (unaudited) update on its use of funds against amounts set out in the Prospects:

Indicative use of funds	Estimated total per prospectus	Actual cash outflows (1 May 24 – 31 Dec 24)
R&D – Project Management & Analysis	\$2,485,000	\$1,054,737
Completion of Phase 2a Fibromyalgia trial at University of Michigan	\$150,000	\$40,756
Completion of Phase 2a IBS trial at Mass General Hospital (Harvard)	\$200,000	-
Completion of TRP-8803 dosing study in Australia including initial GMP manufacturing	\$1,050,000	\$2,505,279
	\$241,000	\$656,761
Completion of Phase 2 trial in Binge Eating Disorder using TRP 8803	\$540,000	-
Completion of Phase 2 trial in Chronic Pain Fibromyalgia using TRP 8803	\$375,000	-
Technical staff	\$700,000	-
Lead Manager/ Corporate Advisor fees	\$462,000	\$471,550
Transaction and IPO costs	\$532,000	\$604,305
Working Capital for Corporate Uses	\$3,870,485	\$2,802,612
Total funds	\$10,605,485	\$8,136,000

This announcement has been authorised for release by the Board of Tryptamine Therapeutics Limited.

-ENDS-

About Tryptamine Therapeutics Limited

Tryp Therapeutics is a clinical-stage biotechnology company focused on developing proprietary, novel formulations for the administration of psilocin in combination with psychotherapy to treat diseases with unmet medical needs. Tryp's lead program, TRP-8803, is a proprietary formulation of IV-infused psilocin (the active metabolite of psilocybin) with potential to alleviate numerous shortcomings of oral psilocybin including: significantly reducing the time to onset of the psychedelic state, controlling the depth and duration of the psychedelic experience, and reducing the overall duration of the intervention to a commercially feasible timeframe. The Company has completed a Phase 2a clinical trial for the treatment of binge eating disorder at the University of Florida, which demonstrated an average reduction in binge eating episodes of greater than 80%.

The Company also has also just completed a Phase 2a clinical trial for the treatment of fibromyalgia in collaboration with the University of Michigan and is completing a Phase 2a clinical trial in collaboration with Massachusetts General Hospital for the treatment of abdominal pain and visceral tenderness in patients suffering from irritable bowel



syndrome. Each of the studies is utilising TRP-8802 (synthetic, oral psilocybin) to demonstrate clinical benefit in these indications. Where a positive clinical response is demonstrated, subsequent studies are expected to utilise TRP-8803 (IV-infused psilocin), that has the potential to further improve efficacy, safety, and patient experience. TRP-8803 has successfully completed a Phase 1b Healthy Volunteer Study in Adelaide, Australia.

For more information, please visit www.tryptherapeutics.com.

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Risks associated with psilocin

All medicines carry risks and specialist prescribers, such as registered psychiatrists are best placed to assess the suitability of a new medication against a patient's individual circumstances and medical history before proceeding. Adverse effects of psilocybin and similar compounds, such as psilocin, can include temporary increase in blood pressure and a raised heart rate. There may be some risk of psychosis in predisposed individuals. These effects of psilocybin and its derivatives are unlikely at low doses and in the treatment regimens used in psychedelic-assisted psychotherapy and appropriately managed in a controlled environment with direct medical supervision.

Forward-Looking Information

Certain information in this news release, constitutes forward looking information. In some cases, but not necessarily in all cases, forward-looking information can be identified by the use of forward-looking terminology such as "plans", "targets", "expects" or "does not expect", "is expected", "an opportunity exists", "is positioned", "estimates", "intends", "assumes", "anticipates" or "does not anticipate" or "believes", or variations of such words and phrases or state that certain actions, events or results "may", "could", "would", "might", "will" or "will be taken", "occur" or "be achieved". In addition, any statements that refer to expectations, projections or other characterizations of future events or circumstances contain forward-looking information. Statements containing forward-looking information are not historical facts but instead represent management's expectations, estimates and projections regarding future events. Forward-looking information is necessarily based on a number of opinions, assumptions and estimates that, while considered reasonable by Tryp as of the date of this news release, are subject to known and unknown risks, uncertainties, assumptions and other factors that may cause the actual results, level of activity, performance or achievements to be materially different from those expressed or implied by such forward looking information, including but not limited to the factors described in greater detail in the "Risk Factors" section of Tryp's Replacement Prospectus available at www.asx.com.au. These factors are not intended to represent a complete list of the factors that could affect Tryp; however, these factors should be considered carefully. There can be no assurance that such estimates and assumptions will prove to be correct. The forward-looking statements contained in this news release are made as of the date of this news release, and Tryp expressly disclaims any obligation to update or alter statements containing any forward-looking information, or the factors or assumptions underlying them, whether as a result of new information, future events or otherwise, except as required by law.

ⁱ MJA 207, Diagnosis and management of irritable bowel syndrome: a guide for the generalist: Ecushla C Linedale & Jane M Matthews

ⁱⁱ <https://gi.org/topics/irritable-bowel-syndrome/#tabs3>

ⁱⁱⁱ <https://pmc.ncbi.nlm.nih.gov/articles/PMC5010380/>

Appendix 4C

Quarterly cash flow report for entities subject to Listing Rule 4.7B

Name of entity

TRYPTAMINE THERAPEUTICS LIMITED

ACN

163 765 991

Quarter ended ("current quarter")

31 December 2024

Consolidated statement of cash flows	Current quarter \$A'000	Year to date (6 months) \$A'000
1. Cash flows from operating activities		
1.1 Receipts from customers	-	-
1.2 Payments for		
(a) research and development	(1,209)	(2,195)
(b) product manufacturing and operating costs	-	-
(c) advertising and marketing	(46)	(88)
(d) leased assets	-	-
(e) staff costs	(436)	(843)
(f) administration and corporate costs	(714)	(1,755)
1.3 Dividends received (see note 3)	-	-
1.4 Interest received	3	4
1.5 Interest and other costs of finance paid	(4)	(6)
1.6 Income taxes paid	-	-
1.7 Government grants and tax incentives	-	-
1.8 Other (provide details if material)	(28)	137
1.9 Net cash from / (used in) operating activities	(2,434)	(4,746)
2. Cash flows from investing activities		
2.1 Payments to acquire:		
(a) entities	-	-
(b) businesses	-	-
(c) property, plant and equipment	(117)	(120)
(d) investments	-	-
(e) intellectual property	-	-
(f) other non-current assets	-	-

Consolidated statement of cash flows		Current quarter \$A'000	Year to date (6 months) \$A'000
2.2	Proceeds from disposal of:		
	(a) entities	-	-
	(b) businesses	-	-
	(c) property, plant and equipment	-	-
	(d) investments	-	-
	(e) intellectual property	-	-
	(f) other non-current assets	-	-
2.3	Cash flows from loans to other entities	-	-
2.4	Dividends received (see note 3)	-	-
2.5	Other (provide details if material)	-	-
2.6	Net cash from / (used in) investing activities	(117)	(120)

3.	Cash flows from financing activities		
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)	2,750	2,750
3.2	Proceeds from issue of convertible debt securities	-	-
3.3	Proceeds from exercise of options	-	-
3.4	Transaction costs related to issues of equity securities or convertible debt securities	(209)	(436)
3.5	Proceeds from borrowings	-	-
3.6	Repayment of borrowings	-	-
3.7	Transaction costs related to loans and borrowings	-	-
3.8	Dividends paid	-	-
3.9	Other (repayment of lease liability)	-	-
	Other (bank guarantee and security deposit)	-	-
3.10	Net cash from / (used in) financing activities	2,541	2,314

4.	Net increase / (decrease) in cash and cash equivalents for the period		
4.1	Cash and cash equivalents at beginning of period	2,768	5,328
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(2,434)	(4,746)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(117)	(120)

Consolidated statement of cash flows		Current quarter \$A'000	Year to date (6 months) \$A'000
4.4	Net cash from / (used in) financing activities (item 3.10 above)	2,541	2,314
4.5	Effect of movement in exchange rates on cash held	67	49
4.6	Cash and cash equivalents at end of period	2,825	2,825

5.	Reconciliation of cash and cash equivalents at the end of the quarter (as shown in the consolidated statement of cash flows) to the related items in the accounts	Current quarter \$A'000	Previous quarter \$A'000
5.1	Bank balances	2,825	2,768
5.2	Call deposits	-	-
5.3	Bank overdrafts	-	-
5.4	Other	-	-
5.5	Cash and cash equivalents at end of quarter (should equal item 4.6 above)	2,825	2,768

6. Payments to related parties of the entity and their associates

- 6.1 Aggregate amount of payments to related parties and their associates included in item 1
- 6.2 Aggregate amount of payments to related parties and their associates included in item 2

**Current quarter
\$A'000**

183

-

Note: if any amounts are shown in items 6.1 or 6.2, your quarterly activity report must include a description of, and an explanation for, such payments

The payments to directors or their associates in 6.1 include gross salaries, superannuation and fees and benefits to executive and non-executive directors.

7. Financing facilities

Note: the term "facility" includes all forms of financing arrangements available to the entity.

Add notes as necessary for an understanding of the sources of finance available to the entity.

7.1 Loan facilities

7.2 Credit standby arrangements

7.3 Other (please specify)

7.4 **Total financing facilities**

Total facility amount at quarter end \$A'000	Amount drawn at quarter end \$A'000
-	-
-	-
-	-

7.5 **Unused financing facilities available at quarter end**

-

7.6 Include in the box below a description of each facility above, including the lender, interest rate, maturity date and whether it is secured or unsecured. If any additional financing facilities have been entered into or are proposed to be entered into after quarter end, include a note providing details of those facilities as well.

8. Estimated cash available for future operating activities

\$A'000

8.1 Net cash from / (used in) operating activities (Item 1.9)

(2,434)

8.2 Cash and cash equivalents at quarter end (Item 4.6)

2,825

8.3 Unused finance facilities available at quarter end (Item 7.5)

-

8.4 Total available funding (Item 8.2 + Item 8.3)

2,825

8.5 **Estimated quarters of funding available (Item 8.4 divided by Item 8.1)**

1.2

8.6 If Item 8.5 is less than 2 quarters, please provide answers to the following questions:

1. Does the entity expect that it will continue to have the current level of net operating cash flows for the time being and, if not, why not?

Answer: Future net operating cash outflows are expected to decrease when compared to current net operating cash outflows due to an expected reduction in corporate and administration costs. In the current period, corporate and administration costs contained one-off legal and IP costs which are not expected to reoccur.

2. Has the entity taken any steps, or does it propose to take any steps, to raise further cash to fund its operations and, if so, what are those steps and how likely does it believe that they will be successful?

Answer: As announced on 30 October 2024, the Company received firm commitments to raise \$6M via a strategic placement. During the quarter, the Company received gross funds relating to the first tranche of the placement (\$2,750,000) with a further \$3,250,000 (before costs) relating to the second tranche expected to be received in Q3FY25. In addition, the Company is anticipating to receive an R&D rebate valued at approximately \$1.1M in the coming months for eligible FY2024 expenses.

3. Does the entity expect to be able to continue its operations and to meet its business objectives and, if so, on what basis?

Answer: Yes, the Company is sufficiently funded to continue its operations and meet its business objectives. The Company will continue to maintain eligibility for nondilutive funding through the R&D Tax Incentive scheme, as well as continue to evaluate its capital requirements and options.

Compliance statement

- 1 This statement has been prepared in accordance with accounting standards and policies which comply with Listing Rule 19.11A.
- 2 This statement gives a true and fair view of the matters disclosed.

30 January 2025

Date:

By Order of the Board

Authorised by:
(Name of body or officer authorising release – see note 4)

Notes

1. This quarterly cash flow report and the accompanying activity report provide a basis for informing the market about the entity's activities for the past quarter, how they have been financed and the effect this has had on its cash position. An entity that wishes to disclose additional information over and above the minimum required under the Listing Rules is encouraged to do so.
2. If this quarterly cash flow report has been prepared in accordance with Australian Accounting Standards, the definitions in, and provisions of, *AASB 107: Statement of Cash Flows* apply to this report. If this quarterly cash flow report has been prepared in accordance with other accounting standards agreed by ASX pursuant to Listing Rule 19.11A, the corresponding equivalent standard applies to this report.
3. Dividends received may be classified either as cash flows from operating activities or cash flows from investing activities, depending on the accounting policy of the entity.
4. If this report has been authorised for release to the market by your board of directors, you can insert here: "By the board". If it has been authorised for release to the market by a committee of your board of directors, you can insert here: "By the [name of board committee – eg Audit and Risk Committee]". If it has been authorised for release to the market by a disclosure committee, you can insert here: "By the Disclosure Committee".
5. If this report has been authorised for release to the market by your board of directors and you wish to hold yourself out as complying with recommendation 4.2 of the ASX Corporate Governance Council's *Corporate Governance Principles and Recommendations*, the board should have received a declaration from its CEO and CFO that, in their opinion, the financial records of the entity have been properly maintained, that this report complies with the appropriate accounting standards and gives a true and fair view of the cash flows of the entity, and that their opinion has been formed on the basis of a sound system of risk management and internal control which is operating effectively.