Telix Pharmaceuticals Limited
ACN 616 620 369
Level 4, 55 Flemington Rd
North Melbourne
Victoria, 3051
Australia

ASX RELEASE

Activities Report and Appendix 4C for December quarter

Melbourne (Australia) – 18 January 2023. Telix Pharmaceuticals Limited (ASX: TLX, Telix, the Company) today issues its Appendix 4C quarterly cash flow statement and accompanying Activities Report for the quarter ended 31 December 2022 (Q4 2022). All figures are in AUD$ unless otherwise stated[1] and provided on an unaudited basis.

Financial Summary

- Telix achieved positive cash flow from operating activities: net operating cash flow improved by $6.9 million over the prior quarter to a $1.6 million inflow for the quarter
- Cash receipts from customers were $72.2 million, up 62% from $44.5 million in the prior quarter
- Telix reports Q4 2022 revenue of $78.2 million from global sales of Illuccix®, up 41% on the prior quarter ($55.3 million, Q3 2022)
- Revenue from sales of Illuccix in the United States up 43% to $76.8 million on the prior quarter (39% on a US dollar basis)

Commercial Activity Report

U.S. commercial update

In Q4 2022, the third quarter of commercial sales, Telix generated $76.8 million (US$50.5 million) revenue from sales of its prostate cancer positron emission tomography (PET) imaging agent, Illuccix®. This represents a 43% increase on the prior quarter ($53.7 million, Q3 2022). Sales momentum continues to build, due to active reimbursement and growth across three major segments of hospital customers, independent imaging centres and government (Veterans Affairs) customers. The Company's distribution network now consists of 190 nuclear pharmacies nationwide, facilitating industry-leading on-time delivery and scheduling flexibility.

Kevin Richardson, CEO Telix Americas said, "We are pleased to see continued sales momentum nine months after launching in the United States and Puerto Rico. We are continuously adding new sites and growing existing accounts, resulting in a steady increase in demand for doses. In 2023, we look forward to building on the foundations of a successful commercial launch to continue to drive sustainable growth and make a positive impact on more patients' lives."

Prostate imaging worldwide revenue

Total revenue of $78.2 million was generated from prostate imaging sales (including commercial sales of Illuccix in the U.S.) during the quarter. Of this, $1.4 million was generated from rest of world sales, predominantly being pre-commercial sales[2] in Europe and the United Kingdom.

Net cash from operating activities

Telix reports its maiden quarter of net operating cash **inflow**, being a significant milestone for the business. The $1.6 million inflow for the quarter is a $6.9 million improvement on the prior quarter's net operating cash outflow of

1. Conversion to AUD is at the average exchange rate for the period. AUD$1 = US$0.66; AUD$1 = €0.64
2. Pre-commercial sales are from investigational, clinical trial, magisterial and compassionate use in accordance with local laws and regulations (not as a commercial diagnostic imaging product sold for routine clinical practice).

$5.3 million and is largely representative of further growth in commercial sales, a continued focus on operating expenditure control and management of customer receivables.

Cash receipts from customers improved 62% to $72.2 million, from $44.5 million in the prior quarter.

Payments for product manufacturing and related costs reflect higher volume of sales and timing of supplier payments, with a gross margin achieved of 63%, up 2% on the prior quarter of worldwide sales.

Operating and selling, general and administration costs were lower by $4.7 million compared to the prior quarter, reflecting improved working capital management.

Reasearch and development (R&D) costs remain well controlled, with $19.2 million invested in R&D, manufacturing and clinical development activities, a $2.9 million increase over the prior quarter.

Illuccix global regulatory update

During the quarter, Health Canada approved Illuccix for use with PET of prostate specific membrane antigen (PSMA) positive lesions in men with prostate cancer:

1. with suspected metastasis who are suitable for initial definitive therapy; and
2. with suspected recurrence with elevated serum prostate specific antigen (PSA) level.

Telix is preparing for commercial launch in Canada in H1 2023 through its partner, Isologic Innovative Radiopharmaceuticals, whose distribution network services 265 hospitals and clinics nationwide.

Telix is making progress on the regulatory refiling in Europe and is targeting to have the updated dossier finalised by the end of Q1 2023, for resubmission to the Danish Medicines Agency (DKMA). The DKMA will advise the revised review timeline upon formal acceptance of the updated dossier. Telix is also progressing marketing authorisation applications in Brazil and South Korea together with its partners.

Clinical Programs Update

Telix continues to progress its core clinical pipeline, with a focus on prostate cancer, renal (kidney) cancer, brain cancer (glioblastoma) and rare diseases (bone marrow conditioning). The Company has over 20 clinical trials underway, including collaborative investigator-initiated studies. Notable updates are included in this section of the activities report.

Renal (kidney) cancer / carbonic anhydrase IX (CAIX) program

The Company reported highly positive top-line data from the ZIRCON (NCT03849118) Phase III study of TLX250-CDx (^{89}Zr-DFO-girentuximab), an investigational product for the PET imaging of clear cell renal cell carcinoma (ccRCC).[1]

The study met all of its primary and secondary endpoints:

- Co-primary endpoints of 86% sensitivity and 87% specificity were delivered, considerably exceeding the confirmatory trial success target required to demonstrate the ability of TLX250-CDx to reliably detect the clear cell phenotype and provide a non-invasive method of diagnosing the presence and spread of ccRCC.
- The key secondary endpoint in detecting ccRCC in tumours <4cm (“T1a” classification), was also delivered, with 85% sensitivity and 89% specificity achieved.

These results mean that, for the first time, there may be a non-invasive way to characterise and diagnose ccRCC, the most aggressive and common form of renal malignancy, which if approved would deliver on a major unmet medical need.

Detailed results from the ZIRCON study will be presented for the first time at the American Society of Clinical Oncology (ASCO) Genitourinary (GU) Cancers Symposium (ASCO GU) on 18 February 2023 in an oral presentation format.[2]

Dr Colin Hayward, Chief Medical Officer at Telix said: “The excellent results from the ZIRCON study validate that the CAIX target is potentially as ground-breaking in ccRCC as PSMA has been for prostate cancer, and that TLX250-CDx could change the standard of care in the diagnosis and management of renal masses. We are excited to present further clinical data at ASCO-GU next month, the leading specialised event for genitourinary cancer care worldwide, and to advance towards the preparation of a Biologics License Application for submission to the FDA.”

1. ASX disclosure 7 November 2022.
2. ASX disclosure 22 December 2022.

TLX250-CDx potential for indication expansion

Beyond ccRCC, CAIX is also expressed by a number of other solid tumours including bladder or urothelial, breast, brain, cervix, colon, oesophagus, head and neck, lung, ovarian, pancreatic and vulval cancers. It is often expressed in hypoxic (oxygenated) tumour cells, characteristic of advanced disease with typically poor treatment outcomes. Hypoxic tumours are typically more aggressive and less responsive to current treatments, particularly immunotherapies.[1]

Based on this potential to target multiple tumour types, investigator-led studies are in progress using TLX250-CDx in imaging of urothelial carcinoma or bladder cancer (ZiP-UP, NCT05046665), metastatic triple negative breast cancer (OPALESCENCE, NCT04758780), and non-muscle invasive bladder cancer (PERTINENCE, NCT04897763), and as proof-of-concept for stand-alone and combination therapies. OPALESENCE and PERTINENCE studies reported positive preliminary data during the quarter at the European Association of Nuclear Medicine (EANM) Annual Congress.[2]

Also during the quarter, Telix announced STARBURST (NCT05563272), a prospective, open-label, Phase II study to explore CAIX expression through TLX250-CDx PET/CT imaging in patients with various solid tumours for diagnostic and therapeutic applications.[3] An investigational new drug application (IND) has been submitted to the FDA with first patients expected to be enrolled in the study during Q1 2023.

Prostate cancer / PSMA therapy program

Telix's PSMA-targeting ProstACT therapeutic program is evaluating the efficacy of Telix's lutetium-177 (^{177}Lu)-labelled therapeutic antibody (TLX591) in various stages of prostate cancer, from first recurrence to advanced metastatic disease.[4]

The ProstACT SELECT study (NCT04786847), a "theranostic" (imaging and therapy) Phase I radiogenomics study to demonstrate the utility of Illuccix to select TLX591 patients for therapy, continues to recruit well with top-line data expected in H1 2023. During the quarter, a first patient was dosed in the Phase II ProstACT TARGET study of TLX591 (NCT05146973), in patients experiencing a first recurrence of prostate-specific antigen (PSA) after initial therapy for prostate cancer.[5]

The Company is progressing manufacturing scale up and regulatory submissions for the ProstACT GLOBAL Phase III study (NCT04876651) in preparation to commence dosing patients in Australia and New Zealand, the U.S. and Europe, subject to the requisite regulatory approvals. The study will be a global randomised controlled trial in patients progressing on novel hormonal therapy in the metastatic setting. Patients will be randomised 2:1 to TLX591 with a total of ~392 patients expected to be enrolled. An interim analysis for safety and efficacy is planned at approximately 120 patients.

Glioblastoma (brain cancer) / LAT-1 program

During the quarter, a first patient was dosed in IPAX-Linz (IPAX-L), a Phase II investigator-initiated study of TLX101 in combination with external beam radiation therapy (EBRT) in patients with recurrent high-grade gliomas (HGG), including glioblastoma multiforme (GBM).[6] TLX101 (4-L-[^{131}I] iodo-phenylalanine, or ^{131}I-IPA) is one of Telix's lead therapeutic clinical programs and has been granted orphan drug designation in the U.S. and Europe. TLX101 targets L-type amino acid transporter 1 (LAT-1), typically over-expressed in many malignant tumours, including HGG/GBM.

The IPAX-Linz study, led by Professor Josef Pichler at Kepler University Hospital in Linz, Austria, builds on encouraging safety and preliminary efficacy data generated in the IPAX-1 study.[7] IPAX-Linz will continue to study the benefit of TLX101 to patients in the second line (refractory) setting at this leading neuro-oncology site in Europe. The goal of this study is to gather additional data on clinical utility.

IPAX-Linz will run concurrently with IPAX-2 (NCT05450744), which is evaluating TLX101 in combination with post-surgical standard of care comprised of EBRT and temozolomide in newly diagnosed (first line) GBM patients. It is expected that the combination of the IPAX-1, IPAX-2 and IPAX-L studies will inform a pivotal trial strategy for this asset by end-2023.

1. Huizing, F.J. et al. Sci Rep 9 2019.
2. ASX disclosure 18 October 2022.
3. ASX disclosure 7 November 2022.
4. ASX disclosure 27 January 2022.
5. ASX disclosure 12 April 2022.
6. Telix media release 22 November 2022.
7. ASX disclosure 21 September 2022.

Research, Innovation and Manufacturing

In November 2022, Telix entered into a collaboration with UniQuest Pty Ltd (UniQuest), the commercialisation company of The University of Queensland (UQ), to develop a radiolabelled molecule targeting an immune checkpoint protein.[1] The goal is that an immune targeting peptide could be used as an imaging agent to determine the presence of certain immune checkpoint proteins in metastatic tumours, in order to guide patient selection for immunotherapy.

The Company also announced its acquisition of Optimal Tracers, a Sacramento (California)-based radiochemistry development company, that provides radiochemistry process development services and research tracers for use in clinical trials.[2] The acquisition of Optimal Tracers expands Telix's translational radiochemistry capability and offers a unique environment for pharma partnerships and collaborations.

In December 2022, Telix published that it has been granted an updated radiation licence by the Belgian Federal Agency for Nuclear Control (FANC) for its European radiopharmaceutical production facility in Brussels South.[3] This licence paves the way for the Company to activate the site for production H2 2023 subject to the requisite regulatory inspections and approvals.

Executive Leadership Changes

Also in December 2022, Telix announced several key executive leadership appointments and promotions.

Richard Valeix, Chief Executive Officer for the Europe, Middle East and Africa (EMEA) operating region since joining Telix in May 2021, was appointed to the newly created role of Group Chief Commercial Officer.

Raphael Ortiz, Chief Operating Officer – EMEA since joining in January 2022, succeeds Richard as Chief Executive Officer – EMEA.

Genevieve Ryan also joined the Company as Group Company Secretary, replacing Melanie Farris who has retired from the role to take on a broader portfolio as Senior Vice President Global Governance, Risk and Compliance (GRC).

These appointments reflect an increased commercial focus of the Company and ongoing succession planning to ensure Telix has an optimal mix of skills and experience as the Company prepares to enter a new phase with a portfolio of multiple commercial products.

Payments to Related Parties

Telix confirms that payments noted under section 6.1 of the accompanying Appendix 4C include payments of $1.3 million to ABX-CRO advanced pharmaceutical services (of which Non-Executive Director Dr. Andreas Kluge is Managing Director) for the provision of clinical and analytical services for the Company's development programs. Payments of $0.2 million to Directors were for Director fees and Managing Director salary.

Investor Call

An investor conference call and webcast will be held at 9.00am on Wednesday 18 January AEDT (5.00pm, Tuesday 17 January, EST).

Participants can register for the conference call at the following link: https://s1.c-conf.com/diamondpass/10028150-m3qed4.html

< ENDS >

1. Telix media release 27 October 2022.
2. ASX disclosure 14 November 2022.
3. Telix social media 21 December 2022.

About Telix Pharmaceuticals Limited

Telix is a biopharmaceutical company focused on the development and commercialisation of diagnostic and therapeutic radiopharmaceuticals. Telix is headquartered in Melbourne, Australia with international operations in United States, Europe (Belgium and Switzerland) and Japan. Telix is developing a portfolio of clinical-stage products that aims to address significant unmet medical need in oncology and rare diseases. Telix is listed on the Australian Securities Exchange (ASX: TLX). For more information visit www.telixpharma.com and follow Telix on LinkedIn.

TLX250-CDx (^{89}Zr-DFO-girentuximab) has not received a marketing authorisation in any jurisdiction. Telix's lead product, Illuccix® or kit for preparation of gallium-68 (^{68}Ga) gozetotide (also known as ^{68}Ga PSMA-11) injection, has been approved by the U.S. Food and Drug Administration (FDA),[1] by the Australian Therapeutic Goods Administration (TGA),[2] and by Health Canada.[3]

Telix Investor Relations
Ms. Kyahn Williamson
Telix Pharmaceuticals Limited
SVP Corporate Communications and Investor Relations
Email: kyahn.williamson@telixpharma.com

This announcement has been authorised for release by the Telix Pharmaceuticals Limited Disclosure Committee on behalf of the Board.

Legal Notices

This announcement is not intended as promotion or advertising directed to any healthcare professional or other audience in any country worldwide (including Australia, United States and the United Kingdom). This announcement may include forward-looking statements that relate to anticipated future events, financial performance, plans, strategies or business developments. Forward-looking statements can generally be identified by the use of words such as "may", "expect", "intend", "plan", "estimate", "anticipate", "outlook", "forecast" and "guidance", or other similar words. Forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause our actual results, levels of activity, performance or achievements to differ materially from any future results, levels of activity, performance or achievements expressed or implied by these forward-looking statements. Forward-looking statements are based on the Company's good-faith assumptions as to the financial, market, regulatory and other risks and considerations that exist and affect the Company's business and operations in the future and there can be no assurance that any of the assumptions will prove to be correct. In the context of Telix's business, forward-looking statements may include, but are not limited to, statements about: the initiation, timing, progress and results of Telix's preclinical and clinical studies, and Telix's research and development programs; Telix's ability to advance product candidates into, enrol and successfully complete, clinical studies, including multi-national clinical trials; the timing or likelihood of regulatory filings and approvals, manufacturing activities and product marketing activities; the commercialisation of Telix's product candidates, if or when they have been approved; estimates of Telix's expenses, future revenues and capital requirements; Telix's financial performance; developments relating to Telix's competitors and industry; and the pricing and reimbursement of Telix's product candidates, if and after they have been approved. Telix's actual results, performance or achievements may be materially different from those which may be expressed or implied by such statements, and the differences may be adverse. Accordingly, you should not place undue reliance on these forward-looking statements. You should read this announcement together with our risk factors, as disclosed in our most recently filed reports with the ASX or on our website.

To the maximum extent permitted by law, Telix disclaims any obligation or undertaking to publicly update or revise any forward-looking statements contained in this announcement, whether as a result of new information, future developments or a change in expectations or assumptions.

1. ASX disclosure 20 December 2021.
2. ASX disclosure 2 November 2021.
3. ASX disclosure 14 October 2022.

Rule 4.7B

Appendix 4C
Quarterly cash flow report for entities subject to Listing Rule 4.7B

Name of entity
Telix Pharmaceuticals Limited

ABN	Quarter ended ("current quarter")
85 616 620 369	31 December 2022

	Consolidated statement of cash flows	Current quarter	Year to date (12 months)
		$A'000	$A'000
1	**Cash flows from operating activities**		
1.1	Receipts from customers	72,227	124,095
1.2	Payments for		
1.2 (a)	- research and development	(19,222)	(73,181)
1.2 (b)	- product manufacturing and operating costs	(30,528)	(50,628)
1.2 (c)	- advertising and marketing	(2,760)	(15,245)
1.2 (d)	- leased assets	-	-
1.2 (e)	- staff costs	(10,724)	(38,596)
1.2 (f)	- administration and corporate costs	(5,026)	(26,114)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	-	1
1.5	Interest and other costs of finance paid	(91)	(131)
1.6	Income taxes paid	(2,278)	(2,278)
1.7	Government grants and tax incentives	-	18,909
1.8	Other (provide details if material)	-	-
1.9	**Net cash from / (used in) operating activities**	**1,598**	**(63,168)**

2	Cash flows from investing activities	Current quarter	Year to date (12 months)
2.1	Payments to acquire or for:		
2.1 (a)	- entities	-	-
2.1 (b)	- businesses	(973)	(973)
2.1 (c)	- property, plant and equipment	(2,981)	(9,201)
2.1 (d)	- investments	-	-
2.1 (e)	- intellectual property	-	(6,823)
2.1 (f)	- other non-current assets	-	-
2.2	Proceeds from disposal of:	-	-
2.2 (a)	- entities	-	-
2.2 (b)	- businesses	-	-
2.2 (c)	- property, plant and equipment	-	-
2.2 (d)	- investments	-	-
2.2 (e)	- intellectual property	-	-
2.2 (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 used in investing activities**	**(3,954)**	**(16,997)**

3	Cash flows from financing activities		
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)	-	175,000
3.2	Proceeds from issue of convertible debt securities	-	-
3.3	Proceeds from exercise of options	1,369	6,005
3.4	Transaction costs related to issues of equity securities or convertible debt securities	-	(8,585)
3.5	Proceeds from borrowings	2,471	3,014
3.6	Repayment of borrowings	-	(12)
3.7	Transaction costs related to loans and borrowings	-	-
3.8	Dividends paid	-	-
3.9	Other (leased assets)	(298)	(1,264)
3.10	**Net cash from financing activities**	**3,542**	**174,158**

4	Net increase / (decrease) in cash and cash equivalents for the period		
4.1	Cash and cash equivalents at beginning of period	117,117	22,037
4.2	Net cash from / (used in) operating activities (item 1.9 above)	1,598	(63,168)
4.3	Net cash used in investing activities (item 2.6 above)	(3,954)	(16,997)
4.4	Net cash from financing activities (item 3.10 above)	3,542	174,158
4.5	Effect of movement in exchange rates on cash held	(1,974)	299
4.6	**Cash and cash equivalents at end of period**	**116,329**	**116,329**

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	116,329	117,117
5.2	- Call deposits	-	-
5.3	- Bank overdrafts	-	-
5.4	- Other (provide details)	-	-
5.5	**Cash and cash equivalents at end of quarter (should equal item 4.6 above)**	**116,329**	**117,117**

6	Payments to related parties of the entity and their associates	Current quarter $A'000
6.1	Aggregate amount of payments to related parties and their associates included in item 1	1,534
6.2	Aggregate amount of payments to related parties and their associates included in item 2	-
6.1 Note	Note: Payments in 6.1 include payments of $1,289k to ABX-CRO advanced pharmaceutical services (of which Non-Executive Director Dr Andreas Kluge is Managing Director) for the provision of clinical and analytical services for the Company's development programs; and payments of $245k to Directors for Director fees and salary.	

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.	Total facility amount at quarter end $A'000	Amount drawn at quarter end $A'000
7.1	Loan facilities	19,028	3,014
7.2	Credit standby arrangements	-	-
7.3	Other (please specify)	-	-
7.4	**Total financing facilities**	19,028	3,014
7.5	**Unused financing facilities available at quarter end**		**16,014**
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.	Telix entered into loan agreements with BNP Paribas and IMBC Group totalling €10.1 million on a 10-year term, and a loan with BNP Paribas totalling €2 million on a two-year, extendable term. All three loans are to fund the construction of the Brussels South manufacturing facility. All loans have a two-year repayment holiday period, with repayments due to commence from March 2024. As at 31 December 2022, Telix has drawn down on €1.9 million of these loan facilities.	

8	**Estimated cash available for future operating activities**	**$A'000**
8.1	Net cash from / (used in) operating activities (item 1.9)	**1,598**
8.2	Cash and cash equivalents at quarter end (item 4.6)	**116,329**
8.3	Unused finance facilities available at quarter end (item 7.5)	**16,014**
8.4	Total available funding (item 8.2 + item 8.3)	**132,344**
8.5	**Estimated quarters of funding available (item 8.4 divided by item 8.1)**	**N/A**
	Note: if the entity has reported positive net operating cash flows in item 1.9, answer item 8.5 as "N/A". Otherwise, a figure for the estimated quarters of funding available must be included in item 8.5.	
8.6	If item 8.5 is less than 2 quarters, please provide answers to the following questions:	
8.6.1	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:	N/A	
8.6.2	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:	N/A	
8.6.3	Does the entity expect to be able to continue its operations and to meet its business objectives and, if so, on what basis?	
Answer:	N/A	
	Note: where item 8.5 is less than 2 quarters, all of questions 8.6.1, 8.6.2 and 8.6.3 above must be answered.	

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.

Date:	18 January 2023

Authorised for release by the Telix Pharmaceuticals Limited Disclosure Committee on behalf of the Board.

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.