Appendix 4C & Quarterly Update

Highlights from the March 2024 quarter:

- **Phase 1 trial results demonstrate that monepantel displays superior safety and tolerability to FDA approved MND/ALS drug Relyvrio®**
- **Preliminary efficacy data shows a 58% reduction in the rate of disease progression for Cohort 2 (High Dose) using the FDA primary efficacy endpoint, ALSFRS-R**
- **FDA provides positive feedback and outlines the path required to potentially receive accelerated and full approval of monepantel for the treatment of MND/ALS**
- **Orphan Drug Designation amendment submitted in March**
- **First patient dosed in the 12-month Open-Label Extension study for patients with MND/ALS, with all eligible patients from the Phase 1 MEND Study expected to be enrolled**
- **Dr Thomas Duthy appointed as Non-Executive Director**
- **World-class Scientific Advisory Board formed**
- **Syngene API development batch completed**
- **Syngene GMP Manufacture Campaign has commenced**

Planned activities for Q2 CY2024:

- **Notification scheduled to be received regarding application for Orphan Drug Designation**
- **Manufacturing and preparations for commencement of adaptive Phase 2/3 clinical trial**
- **Human Research Ethics Committee submission for the pivotal adaptive Phase 2/3 clinical trial in Australia**
- **GMP Manufacture Campaign continues**
- **Liquid formulation development of MPL initiated**

30 April 2024 – Perth, Australia: PharmAust Limited (ASX: PAA & PAAOA) ("PharmAust" or "the Company"), a clinical-stage biotechnology company, is pleased to present its Appendix 4C and Quarterly Activities Report for the period ended 31 March 2024.

PharmAust's Interim CEO John Clark commented:
The March quarter was particularly important and successful for PharmAust, headlined by the positive Phase 1 trial top-line data for monepantel (MPL) in Motor Neurone Disease (MND)/Amyotrophic Lateral Sclerosis (ALS). This gives us a strong foundation to push forward with both the open-label extension study and the pivotal adaptive Phase 2/3 clinical trial. The positive FDA feedback has provided us with a clear path towards potential accelerated approval.

The broader team has been bolstered in recent months with key appointments to both the management team and the Board of the Company. This has us well equipped to continue advancing the clinical development of MPL as planned. The early exit of Dr Michael Thurn as CEO has been accommodated within the current team.

We thank those involved in the Phase 1 study for their efforts to date and moving forward, including the trial participants, trial sites and the principal investigators. Alongside Associate Professor Susan Mathers and one of our trial participants, I was very pleased to speak to Channel 7 on MPL and its impact on MND patients in a story that received national coverage.

We remain on schedule for the commencement of our pivotal adaptive Phase 2/3 clinical trial starting in CY2024. I'm looking forward to leading the Company through this exciting time, and we'll be communicating further updates to shareholders as they become available.".

Positive top-line results received from Phase 1 MEND Study

In February, the Company announced positive top-line results from the Phase 1 MEND Study for MPL, revealing its superior safety profile and preliminary efficacy in slowing disease progression in patients MND/ALS.

The study found a 58% reduction in the rate of disease progression for the high-dose cohort. MPL and its active metabolite were detected in the cerebrospinal fluid, indicating the compounds' ability to cross the blood-brain barrier. This significant finding has led to identifying an optimal dose for the upcoming pivotal Phase 2/3 clinical study, slated to begin in 2024.

The MEND Study was a multicentre trial that involved 12 patients and demonstrated MPL's safety and tolerability, with no dose-limiting toxicities or serious adverse effects. Importantly, all participants opted to continue MPL treatment following the conclusion of the MEND Study via a special access scheme.

The trial utilised the ALS Functional Rating Scale-Revised (ALSFRS-R) as a primary efficacy measure, and the results were compared with matched controls from the PRO-ACT database. The analysis indicated the potential for MPL to provide a significant clinical benefit, with the possibility of prolonging patients' lives by 13.5 to 56.5 months, depending on the severity of the disease at baseline. These outcomes are especially notable compared to currently approved treatments, which only extend life expectancy by 2 to 6 months.

Orphan Drug Designation update

In March, the Company submitted this additional clinical data to the FDA to support its Orphan Drug Designation (ODD) request for MPL. This follows the FDA's previous request for more data, with a response expected by mid-June 2024. Recent clinical trial failures of leading FDA-approved drugs for MND/ALS highlight the significant unmet need for effective treatments, positioning MPL as a potential alternative.

MND Extension Study Commences

During the quarter, PharmAust announced that it had commenced an Open-Label Extension (OLE) Study for MPL after receiving approval from the Monash Health Human Research Ethics Committee. The study is a 12-month multicentre trial, with patients from the Phase 1 MEND Study invited to continue treatment with MPL and participate in the OLE study, where they will receive a daily dose of 10 mg/kg body weight of MPL for a year. This study is an important opportunity to gather long-term safety and tolerability data and to assess both the therapeutic benefits and biomarkers related to the disease.

All nine patients at Calvary Health Care Bethlehem, Melbourne have been enrolled and continue to receive MPL. After the end of the quarter, PharmAust announced that Macquarie University, Sydney had received ethics approval to commence the OLE study. Sadly, one patient passed away while on the special access program of 6mg/kg. This patient was from Cohort 1 (2mg/kg and 6mg/kg), and on the drug for 9.5 months, surviving 21 months since disease onset. This patient was diagnosed with bulbar onset MND, which typically displays an increased disease progression and has the shortest expected survival. As the patient was not on study at the time, their death was not formally notified.

FDA Outlines Pathway to Accelerated Approval for Monepantel in MND

Following a productive Pre-Investigational New Drug (Pre-IND) meeting with the FDA in February, the Company has a clear pathway towards accelerated and full MPL approval.

In this meeting, the FDA provided positive feedback on PharmAust's proposed development program for MPL. This includes specific guidance on the requirements for non-clinical and clinical pharmacology, clinical chemistry, and manufacturing controls. Importantly, the FDA indicated that the forthcoming adaptive Phase 2/3 clinical study could potentially support accelerated approval of MPL, provided the study demonstrates substantial evidence of effectiveness and an adequate safety profile.

The pivotal and adaptive Phase 2/3 study is expected to commence later in CY2024 and will be a global study with clinical sites planned in Australia, Europe, and the United States. This strategy aims to expedite recruitment and leverage data to support simultaneous approval efforts in multiple regions.

PharmAust plans to conduct this study as a multicentre, randomised, placebo-controlled trial. An interim analysis slated for Week 24 could open the door for accelerated FDA approval. The trial will continue for 48 weeks, ensuring the ability to submit successful data to both Europe and the US for regulatory approval. The pivotal trial will primarily assess the efficacy of MPL against ALS progression using the ALS Functional Rating Scale-Revised (ALSFRS-R) total score and survival rates.

This development represents a critical step for PharmAust, positioning the company at the forefront of providing a new therapy for MND/ALS, a disease with limited effective treatments and a high unmet medical need.

Berry Consultants engaged ahead of Phase 2/3 MND/ALS study

PharmAust engaged Berry Consultants, a company specialising in clinical study design and statistical analysis, to design and analyse the pivotal and adaptive Phase 2/3 clinical study for the treatment of MND/ ALS using MPL. Berry Consultants, recognised for its innovative trial designs and FDA interactions, will help position MPL for FDA approval. The collaboration aims to evaluate the potential of MPL in slowing ALS disease progression. The lead statistician for PharmAust's Phase 2/3 study will be Berry Consultants' Director & Senior Statistical Scientist Dr Melanie Quintana, an expert in innovative clinical trial design of rare neurodegenerative diseases.

Manufacturing process development agreements

Post quarter end, PharmAust announced manufacturing process development agreements with global leaders Syngene International and Catalent Pharma Solutions to commence validation and registration batches of MPL at scale, to support regulatory approval and commercialisation.

Under these agreements, Syngene will manufacture 60 kgs of GMP monepantel consisting of 1 x 15 kg engineering batch followed by 3 x 15 kg process validation batches designed to validate the GMP manufacturing process, support product registration and prepare the Company for commercial supply. Catalent Pharma Solutions will be responsible for the GMP manufacture of 3 registration batches, totalling more than a million tablets, which will be required to support product registration and facilitate commercial scale-up activities. The product manufactured will be used to support the upcoming pivotal registration Phase 2/3 clinical study. The manufacturing process development agreements are anticipated to be followed by a commercial supply agreement.

CORPORATE

Investor Relations

During the Quarter, PharmAust attended the Spark+ Singapore Healthcare Day, NWR Virtual Healthcare Conference, NEALS Clinical Trials Workshop: ALS Clinical Trials of the Future held in Boston as well as the American Academy of Neurology Annual Meeting held in Denver, Colorado USA. John Clark and Michael Thurn attended multiple meetings around the design and execution of the adaptive Phase 2/3 clinical study, business development and meetings with key opinion leaders.

John Clark appointed Interim CEO, resignation of Dr Michael Thurn

John Clark, PharmAust's experienced Chief Operating Officer, has been appointed interim Chief Executive Officer after Dr. Michael Thurn resigned as CEO of the Company, citing personal reasons. John will continue to be assisted by Dr Thurn and the Board as part of the transition of the CEO role over the next four months.

John has more than 20 years of pharmaceutical industry experience in phase 1-4 clinical trials across numerous therapeutic areas and multiple geographical regions. Before joining PharmAust, John served as Senior Project Manager at a Global CRO, leading the Clinical Operations team, and providing cross-functional oversight on a national CNS trial. Before that, John held various clinical operations leadership roles responsible for implementing clinical programs. John has a proven project management and stakeholder engagement record, with a thorough knowledge of ICH-GCP and regulatory requirements. John earned his B.Sc. in Biomedical Sciences from the University of the West of England.

Since joining PharmAust, John has established relationships with multiple key stakeholders involved in the clinical development of monepantel, including attendance at the recent NEALS Clinical Trials Workshop: ALS Clinical Trials of the Future held in Boston as well as the American Academy of Neurology Annual Meeting held in Denver, Colorado USA.

Dr Thomas Duthy appointed as Non-Executive Director

In February, the Company announced the strategic appointment of Dr Thomas Duthy as a Non-Executive Director to its board, enhancing its governance and business development acumen. Dr Duthy is distinguished by his extensive background in the biotechnology industry, corporate advisory, and investor relations. With over 19 years of experience, he has played pivotal roles in notable business transactions and has served in various executive and advisory capacities, including his consultancy role with Nova Eye Medical, leading to significant returns to those shareholders.

Dr Duthy also sits on the boards of other ASX-listed life sciences companies including Arovella Therapeutics, Neurotech International and Invex Therapeutics. His appointment is expected to be highly beneficial for PharmAust during a critical phase of growth and development, especially given the company's focus on advancing MPL for the treatment of MND/ALS.

As part of the board restructuring, Robert Bishop asked to move from an Executive Director to a Non-Executive Director role.

Dr Herbert Brinkman appointed Head of Manufacturing

Following the end of the quarter, Dr Herbert Brinkman was appointed Head of Manufacturing. This comes at a pivotal time in the fast-track development of MPL for the treatment of patients with MND/ALS.

Dr Brinkman, based in Denver, Colorado, has over 30 years of experience in the pharmaceutical industry. He has prepared over 25 Chemistry Manufacturing and Control (CMC) sections and updates for multiple Investigational New Drug (IND), New Drug Application (NDA), supplementary NDA (sNDA), Investigational Medicinal Product Dossier (IMPD), and Abbreviated NDA (ANDA) filings for United States Food and Drug Administration (FDA) and European regulatory agencies. Dr Brinkman has filed and commercially launched nine products encompassing oncology, metabolic, dermatology, and endocrinology therapeutic areas and contributed to filing 21 ANDAs for various semi-solid and parenteral products. He is also an inventor on 14 patents. His expertise includes current Good Manufacturing Practice (cGMP) systems applied to API manufacture / Drug Product manufacture and addressing regulatory issues.

PharmAust forms Scientific Advisory Board

During the quarter, the Company announced formation of its Scientific Advisory Board (SAB). The SAB, which includes internationally renowned experts in MND/ALS drug discovery and clinical development, will provide strategic guidance in the development of MPL.

Members of the Scientific Advisory Board include:

Professor Leonard van den Berg – Professor of Neurology who holds a Chair in Experimental Neurology of motor neuron diseases at the University Medical Center Utrecht in the Netherlands. He also is Director of the centre's Laboratory for Neuromuscular Disease, Director of the Netherlands ALS Center, Chairman of the Neuromuscular Centre the Netherlands, and Chairman of the European Network to Cure ALS (ENCALS), a network of the European ALS Centres.

Dr Sabrina Paganoni – Co-Director of the Neurological Clinical Research Institute at the Massachusetts General Hospital, Assistant Professor at Harvard Medical School, and physician investigator at the Sean M. Healey and AMG Center for ALS at Mass General. Dr Paganoni's research focuses on clinical trials and therapy development for ALS.

Dr Melanie Quintana – Director and Senior Statistical Scientist at Berry Consultants, specialising in designing Bayesian adaptive clinical trials across a wide range of therapeutic areas. Her work has included numerous examples in designing platform trials, including the HEALEY ALS Platform Trial and clinical trials in rare and progressive diseases, focusing on developing disease progression models to design better and more powerful clinical trials.

Dr Christian Freitag – brings over 20 years of experience in the pharmaceutical industry with positions in companies including Hoffmann La Roche, Shire, and BTG, where he led global clinical development projects. Dr. Freitag has held the position of Chief Medical Officer at Dynacure and Azafaros, where he was responsible for medical and regulatory strategy, including clinical development of their lead compound in rare diseases. Dr Freitag was the Medical Monitor on PharmAust's Phase 1 MEND study and oversaw medical and clinical activities.

Planned activities for Q2 CY2024

A response from the FDA regarding PharmAust's ODD application for MPL is expected by mid-June 2024. The FDA grants ODD status to assist and encourage companies to develop safe and effective treatments for rare diseases and disorders (impacting less than 200,000 persons in the US). Under the US Orphan Drug Act, Orphan Drug status provides incentives, including tax credits, grants, waiver of some administrative fees for clinical trials, and seven years of market exclusivity following drug approval.

Manufacturing and preparations for commencement of the adaptive Phase 2/3 clinical trial are underway. Process development agreements have been executed with Syngene International and Catalent Pharma Solutions, global leaders in GMP manufacture and commercial supply of pharmaceutical products, to commence validation and registration batches at scale to support regulatory approval and commercialisation.

Development of the Phase 2/3 clinical trial protocol is well underway, with expert advice on trial design received from the Scientific Advisory Board and Key Opinion Leaders.

Veterinary Program

The program for the treatment of veterinary cancers remains ongoing.

APPENDIX 4C QUARTERLY CASH FLOW REPORT

PharmAust's cash position at 31 March 2024 was $3.941 million with available funding of $4.887 million. The company will continue to demonstrate appropriate fiscal management.

During the quarter, payments for Research and Development of $1.920 million represented costs involved with the development of the Company's primary drug candidate, MPL including manufacturing costs of Active Pharmaceutical Ingredient (API) and preparations for commencement of adaptive Phase 2/3 clinical trial.

Payments for Staff Costs represent salaries for directors, executive and general management.

Payments for Administration and Corporate Costs represent general costs associated with running the Company, including ASX fees, share registry, legal fees, rent, etc.

The aggregate amount of payments to related parties and their associates included in the current quarter Cash flows from operating activities were $0.103 million comprising Directors' fees, salaries, and superannuation.

Cash outflows for the quarter were in line with management expectations. Please refer to the attached Appendix 4C for further details on cash flows for the quarter.

The Board authorises this announcement.

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About PharmAust Limited:

PharmAust Limited is listed on the Australian Securities Exchange (ASX Code: PAA). PAA is a clinical-stage biotechnology company developing therapeutics for human and animal health applications. The company is focused on repurposing monepantel (MPL) for human neurodegenerative diseases.

MPL is a potent and safe inhibitor of the mTOR pathway. This pathway plays a central role in the growth and proliferation of cancer cells and degenerating neurons. The mTOR pathway regulates the cellular "cleaning process," where toxic protein is broken down into macromolecules to be reused. This autophagic process is disrupted in most neurodegenerative diseases, including motor neuron disease (MND/ALS).

PAA's lead MPL program is for the treatment of MND/ALS, a rare, incurable disease. The company recently announced positive top-line results for its Phase 1 study in patients with MND/ALS. PAA anticipates commencing enrolment in its pivotal registration adaptive Phase 2/3 clinical study in H2 CY 2024 that could lead to accelerated approval with the US Food and Drug Administration in 2026.

The Neurodegenerative Disease Market size is estimated at USD 55.12 billion in 2024, and is expected to reach USD 77.82 billion by 2029, growing at a CAGR of 7.14% during the forecast period (2024-2029).[1]

[1] https://www.mordorintelligence.com/industry-reports/neurodegenerative-disease-market

PharmAust Investor Hub:

We encourage you to utilise our Investor Hub for any enquiries regarding this announcement or other aspects concerning PharmAust. This platform offers an opportunity to submit questions, share comments, and view video summaries of key announcements.

Access the investor hub by scanning the QR code or visiting: https://investorhub.pharmaust.com/

Appendix 4C

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

Name of entity	
PharmAust Limited	
ABN	**Quarter ended ("current quarter")**
35 094 006 023	March 2024

Consolidated statement of cash flows		**Current quarter $A'000**	**Year to date (9 months) $A'000**
1.	**Cash flows from operating activities**		
1.1	Receipts from customers		461
1.2	Payments for		
	(a) research and development	(1,920)	(2,917)
	(b) product manufacturing and operating costs		(58)
	(c) advertising and marketing	(46)	(99)
	(d) leased assets		
	(e) staff costs	(140)	(530)
	(f) administration and corporate costs	(292)	(914)
1.3	Dividends received (see note 3)		
1.4	Interest received	2	5
1.5	Interest and other costs of finance paid		
1.6	Income taxes paid		
1.7	Government grants and tax incentives		553
1.8	Other (GST)	3	(15)
1.9	**Net cash from / (used in) operating activities**	**(2,392)**	**(3,514)**

2.	**Cash flows from investing activities**		
2.1	Payments to acquire or for:		
	(a) entities		
	(b) businesses		
	(c) property, plant and equipment		
	(d) investments		
	(e) intellectual property		
	(f) other non-current assets		

Consolidated statement of cash flows		Current quarter $A'000	Year to date (9 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**		

3.	**Cash flows from financing activities**		
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)	870	4.903
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		
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 (Epichem closing cash at bank)		(165)
3.10	**Net cash from / (used in) financing activities**	**870**	**4,738**

4.	**Net increase / (decrease) in cash and cash equivalents for the period**		
4.1	Cash and cash equivalents at beginning of period	5,463	2,717
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(2,392)	(3,514)
4.3	Net cash from / (used in) investing activities (item 2.6 above)		

Consolidated statement of cash flows		Current quarter $A'000	Year to date (9 months) $A'000
4.4	Net cash from / (used in) financing activities (item 3.10 above)	870	4,738
4.5	Effect of movement in exchange rates on cash held		
4.6	**Cash and cash equivalents at end of period**	**3,941**	**3,941**

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	1,929	5,451
5.2	Call deposits	2,012	12
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)**	**3,941**	**5,463**

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	103
6.2	Aggregate amount of payments to related parties and their associates included in item 2	

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.

Director's Salaries & Superannuation

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	946	0
7.2	Credit standby arrangements		
7.3	Other (please specify)		
7.4	**Total financing facilities**	946	0

7.5	**Unused financing facilities available at quarter end**	946

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.

The available loan facility is with Innovation Structured Finance Co., LLC serviced via Radium Capital and is an advance on 80% of the Company's R&D Tax Incentive (RDTI) for the for the FY2024. The interest rate for the loan facility is 15% per annum. Repayment is timed to coincide with receipt of PharmAust's 2024 FY RDTI refund. No funds have been drawndown.

8.	**Estimated cash available for future operating activities**	**$A'000**
8.1	Net cash from / (used in) operating activities (item 1.9)	(**2,392**)
8.2	Cash and cash equivalents at quarter end (item 4.6)	3,941
8.3	Unused finance facilities available at quarter end (item 7.5)	946
8.4	Total available funding (item 8.2 + item 8.3)	4,887
8.5	**Estimated quarters of funding available (item 8.4 divided by item 8.1)**	2.04

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.

30 April 2024

Date: .....

By 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.