

Executive summary and recommendations

This report provides the results of the recently concluded review of the Australian Stem Cell Centre (ASCC) undertaken by Growing Your Knowledge (GYK). The purpose of the review was to consider the Centre's progress in meeting its Objective under the Biotechnology Centre of Excellence (BCE) Deed of Agreement. Through the BCE Deed the Australian Government undertook to contribute almost \$100 million over the period 2002 to 2011 (and \$5.5 million was provided through the Major National Research Facility (MNRF) scheme). The Victorian Government has also contributed \$11.375 million to the Centre. In addition a number of stakeholders involved in the venture have provided both cash and in-kind funding, with significant contributions from Monash University (MU) and more recently the University of Queensland (UQ). The review considers what has been achieved with the funding to date, whether the funding contributed by the Commonwealth has been well spent and how the ASCC is progressing.

The Science Review

The outcomes of the Science Review of the ASCC undertaken in May 2008 are fundamental to the wider review and the Science Panel's findings have influenced and largely have been incorporated into this Report. The Science Panel considered that 'a well funded centre of research excellence in the stem cell arena is essential to Australia's future competitive position in health, science and commercial research'.

The Science Panel identified and documented four major issues for the ASCC:

- i) An absence of a clearly enunciated strategy underlying the Centre's activities from research to commercialisation
- ii) The poor morale of the Principal Investigators (PIs) due to their marginal role in the strategic direction of the Centre and the lack of transparency in decision making
- iii) The lack of due diligence in the Centre's approach to commercialisation and translational research

- iv) The inappropriate limitation of options for generating and exploiting intellectual property (IP), including a rigid view about ownership of IP.

GYK considers the findings of the Science Review are of such significance that the *Science Report on the Australian Stem Cell Centre* should be read in its entirety as a stand alone document.

The more comprehensive review covered a much wider scope than the Science Review, including compliance with governance and Deed requirements, assessment of the Centre's progress towards achieving its Objective and success in meeting its KPIs. In addition it evaluated progress towards achieving its long term viability; and the Centre's reporting structures and its standing within the research and biotechnology community. The review also considered the agreements and arrangements between the Centre and its stakeholders, as well as the extent to which previous review recommendations have been implemented. The review endorsed the findings of the Science Panel and identified a number of further issues for ASCC.

These issues included:

- i) the lack of a clear understanding by its scientists and staff of the Centre's identity and purpose
- ii) weakness in strategic management, financial planning and modelling, business and commercialisation planning
- iii) potential financial difficulties over the next three to five years, with the possibility of insolvency prior to the completion of the present BCE funding term, depending on the receipt of increased revenue and interventionist actions taken by the ASCC Board and management
- iv) a declining level of investment in research going forward in both absolute terms and relative to corporate and other infrastructure costs
- v) poor management of stakeholder interests, resulting in the Centre becoming isolated from its member stakeholders, limiting its collaborative capacity and risking reputational damage

- v) high staff turnover and difficulty in attracting scientists to the Centre
- vi) ineffective performance management of the CEO
- vii) a poor record of achieving the Centre KPIs
- viii) failure to accept and apply previous advice and to effectively implement the recommendations of the GYK 2006 Review.

Achievements of the ASCC

Since it commenced operations approximately five years ago the ASCC has established itself as an independent not-for-profit entity separate from its member stakeholders. The physical infrastructure created by the Centre at MU and the UQ is state of the art. The technical expertise of the scientists within those facilities is well respected. The organisation met the formal compliance obligations that GYK examined, with the exception of some of its obligations to stakeholders.

The Science Panel noted the high calibre of the ASCC funded researchers (internal and external) and the excellence of their research. Research outputs in terms of publications and presentations were of a high standard and growing as the Centre matured. Whilst the ASCC's reputation was diminished to some extent by the departure of some high profile scientists in 2006 and 2007, nevertheless the PIs supported by the ASCC are well respected and include a number of talented younger scientists.

The post-graduate programs sponsored by the Centre have attracted many students and the Centre established a good record in this area in cooperation with its stakeholder institutions. This was particularly the case in its early years. The new post-graduate programs are as yet unproven. The Centre has developed sound links with international stem cell networks. It has succeeded through its public affairs operation in providing public education, advocacy and support for policy development in Australia. From these comments it can be assessed that value has been created. In the opinion of the Science Panel, the ASCC's value resides primarily in its research capability, and was less evident in commercial outcomes.

Progress against the Objective and meeting performance targets

The ASCC has made progress in establishing a world-class research capability. As noted above, research strength is the strongest attribute of the ASCC. The ASCC has experienced difficulty in making significant progress in achieving some of the other elements of the Objective including:

- successfully commercialising stem cell research
- becoming globally recognised as an ethical best-in-class biotechnology Centre of Excellence, (COE) and
- attracting and retaining international expertise to build capacity and sustainability.

With regard to its aim to successfully commercialise outcomes of stem cell research ASCC has formed a commercial partnership with Millipore Corporation through which it commercialises research reagents and tools. Current and projected net income from this source is, however, modest.

The ASCC may have found it difficult to make a significant impact in this area due to the challenging nature of achieving commercial success in the stem cell field, which is at such an early phase of development. The ASCC has invested in research projects and programs which are at an early stage of development, being primarily focussed on basic research. The Science Panel was critical of the ASCC's restrictive commercialisation approach and strategy, and recommended the ASCC take a broader approach to potential commercialisation opportunities.

GYK considered that the ASCC has not at this stage developed the scale and resources to attract significant investment in the Centre. Had the Centre been more successful in attracting investment from industry, governments, research institutions and funding bodies it could have leveraged its Commonwealth funding by a factor of two or three creating a significant (and possibly continuing) funding stream.

The infrastructure it has created, with overhead expenses and two nodes, is resourced to support a much larger Centre. Corporate and research services costs (as described by the ASCC) are approximately half of the total cash expenditure and are forecast to increase, relative to research expenditure, over coming years. It could be argued that the Centre's intramural research program, which currently consists of eight projects with 23 research scientists, is costly to support and is too small to attain critical mass.

Despite a strong commencement with excellent founding scientists (from its original stakeholders) the ASCC has struggled to form strong research collaborations and to grow organically. The ASCC has not convincingly demonstrated it has achieved the scale and reputation to attract and retain high calibre scientists. This is evident from its recruitment statistics. Reputation depends on multiple factors, including the quality of leadership and management as well as Centre affiliations, and not only on the standing of the scientists associated with the Centre.

Human resource management may become a major problem for the Centre over the next three years. The lack of clarity about future funding may already be a factor affecting recruitment. Should the ASCC not be assured of future security (through guaranteed further funding) its scientists may be attracted to join other institutions offering greater job stability and security.

Many of these issues are reflected in the difficulties the ASCC has had in meeting some of its KPI targets: specifically the targets for revenue, developing new research and commercial partnerships and international recruitment. The Centre has not performed well in these areas during the last two financial years.

ASCC identity, purpose and model

A fundamental issue which arose during the Science Review and emerged even more strongly in conversations with stakeholders was the lack of a clear definition of Centre identity and purpose. The wording in the Objective, as stated in the Deed is

clear and unambiguous. The Centre has used the wording from the Objective in its Vision and Mission statements. However, research scientists supported by the Centre, ASCC management and staff, the Board and the stakeholders do not appear to share a common understanding of the Centre and its strategy. The manner in which management has interpreted the Objective and failed to define a clear strategy has resulted in uncertainty and a diversity of opinion.

The Centre needs to explore this issue in partnership with its stakeholders and its government funders, against the backdrop of the founding Deed. This issue was apparent, and commented on, in the last review (*The GYK 2006 Review*). It deserves urgent attention. The Science Panel also made a very similar recommendation on this issue (Science Panel Recommendation 1).

Recommendation:

- 1) It is recommended that the Board together with senior management review the identity and purpose of the ASCC, consulting with government and stakeholders (as recommended in the Science Panel Recommendation 1).

Planning and financial management

A major finding of the review was that the ASCC is unlikely to be independent of government funding for the foreseeable future. Moreover, the ASCC faces serious financial difficulties in the next three to five years, assuming it continues to fund research as a COE.

It may not be able to continue funding research projects and programs at present levels. It should be noted, however, that the Science Panel made recommendations designed to strengthen the ASCC as a world class COE in stem cell research, and implementing some of those recommendations will require additional expenditure.

The ASCC has not exhibited expertise in financial planning and modelling. The ASCC forecasts have included assumptions about future 'unconfirmed revenue' that

2008 Review of the ASCC

GYK assesses as overly optimistic. The failure to make planning adjustments for this unrealised income suggests an over-confident attitude about revenue as well as a lack of realism about adapting to declining revenues in later years, under the BCE Deed funding schedule.

An analysis of a range of scenarios undertaken by GYK highlights the difficulties ahead. GYK constructed a high level analysis of the ASCC's forecast cash position. Three scenarios were created, a best case, a mid case and a worst case. These scenarios excluded the projected cost of additional spending on translational research that was canvassed by the ASCC in the *ASCC 2008-09 Business Plan*¹.

On current projections the ASCC will be most unlikely to expand (or even maintain) its current level of research expenditure in the three remaining years of BCE Deed funding. It was of concern that the worst case scenario indicated the ASCC was likely to become insolvent in 2009-10 and the mid case indicated this was likely in 2010-11.

There are many permutations affecting cash flows and GYK acknowledges that the ASCC has some flexibility, should its Board and management take interventionist action to reduce ASCC outlays (by for example cutting back on research or reducing its expenditure on corporate costs or research services). It would be most disappointing, however, if ASCC reduced its research support in the years 2009-10 and 2010-11.

A second serious issue was the current high level of corporate expenditure (covering administration overheads, Board and senior management costs) which is currently forecast to reach \$8.4 million in 2008-09². This forecast is based on budget figures, as supplied, at 22 July 2008, however, these indicative budget allocations are subject to amendment by ASCC management.

¹ The business plan which was submitted to government on April 10 2008 was not accepted, as conveyed in the government's letter to the ASCC dated 9 May 2008. This remains the position at the date of writing this report.

² From 2009 Budget Corporate Expenses Detail – Scenario :Base, as supplied by the CFO 22 July 2008

Corporate expenditure is projected to rise over the next five years from the present 37.8% to 39.7% (as a percentage of total expenditure)³. When research services and science management charges (\$3.7 million in 2008-09) are added to corporate costs the total non-research spending as a proportion of total expenditure is projected to be 54.5% in 2008-09 rising to 57.7% in five years. This corporate overhead represents an administration of a size and sophistication that should be overseeing research expenditure significantly larger than that currently being administered.

The implications for administration are quite different depending on the balance of activities the ASCC is undertaking. The infrastructure requirements for the ASCC should it make a decision to concentrate on becoming a COE in basic stem cell research are different to those should it decide to devote more of its resources to translational research and commercialisation.

Recommendations:

- 2) GYK recommends the preparation of contingency plans for the smooth running of the ASCC until the end of June 2011 should BCE funding cease.
- 3) GYK recommends that the ASCC refines its financial forecasts and scenarios to develop operational plans that ensure the Centre's research output is maintained to the extent possible, commensurate with funding and timing constraints.
- 4) GYK recommends the ASCC conduct an analysis of the corporate structure and a critical examination of the corporate and research services budgets to reduce the current high level of administration and overheads.

See also Science Panel Recommendations 2 and 3.

Governance arrangements

GYK has undertaken a comprehensive assessment of the governance structure and systems of the ASCC by applying the Wigginton framework. In the process, as requested by the Government, special consideration has been given to stakeholder

³ ASCC 2008-09 Business Plan

relations and the Board/management interface. These topics as well as risk management are the subject of separate sections in this executive summary.

The ASCC has complied with Deed requirements in the manner in which the Board is constituted. The Board membership should, however, be reviewed to ensure it is suitable for the future direction of the Centre. A board performance review by self-appraisal was undertaken a year ago. The results indicated that the Board should increase its focus on:

- strategy
- monitoring the external environment
- achieving a better balance between research and commercialisation
- assurance on compliance
- the reliability of internal reporting, and
- the importance of maintaining sound stakeholder relations.

GYK was not presented with any evidence to indicate that these matters have been adequately addressed.

GYK noted the relatively narrow base of the ASCC's membership accentuated by the recent resignation of two of the six founding members. It should be emphasised that ultimately the Board is appointed by and is accountable to its members.

In addition, the Board through the mechanism of the BCE Deed, is also accountable to its (government) funders. The Board must clearly define strategic direction and demonstrate through its stewardship of the Centre a capacity to deliver the outcomes forecast in the annual business plan, as provided to government in the biannual and quarterly Reports.

There are deficiencies in the manner in which the ASCC has moved to a focussed research program in haematology. The ASCC has not developed sound evidence and

rationale for the strategy. The strategy lacks transparency. There is inadequate documentation and dissemination of the strategy, leading to stakeholder concerns with many questioning the logic and justification of the strategy.

Regular, disciplined reviews of the strategy and the evidence supporting the strategy do not appear to have been undertaken by the Board and Centre management.

Stakeholder relations

There has been a significant shift in stakeholder relationships with ASCC since 2005. A major finding of the review is that changes have been made to the structure of the Centre by dissolving various stakeholder-based advisory committees that have diminished the spirit of openness and collaboration expressed in the BCE Deed and the Stakeholders Agreement.

Moreover, disbanding the Commercialisation Committee has put at risk the legal certainty of some of the provisions in the Stakeholders Agreement. The intention expressed in that document (and presumably the intention of the founding members) was for the stakeholders to be able to work together, whilst still protecting IP created within the ASCC programs and enabling the ASCC to develop that IP.

Stakeholders have not been routinely involved in approving the annual ASCC business plans nor have they received copies of the biannual and quarterly reports as required by the Stakeholders Agreement. Whilst the stakeholders themselves appear to have been neither pro-active about asserting their rights nor demanding in their involvement in the Centre's operations, the outcome has been to diminish the profile of the Centre, and the effectiveness of its operations reducing its capacity to build a collaborative organisation.

More importantly, a number of stakeholders have provided evidence of the ASCC's poor record in managing external relationships, particularly in dealing with its primary stakeholders. This ranged over the following areas, dissatisfaction with the

Centre's science strategy, the research project agreements and their negotiation, the protracted nature of business dealings, impediments in resolving disputes, a lack of professional business practice especially in relation to IP and generally ineffective communications.

Recommendations:

- 5) It is recommended that the Board give consideration to appointing new members to ASCC representing stakeholder interests and also examine whether the Constitution should be amended to remove the current restriction on the number of members.
- 6) It is recommended that the Board:
 - commissions an analysis of the skills required for the Board
 - assesses the skills of current members with a view to facilitating the appointment of one or more new board members and
 - establishes and tasks a Nominations Committee (with member representation) to review the Board's competency profile and identify candidates for appointment to the Board.
- 7) GYK recommends that the ASCC reinstate the Commercialisation Committee specified in clause 8 of the Stakeholders Agreement.
- 8) It is recommended that the Board should:
 - review the extent to which the Board and the ASCC are fulfilling accountability to stakeholders
 - review the Centre's engagement with stakeholders
 - engage in active consultation with stakeholders and consider reinvigoration of the Advisory Committee system envisaged in the Deed and Stakeholders Agreement and
 - resolve outstanding stakeholder IP and financial issues.

The Science Review made a number of recommendations about enhancing stakeholder relations. Science Panel Recommendations 2, 6 and 7 refer to these points. Furthermore, the Science Review made recommendations on improving

negotiations on IP and related matters and adopting alternative commercialisation approaches (Science Panel Recommendations 6, 10 and 11).

Leadership and management

The Centre has been established with reasonably sound systems and resources, and it has substantial capability in public education, external affairs and issues management. The ASCC has a well resourced senior management team. It has established satisfactory financial, IP education and protection, science management and HR systems.

On the other hand, there are aspects that cause concern, most of which reflect on poor leadership. In particular, the culture of the organisation is internally focused, secretive, lacks trust, exhibits poor internal communications, lacks a clear delegation of responsibility and operates in a silo-based management environment. The ASCC exhibits weakness in strategic management, financial planning and modelling and in understanding and planning for commercialisation.

Although there is due process, GYK noted a number of deficiencies in reporting to the Board in terms of receiving assurance on the existence and management of operational systems, adequacy and timeliness of reporting to government, strategic and external relations, including the maintenance of good relations with stakeholders and others in the external environment.

The ASCC Board is required to approve the business plans and reports that are provided to government. While there has, at the Commonwealth's persistent urging, been a greater alignment between reporting to the Board and the Commonwealth, there appear to have been many instances where the Commonwealth has not been satisfied with the details in reports or business plans or has identified serious omissions in them and has therefore sought additional information from the Centre. At times this has meant unnecessary duplication of effort. The CEO and management should work to more fully integrate reporting to the Board and the government.

The CEO is responsible for the performance of the organisation. Organisational performance, as judged by progress towards the Objective and the achievement of KPIs, has been less than adequate. The Board reviews the CEO's performance, using an agreed performance plan. The CEO's performance agreement does not, however, contain specific quantitative measures or timeframes, which places relatively little pressure to achieve firm targets on the CEO and does not allow for the adequate measurement of performance. GYK has therefore recommended a higher standard of CEO performance management by the Board including both quantitative and time bound targets.

Recommendation:

9) It is recommended that the Board with the CEO:

- review the ASCC reporting format to the Board, with a view to increasing strategic and external relations content as well as including more due diligence on ASCC operating systems
- more fully integrate Board and Commonwealth reporting and
- agree on a performance plan for the CEO that incorporates the ASCC Objective and is linked to measures of success, with defined outcomes, milestones and timeframes.

Risk management

The ASCC has made a commitment to risk analysis and management, however, GYK believes that the Board should review progress in implementing its risk management plans for some of the issues considered in this review. Also, the ratings for known risks should be reviewed. There are additional risks which the organisation should identify and for which treatment plans should be developed.

Recommendation:

10) It is recommended that risk management is assigned a higher priority within the ASCC, as there are some risks for which the current rating is insufficient and

other risks which are recommended for serious consideration, with the Board having a closer involvement in setting the ratings.

Science management

The Science Report on the Australian Stem Cell Centre made a number of recommendations aimed at enhancing the development of the Centre to position itself to become more successful in attracting grants and increase its competitiveness. It was recommended that the ASCC build large-scale, multi-disciplinary collaborations and enhance its strategic alliances. It was also suggested that the ASCC maximise the use of its stakeholders' infrastructure. See Science Panel Recommendations 6, 7 and 8.

The ASCC should improve the fairness and transparency of its grant application process, its management of research projects, (on the basis of a better articulated research strategy), scientific reporting and internal communications and should review its project assessment processes to bring them to best practice. See Science Panel Recommendations 17, 18, 19, 20 and 21.

Interactions with the external environment

GYK noted that ASCC relationships with individuals and institutions could be improved. The Science Panel further proposed that the ASCC undertake a landscape review of Australian stem cell science, play a leadership role in bringing Australian researchers together and increase the versatility of the organisation to respond to the changing environment. See Science Panel Recommendations 4, 9 and 14.

Human resource management

Retaining key scientists and senior managers is a critical issue for the ASCC. There is a relatively small pool of people with stem cell expertise in Australia. The ASCC has seen a great deal of churn in its senior management positions (including the CEO, CSO and COO positions) during its five year life. Over the last year the ASCC has found it more difficult to attract scientists to fill internal positions. The ASCC has a very high staff turnover rate; however, this is most evident amongst its corporate support staff. In the future, as the Centre approaches the end of the BCE funding

period (unless there is certainty on refunding) there is likely to be an increased migration of scientists and managers to other institutions that offer a more secure and stable future.

Recommendation:

- 11) GYK recommends the ASCC makes strenuous efforts to retain its key research personnel, as they are likely to receive attractive job offers.

See also recommendations on improving the ASCC's engagement with its scientists, improving the length and security of funding and their knowledge of IP policies in Science Panel Recommendations 5, 15 and 16.

Commercialisation

The Science Panel made a series of recommendations concerning the ASCC's approach to commercialising its IP, its commercialisation strategy and its business development techniques. These include Science Panel Recommendations 10, 11, 12 and 13. GYK endorses these recommendations. Both the Science Panel and GYK were critical of the quality and depth of the analysis of the ASCC's commercialisation targets, particularly its competitor analysis. GYK recommends that the ASCC takes external, independent advice from a recognised expert in commercialising Australian biotechnology.

Recommendations:

- 12) GYK recommends that the ASCC develops a comprehensive research and business competitor analysis and adopts a more tactical approach to intelligence gathering. This should involve the ASCC's key research scientists and business development personnel working more cohesively in assessing competitive threats in the Centre's principal research fields.
- 13) The ASCC should engage a well recognised consulting group with a track record of advising Australian biotechnology companies to undertake an independent technology evaluation of its leading commercialisation programs.

Reporting and government relations

Reporting structures were a significant issue in the past as noted in the 2006 GYK Report. A number of amendments were made to the Deed following that report and by and large these changes appear to have improved relations between the ASCC and its funders.

The Commonwealth has made consistent efforts to identify issues for the ASCC in relation to the GYK 2006 Review (and the implementation of its recommendations), as well as providing constructive advice on the relevant ASCC draft business plans (2006-07 and 2007-08) and various reports.

Performance issues have, nevertheless, become apparent, particularly over the last eighteen months. This has resulted in an increased frequency of correspondence and consultation with a consequent lengthening of the timeframes for approval of reports and business plans. GYK notes that there have been a series of reporting issues between the ASCC and the Commonwealth over recent years. This has culminated in the government's decision to refuse to accept both the *ASCC 2008-09 Business Plan* and the *June 2008 Quarterly Report*.⁴

GYK appreciates that there are often sound reasons why exchanges between the Commonwealth and ASCC should be in writing. We do, however, perceive an apparent preference on both sides to deal with issues in writing, often concerning trivial matters. GYK advises that more regular face to face meetings may assist in developing closer working relationships and achieving greater levels of understanding.

GYK has reviewed the KPIs and considers most of them to be adequate. GYK suggests that for greater clarity in understanding the various ASCC income streams

⁴ The government advised the ASCC by letter on 25 July 2008 that it required ASCC to submit a revised *ASCC June 2008 Quarterly Report* and also to provide written evidence of a satisfactory Performance Strategy to address meeting the KPIs.

(and hence their ability to supplement BCE funding) minor revisions to the present financial KPIs should be considered.

Recommendations:

- 14) GYK recommends that representatives of the Commonwealth and the ASCC confer face to face at least quarterly to assess the ASCC's progress.
Representatives should have authority from their principals to resolve, wherever possible, operational issues.
- 15) It is recommended that the existing KPIs 10, 11 and 12 be discontinued and replaced with five new KPIs measuring:
 - i) non-BCE funding from all sources (cash and 'in kind') as a percentage of total funding (i.e. both BCE and non-BCE funding in cash and 'in kind')
 - ii) non-BCE cash funding as a percentage of total funding
 - iii) non-BCE 'in kind' funding as a percentage of total funding
 - iv) funding derived from commercialisation activities as a percentage of total funding
 - v) funding derived from other research grants (i.e. non-BCE funding) as a percentage of total funding.

Benchmarking

A review of the international landscape and of comparable institutions in other countries revealed that the closest match with the ASCC is the Canadian Stem Cell Network (SCN). SCN has pursued a different pathway to the ASCC. To some extent this may have been determined by the Canadian criteria (for a COE network) that require an emphasis on collaboration, networking and inclusiveness. The SCN appears to have achieved a great deal in its seven years of operations. GYK believes that the ASCC could learn a great deal from the SCN, which has a smaller budget than the ASCC and yet faces similar challenges in a comparable commercial, academic and demographic environment.

Recommendation:

- 16) GYK recommends that the ASCC intensifies its dialogue with the Canadian Stem Cell Network, with a view to developing a formal, long-term benchmarking relationship and pursues areas of collaboration between Australian and Canadian researchers associated with the ASCC and the Canadian networks.

Future funding of the ASCC

BCE funding is scheduled to conclude in 2011. The ASCC has calculated that in order to continue to operate at its current level of expenditure beyond 2011 it will require ongoing funding of at least \$17 million per annum (according to the *ASCC 2008-09 Business Plan*). It is noted that these are preliminary estimates and that more accurate figures will be available when and if ASCC makes a formal bid for re-funding. In any case, the ASCC needs to take some hard decisions very soon concerning its plans and expenditure in the period to 2011. Contingency plans must be put in place speedily if the decision is taken that the Centre is not to be refunded under the BCE Deed.

A lengthy period of indecision about future refunding will make it far more difficult for the Board and senior management to manage the situation. GYK strongly advises that the Commonwealth makes its decision on future funding at the earliest possible time, noting that refunding decisions will most likely take place in the 2009-10 federal budget context.

There is a clause in the BCE Deed (clause 3(b)(ii)) which GYK considers is capable of being interpreted as requiring ASCC to concentrate a high proportion of its efforts on delivering commercial outcomes, to ensure that the Centre is not reliant on government funding post the BCE Deed term. This interpretation is inconsistent with the Objective and with the government's stated intent.

2008 Review of the ASCC

The ASCC has included in its business plans since 2006-07 the statement that 'Self-sustainability is not a realistic goal in the timeframe of the current ASCC funding window.' The government has accepted and approved both the ASCC 2006-07 and 2007-08 business plans containing this statement. Therefore, GYK believes it is not in contention that the Centre should be expected to achieve self-sufficiency within the BCE funding term. The ASCC has, however, been urged to become less reliant on BCE funding and its financial KPIs measure the extent to which this being achieved.

GYK considers that clause 3(b)(ii) is ambiguous. It is understood that the emphasis from government was for ASCC to expand and diversify its sources of revenue, including research grants, commercial partnerships, infrastructure grants and commercialisation revenue to reduce its dependence on BCE funding. If there is any remaining expectation that the ASCC should have achieved self-sustainability by now, or within the next three years, this notion should now be discarded.

Recommendations:

- 17) GYK recommends that a decision on funding under the BCE Deed beyond 2011 be made by Government at the earliest possible time.
- 18) GYK recommends that clause 3(b)(ii) of the BCE Deed be redrafted to accurately reflect the Objective of the ASCC and remove the possibility of ambiguity.

Final comments

A theme throughout this report (and in *The 2006 GYK Review*) relates to the unrealistic expectations at the formation of the ASCC on the part of both Government and the founders of the ASCC concerning the potential for significant commercial outcomes to be realised from stem cell research in less than ten years.

With the passage of time, it has become apparent that these early expectations were unduly optimistic and exaggerated. Lengthy timeframes will be required to convert research findings and discoveries into clinical and commercial outcomes. This is particularly the case when considering the development of new cellular therapies.

*Notes
request*

GYK understands that following the last review, the ASCC and the government revised the ASCC Objective to make the wording more consistent with reasonable outcomes, taking into account the timing of the Centre's funding arrangements. Thus the ASCC is required to undertake research and 'ultimately commercialise new therapies for human disease' which makes it clear that this may be a long term project.

Whilst the Deed sets out a clear Objective for the ASCC there is more than one model under which the Objective could be achieved. It may be timely for the ASCC to reconsider the model under which it operates. The expectation that the Centre is likely to metamorphose into a commercial entity, independent of government funding by 2011, should be abandoned. This allows for the possibility to reconsider what would be the best model for an Australian biotechnology COE in the stem cell field.

The ASCC has operated as a hybrid of a funding agency, a medical research centre, a network, a CRC and a biotechnology company, as well as playing a role in public advocacy. Whilst many organisations incorporate elements of this mix, few have successfully embraced all these functions.

The ASCC appears to be suffering from diseconomies in undertaking a multiplicity of functions. Operating in this fashion has been accompanied by very high infrastructure costs with over 50% of Centre expenditure being devoted to corporate costs and research services.

It could be argued that the ASCC has suffered other disadvantages from pursuing this hybrid approach, including a lack of clarity as to its identity and purpose amongst its research scientists, its management and its external stakeholder institutions. A different management team and approach may, however, have produced a different result. Other problems associated with the Centre are the disaffection of its stakeholders, (as it has distanced itself from them), a loss of

2008 Review of the ASCC

connectivity with and accountability to its members, a culture of secrecy and excessive process, poor relationships and interactions with the external environment and difficulty in making progress and towards meeting many of its KPIs.

GYK has proposed and described four potential operating models and endorses the further consideration of two of those models. GYK believes that both these models would satisfy the ASCC, its stakeholder members, government funding agencies as well as allowing the ASCC to meet its Deed Objective. These models could be described as 'the virtual MRI' and the 'translational research network' model.

The virtual MRI would be similar in some ways to the current ASCC, except that all the research would be performed in member stakeholder institutions within defined programs (not as individual research projects) with the creation of greater critical mass. The stakeholders would assume ownership of and operational responsibility for the laboratories and the staff. The ASCC management executive would be formed from stakeholder research leaders and technology offices. The ASCC would contract, with a much reduced infrastructure, and thus would achieve considerable efficiencies and greater returns on the research dollar spend.

Alternatively, a model such as the SCN Canada could be adopted where a small central management team draws extensively on stakeholder input for its scientific direction, provides a strong incentive for collaboration and funds only external (peer-reviewed) research based on excellence, which could take place in any Australian institution. There would be no intramural research program.

A defined focus would be needed, since clearly not all Australian stem cell research could be funded. This model could adopt the same translational focus as SCN (where there is a strong emphasis on linkages with industry and clinical researchers), thus potentially increasing the likelihood of early returns. This would fit well with the intent of government to see clinical and commercial outcomes from ASCC.

Both these models allow for greater efficiencies (reduced infrastructure) and facilitate collaborations and multi-disciplinary, multi-institution research, a major failing in the current Centre. The models should also facilitate a greater openness, esprit de corps and engagement with the member stakeholders, although this would depend on the ASCC providing competent and visionary leadership with a strong commitment to stakeholders.

In conclusion, the GYK Review and the accompanying Science Review identified achievements of the ASCC in fostering and funding stem cell research in Australia and in representing Australian stem cell science internationally. Both reviews, however, had issues with the direction of the Centre in terms of its research and business strategy and the management of the Centre. The fundamental need was identified for the ASCC to communicate more effectively with its key stakeholders and research staff, and to have a clear vision of its shared objective. The ASCC needs to adopt a much more inclusive and collaborative approach to its management of stem cell science, in order to leverage Australian capability more broadly in this vital and rapidly developing area of science that holds such promise for mankind

Editorial note: In the body of the full report, in addition to the recommendations that have been consolidated in the section above, GYK has made a series of advisory comments, which, while important, are not considered to be of the same level of priority as formal recommendations.

These advisories are in the same font as this text in indented format, similar to the recommendations as they appear in the body of the report. The recommendations are additionally highlighted in yellow to give them greater prominence.