

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549
FORM 20-F**

(Mark One)

REGISTRATION STATEMENT PURSUANT TO SECTION 12(b) OR (g) OF THE SECURITIES EXCHANGE ACT OF 1934

OR

ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended June 30, 2004

OR

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from _____ to _____
Commission file number 000-29228

PROGEN INDUSTRIES LIMITED

(Exact name of Registrant as specified in its charter)

(Translation of Registrant's Name into English)

Australia

(Jurisdiction of incorporation or organization)

2806 Ipswich Road, Darra, Queensland 4076, Australia

(Address of Principal Executive Offices)

Securities registered or to be registered pursuant to Section 12(b) of the Act.

<u>Title of each Class</u>	<u>Name of each Exchange on which Registered</u>
None	None

Securities registered or to be registered pursuant to Section 12(g) of the Act,

Ordinary Shares

(Title of Class)

Securities for which there is a reporting obligation pursuant to Section 15(d) of the Act.

None

(Title of Class)

Indicate the number of outstanding shares of each of the issuer's classes of capital or common stock as of the close of the period covered by the annual report: 34,521,065 (35,510,121 as of December 2, 2004)

Indicate by checkmark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

Yes No

Indicate by check mark which financial statement item the registrant has elected to follow.

Item 17 Item 18

(APPLICABLE ONLY TO ISSUERS INVOLVED IN BANKRUPTCY PROCEEDINGS DURING THE PAST FIVE YEARS)

Indicate by check mark whether the registrant has filed all documents and reports required to be filed by Sections 12, 13 or 15(d) of the Securities Exchange Act of 1934 subsequent to the distribution of securities under a plan confirmed by a court.

Yes No

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References in this annual report to “Progen,” “we,” “our”, “us” and “the Company” refer to Progen Industries Limited.

All references to dollars or \$ are to the currency of the United States of America; and references to Australian dollars or A\$ are to the currency of Australia.

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This annual report contains forward-looking statements that involve risks and uncertainties. Forward-looking statements relate to future events or our future financial performance and include information concerning our possible or assumed future results of operations, business strategies, financing plans, competitive position, industry environment, potential growth opportunities, the effect of future regulation and the effects of competition. These statements are based on our current expectations, beliefs and assumptions, and on information currently available to our management. In some cases, you can identify forward-looking statements by the use of words such as “anticipate,” “expect,” “intend,” “plan,” “seek,” “may,” “will,” “should,” “could,” “would,” “believe,” “estimate,” “project,” “predict,” “potential,” “continue,” or the negative of such terms or similar expressions. These forward-looking statements are only predictions and involve known and unknown risks, uncertainties and other factors which may cause our actual results, levels of activities, performance and other factors to be materially different from those anticipated in such forward-looking statements. Factors that might cause such differences include the risks discussed in “Item 3. Key Information – Risk Factors,” “Item 4. Information on the Company” and “Item 5. Operating and Financial Review and Prospects,” as well as those discussed elsewhere in this annual report.

We caution you not to place undue reliance on these forward-looking statements, which reflect our management’s view only as of the date of this annual report. We will not update any forward-looking statement to reflect events or circumstances after the date hereof or to reflect the occurrence of unanticipated events.

PART I

ITEM 1. IDENTITY OF DIRECTORS, SENIOR MANAGEMENT AND ADVISERS

Not applicable.

ITEM 2. OFFER STATISTICS AND EXPECTED TIMETABLE

Not applicable.

ITEM 3. KEY INFORMATION

Item 3.A Selected Financial Data

The following selected financial data for the five years ended June 30, 2004 should be read in conjunction with “Item 5. Operating and Financial Review and Prospects” below and our financial statements and related notes contained elsewhere in this annual report. The balance sheet information as at June 30, 2003 and 2004 and the statement of operations data for fiscal 2002, 2003 and 2004 are derived from our audited financial statements included in this annual report. Balance sheet information as of June 30, 2000, 2001 and 2002 and statement of operations information for fiscal 2000 and 2001 are derived from our audited financial statements which are not included in this annual report.

	For the Years Ended June 30,				
	2000	2001	2002	2003	2004
Statement of Operations Data:					
Revenue From Operations	\$ 173,661	\$ 198,331	\$704,044	\$1,051,695	\$1,394,589
Cost of Operations:					
Research and development	2,757,628	2,374,319	2,185,066	2,435,896	3,183,278
Selling, general and administrative costs	869,266	862,031	1,214,771	1,958,355	2,494,570
Total Cost of Operations	<u>4,241,123</u>	<u>3,757,915</u>	<u>4,104,544</u>	<u>5,018,983</u>	<u>6,299,231</u>
Gross Loss	(4,067,462)	(3,716,051)	(3,601,294)	(4,391,353)	(5,277,908)
Total Other Income (Expenses)	<u>(206,050)</u>	<u>402,528</u>	<u>417,658</u>	<u>537,991</u>	<u>1,078,787</u>
Net Loss from continuing operations	\$(4,273,512)	\$(3,313,523)	\$(3,183,636)	\$(3,853,362)	\$(4,199,121)
Discontinued operations	<u>(206,621)</u>	<u>41,341</u>	<u>104,421</u>	<u>288,213</u>	<u>654,666</u>
Net Loss	<u>(\$4,480,133)</u>	<u>(\$3,272,182)</u>	<u>(\$3,079,215)</u>	<u>(\$3,565,149)</u>	<u>(\$3,544,455)</u>
Profit/(Loss) Per Ordinary Share					
Continuing operations	<u>\$(0.22)</u>	<u>\$(0.14)</u>	<u>\$(0.13)</u>	<u>\$(0.16)</u>	<u>\$(0.13)</u>
Discontinued operations	<u>\$(0.01)</u>	<u>-</u>	<u>-</u>	<u>\$0.01</u>	<u>\$0.02</u>
Net loss per ordinary share	<u>\$(0.23)</u>	<u>\$(0.14)</u>	<u>\$(0.13)</u>	<u>\$(0.15)</u>	<u>\$(0.11)</u>
Weighted Average Number of Ordinary Shares Outstanding	19,729,300	23,404,883	24,391,869	24,391,869	32,675,867

For the Years Ended June 30,

	2000	2001	2002	2003	2004
Balance Sheet Data:					
Cash and Cash Equivalents	\$ 6,529,982	\$ 8,391,775	\$6,430,377	\$8,001,842	\$9,885,656
Working Capital	6,277,381	9,517,072	7,174,683	7,332,942	9,039,396
Total Assets	10,440,838	11,649,736	9,865,368	10,230,017	11,208,140
Long-Term Debt	-0-	-0-	-0-	-0-	-0-
Capital Stock	35,737,563	41,800,156	41,800,156	44,153,011	48,869,981
Accumulated Deficit	(25,499,114)	(28,771,296)	(31,850,511)	(35,415,660)	(38,960,115)
Total Stockholders' Equity	\$ 9,468,280	\$10,823,825	\$8,523,149	\$8,504,942	\$9,934,555

Item 3.D. Risk Factors

The risks and uncertainties described below are not the only ones that we face. Additional risks and uncertainties not presently known to us or that we currently believe to be immaterial may also adversely affect our business. If any of the following risks and uncertainties develop into actual events, our business, financial condition and results of operations could be materially and adversely affected, and the trading price of our ordinary shares could decline.

We are at an early stage in the development of pharmaceutical products and our success is uncertain

We are at an early stage in the development of our pharmaceutical products. Although we are presently generating revenues from the sale of contract manufacturing services, we have not sufficiently advanced the development of our lead product candidates, PI-88 and PI-166 to enable their registration, and, accordingly, have not begun to market or generate revenues from their commercialization. PI-88, PI-166 and future pharmaceutical product candidates will require significant additional investment in research and development, preclinical testing and clinical trials, drug manufacture and supply, regulatory and sales and marketing activities, and regulatory approval prior to any commercial sales. We cannot make any assurances that PI-88, PI-166 or any other product candidates, if successfully developed, will generate sufficient or sustainable revenues to enable us to be profitable.

There is a significant risk that we may not be able to complete the development of PI-88 or PI-166, or develop other pharmaceutical products

We cannot make any assurances that we will be able to develop PI-88, PI-166 or any future pharmaceutical product candidates adequately to attract a suitable collaborative partner, or that our research will lead to the discovery of additional product candidates, or that any of our current and future product candidates will be successfully developed, prove to be safe and efficacious in clinical

trials, meet applicable regulatory standards and receive regulatory approval, be capable of being produced in commercial quantities at reasonable costs, or be successfully or profitably marketed, either by us or a collaborative partner. We also cannot make any assurances that the products we develop will be able to penetrate the potential market for a particular therapy or indication or gain market acceptance among health care providers, patients and third-party payors. We cannot predict if or when PI-88, PI-166, or any of our other pharmaceutical products under development will be commercialized.

The results of clinical trials of PI-88 and PI-166 are uncertain and we will not be able to commercialize PI-88, PI-166 or any of our other product candidates if we fail to adequately demonstrate their safety, efficacy and superiority over existing therapies

Before obtaining regulatory approvals for the commercial sale of any of our pharmaceutical products, we must demonstrate through preclinical testing and clinical studies that our product candidates are safe and effective for use in humans for each target indication. Conducting preclinical testing and clinical studies is an expensive, protracted and time-consuming process. Furthermore, the results of preclinical *in vitro* (within an artificial environment) and animal studies may not necessarily be predictive of results obtained in human clinical testing. Likewise, results from early clinical trials may not be predictive of results obtained in large-scale, later-stage clinical testing. In addition, even though a potential drug product shows promising results in clinical trials, regulatory authorities may not grant the necessary approvals without sufficient safety and efficacy data.

We are currently conducting three Phase II clinical trials of PI-88 in cancer patients in the United States, Taiwan and Australia and have planned further trials. We also are conducting a Phase I clinical trial of PI-166 in Australia and, depending on the results of this trial, may conduct additional clinical trials. We plan to enter into collaborative arrangements with a suitable pharmaceutical or biotechnology company to commercialize PI-88 and PI-166. We cannot make any assurances that we will be able either to complete the current clinical trials of PI-88 and PI-166 successfully, commence additional clinical trials of PI-88 or PI-166 as anticipated, or at all, or to demonstrate the safety and efficacy or superiority of PI-88 or PI-166 over existing therapies or enter into any collaborative arrangement to commercialize PI-88 and PI-166 on terms acceptable to us, or at all. Clinical trial results that show insufficient safety and efficacy could have a material adverse effect on our business, financial condition and results of operations.

Clinical trials may take up to several years to complete. The length of time varies substantially according to the type, complexity, novelty, patient recruitment into and intended use of the product candidate. We cannot make any assurances that, when Phase II clinical trials are completed, we will be able to enter into a collaborative arrangement with a suitable pharmaceutical or biotechnology company to complete the development of, or commercialize PI-88 or PI-166. Nor can we make any assurances that once clinical trials are completed by us or a collaborative partner, we will be able to submit as scheduled a marketing approval request to the Australian Therapeutic Goods Administration's (TGA) Drug Safety and Evaluation Branch, the U.S. Food and Drug Administration (FDA) or any other authority, or, that such request and application will be reviewed and cleared by any of these authorities, as applicable, in a timely manner, or at all.

During the course of clinical trials and toxicology studies, PI-88, PI-166 and our other product candidates may exhibit unforeseen and unacceptable drug-related toxicities or side effects. If

any unacceptable toxicities or side effects were to occur, we may, or regulatory authorities may require us to, interrupt, limit, delay or abort the development of our potential products. In addition, unacceptable toxicities could ultimately prevent the clearance of our product candidates by the TGA or the FDA for any or all targeted indications. Even after being cleared by the TGA or the FDA, any of our products may later be shown to be unsafe or not to have its purported effect, thereby preventing widespread use or requiring withdrawal from the market. We cannot make any assurances that PI-88, PI-166 or any of our other product candidates will be safe or effective when administered to patients.

We may experience delays in our clinical trials that could adversely affect our business and operations

We do not know whether planned clinical trials will begin on time or whether we will complete any of our clinical trials on schedule or at all. Our ability to commence and complete clinical trials may be delayed by many factors, including:

- Government or regulatory delays, including delays in obtaining approvals from applicable hospital ethics committees and internal review boards;
- Slower than expected patient recruitment;
- Our inability to manufacture or prepare, as applicable, sufficient quantities of PI-88, PI-166 or any of our other product candidates;
- Unforeseen safety issues; and
- Lack of efficacy during the clinical trials.

Patient enrollment is a function of, amongst other things, the nature of the clinical trial protocol, the existence of competing protocols, the size and longevity of the target patient population, and the availability of patients who comply with the eligibility criteria for the clinical trial. Delays in planned patient enrollment may result in increased costs, delays or termination of clinical trials. Moreover, we have limited experience in conducting and managing clinical trials and rely on third parties to assist us in managing and monitoring clinical trials. Any failure by these third parties to perform under their agreements with us may cause the trials to be delayed or result in a failure to complete the trials.

Product development costs to our collaborators and us will increase if we have delays in testing or approvals or if we need to perform more or larger clinical trials than planned. Significant delays could have a material adverse effect on the commercial prospects of our product candidates and our business, financial condition and results of operations.

We have limited manufacturing experience, and delays in manufacturing sufficient quantities of PI-88 and PI-166 for preclinical and clinical trials may negatively impact our business and operations

We believe that we have the capability to manufacture PI-88 and prepare PI-166 for preclinical studies and early stage (Phase I and Phase II) clinical trials. We cannot, however, make any assurances that we will be able to manufacture or prepare, as applicable, sufficient quantities of PI-88, PI-166 or any of our other product candidates in a cost-effective or timely manner. Any delays in production would delay our preclinical and clinical trials which could have a material adverse effect on our business, financial condition and results of operations.

We may be required to enter into contracting arrangements with third parties to manufacture or prepare, as applicable, PI-88, PI-166 and our other product candidates for large-scale, later-stage clinical trials. We cannot make any assurances that we will be able to make the transition to commercial production. We may need to develop additional manufacturing resources, enter into collaborative arrangements with other parties who have established manufacturing capabilities, or have third parties manufacture or prepare our products on a contract basis. We cannot make any assurances that we will have access on acceptable terms to the necessary and substantial financing that would be required to scale-up production and develop effective commercial manufacturing processes and technologies. We also cannot make any assurances that we will be able to enter into collaborative or contracting arrangements on acceptable terms with parties that will meet our requirements for quality, quantity and timeliness.

If we are unable to establish or manage strategic collaborations to develop PI-88, PI-166 or any of our other product candidates, we may have to reduce or delay product development and/or increase our expenditures

Our strategy for developing and commercializing our product candidates includes entering into various relationships with pharmaceutical or biotechnology companies to provide us with funding and/or to perform research, clinical development, regulatory clearance, commercial scale manufacturing, sales, marketing or distribution activities relating to PI-88, PI-166 or some or all of our current or future product candidates. To date, we have not entered into any agreements with third parties capable of providing those services. Establishing strategic collaborations is difficult and time-consuming. Our discussions with potential collaborators may not lead to the establishment of collaborations on favorable terms, if at all. If we are unable to establish collaborative arrangements, we may have to reduce or delay further development of PI-88, PI-166 and our other product candidates and/or increase our expenditures and undertake the development and commercialization activities at our own expense. If we elect to fund our research and development programs on our own, we will need to obtain additional financing which may not be available on acceptable terms, or at all.

If we successfully establish strategic collaborations, the management of our relationship with collaborators will require significant time and effort from our management team, coordination of our research and development programs with the research and development priorities of our collaborators, and effective allocation of our resources to multiple projects. We cannot be certain that these relationships will result in the successful development or commercialization of our product candidates or the generation of sales revenue. If we enter into strategic collaborations at an

early phase of product development, our success will in part depend on the performance of our corporate collaborators. Factors that could harm a successful collaboration include:

- Collaborators may delay clinical trials, underfund a clinical trial program, stop a clinical trial or abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing;
- Collaborators could independently develop, or develop with third parties, products that could compete with our current and future product candidates;
- Collaborators may not commit enough resources to the marketing and distribution of our product candidates, limiting potential revenues from the commercialization of a product;
- Collaborators may not pursue further development and commercialization of compounds resulting from collaborations or may elect not to continue or renew research and development programs;
- The terms of our agreements with collaborators may not be favorable to us;
- Disputes may arise delaying or terminating the research, development or commercialization of our product candidates, resulting in significant litigation or arbitration, or causing collaborators to act in their own self-interest and not in the interest of our shareholders; and
- Collaborators may terminate their agreements with us if, for example, we fail to meet a required milestone or observe other obligations in those agreements.

Our efforts to discover, develop and commercialize new product candidates from our proprietary glycobiology technology platform beyond PI-88 are in a very early stage and, therefore, these efforts are subject to a high risk of failure

The process of successfully developing product candidates is very time consuming, expensive and unpredictable. Although we have recently begun to direct significant effort toward the expansion of our scientific staff and research capabilities to identify and develop product candidates in addition to PI-88, we may not identify, develop or commercialize any additional new product candidates from our proprietary glycobiology technology platform or other technologies.

If we cannot enter into new licensing arrangements, our ability to develop a broad product portfolio could be limited

A component of our business strategy is in-licensing drug compounds developed by other commercial or academic entities. Competition for promising compounds is intense. If we are not able to identify additional licensing opportunities or enter into licensing arrangements on acceptable terms, if at all, we will be unable to develop a diverse portfolio of product candidates.

We require substantial additional financing in the future to sufficiently fund our operations and research

We have been unprofitable to date and expect to incur losses over the next several years as we expand our drug discovery and development programs and preclinical testing and as we conduct clinical trials of PI-88, PI-166 and our other product candidates. Although our future capital requirements will depend on many factors, we believe that our existing cash and investments resources will be adequate to satisfy the requirements of our current and planned operations through to March 2006. We cannot, however, make any assurances that such funds will be sufficient to meet our actual operating expenses and capital requirements during such period. Our actual cash requirements may vary materially from those now planned and will depend upon numerous factors, including:

- The continued progress of our research and development programs;
- The timing, scope, results and costs of preclinical studies and clinical trials;
- The progress of licensing efforts
- The cost, timing and outcome of regulatory submissions and approvals;
- Determinations as to the commercial potential of our product candidates;
- Our ability to successfully expand our contract manufacturing services;
- Our ability to establish and maintain collaborative arrangements;
- The status and timing of competitive developments; and
- Other factors.

Notwithstanding that revenues may be produced from contract manufacturing operations, we anticipate that we will require substantial additional funds in order to achieve our long-term goals and complete the research and development of our pharmaceutical product candidates. In addition, we will require additional funds to pursue regulatory clearances, prosecute and defend our intellectual property rights, establish commercial scale manufacturing facilities, develop marketing and sales capabilities and fund operating expenses. We have no established bank financing arrangements, and we cannot be certain that we will be able to establish such arrangements on satisfactory terms, or at all. We intend to seek such additional funding through public or private financings and/or through strategic alliances or other arrangements with corporate partners. We cannot, however, be certain that such additional financing will be available from any sources on acceptable terms, or at all, or that we will be able to establish strategic alliances or other arrangements with corporate partners on acceptable terms, or at all. Any shortfall in funding could result in our having to curtail our operations, including our research and development activities, which could have a material adverse effect on our business, financial condition and results of operations.

We have a history of operating losses and may not achieve profitability in the near future

We have incurred net operating losses in each year since we began operations in 1989. As of June 30, 2004, we had an accumulated deficit of approximately \$39.0 million, primarily attributable

to our research and development activities. We expect to incur additional operating losses over at least the next several years and to increase our cumulative losses substantially as we expand our research and development and preclinical activities and commence additional clinical trials of PI-88 and PI-166.

Our success depends upon our ability to protect our intellectual property and our proprietary technology

Our success will depend in large part on whether we can:

- Obtain and maintain patents to protect our own products;
- Obtain licenses to the patented technologies of third parties;
- Operate without infringing on the proprietary rights of third parties; and
- Protect our trade secrets and know-how.

Patent matters in biotechnology are highly uncertain and involve complex legal and factual questions. Accordingly, the availability and breadth of claims allowed in biotechnology and pharmaceutical patents cannot be predicted. Statutory differences in patentable subject matter may limit the protection we can obtain on some or all of our inventions outside Australia or prevent us from obtaining patent protection outside Australia, either of which could have a material adverse effect on our business, financial condition and results of operations. For example, methods of treating humans are not patentable in many countries outside Australia and the United States. Moreover, since patent applications in Australia and the United States are maintained in secrecy until the patent is issued, and since publication of discoveries in the scientific or patent literature often lags behind actual discoveries, we cannot be certain that we or any of our licensors were the first creator of inventions covered by pending patent applications or that we or our licensors were the first to file patent applications for such inventions. Additionally, the enforceability of a patent is dependent on a number of factors that may vary between jurisdictions. These factors may include the novelty of the invention, the requirement that the invention not be obvious in the light of prior art (including prior use or publication of the invention), the utility of the invention, and the extent to which the patent clearly describes the best method of working the invention.

While we intend to seek patent protection for our therapeutic products and technologies, we cannot be certain that any of the pending or future patent applications filed by us or on our behalf will be approved, or that we will develop additional proprietary products or processes that are patentable or that we will be able to license any other patentable products or processes. We also cannot be certain that others will not independently develop similar products or processes, duplicate any of the products or processes developed or being developed by us or licensed to us, or design around the patents owned or licensed by us, or that any patents owned or licensed by us will provide us with competitive advantages. Furthermore, we cannot be certain that patents held by third parties will not prevent the commercialization of products incorporating the technology developed by us or licensed to us, or that third parties will not challenge or seek to narrow, invalidate or circumvent any of the issued, pending or future patents owned or licensed by us.

Our commercial success will also depend, in part, on our ability to avoid infringement of patents issued to others. If a court determines that we were infringing any third party patents, we could be required to pay damages, alter our products or processes, obtain licenses or cease certain activities. We cannot be certain that the licenses required under patents held by third parties would be made available on terms acceptable to us or at all. To the extent that we are unable to obtain such licenses, we could be foreclosed from the development, manufacture or commercialization of the product requiring such license or encounter delays in product introductions while we attempt to design around such patents, and any of these circumstances could have a material adverse effect on our business, financial condition and results of operations.

We may have to resort to litigation to enforce any patents issued or licensed to us or to determine the scope and validity of third party proprietary rights. Such litigation could result in substantial costs and diversion of effort by us. We may have to participate in opposition proceedings before the Australian Patent and Trademark Office or another foreign patent office, or in interference proceedings declared by the United States Patent and Trademark Office, to determine the priority of invention for patent applications filed by competitors. Any such litigation, interference or opposition proceeding, regardless of outcome, could be expensive and time consuming, and adverse determinations in any such proceedings could prevent us from developing, manufacturing or commercializing our products and could have a material adverse effect on our business, financial condition and results of operations.

In addition to patent protection, we rely on unpatented trade secrets and know-how and proprietary technological innovation and expertise that are protected in part by confidentiality and invention assignment agreements with our employees, advisors and consultants. We cannot make any assurances that we will have adequate remedies for any breach. In addition, third parties could independently develop the same or similar technologies.

We may not be able to obtain the extensive government approvals required to bring our pharmaceutical products to market

Our ongoing research and development activities are, and the production and marketing of our pharmaceutical product candidates derived there from will be, subject to regulation by numerous governmental authorities in Australia, principally the TGA, and by the FDA in the United States, the Medicines & Healthcare Products Regulatory Agency in the United Kingdom and the European Medicines Evaluation Authority. Prior to marketing, any therapeutic product developed must undergo rigorous preclinical testing and clinical trials, as well as an extensive regulatory approval process mandated by the TGA and, to the extent that any of our pharmaceutical products under development are marketed abroad, by foreign regulatory agencies including the FDA in the United States and the Medicines Control Agency in the United Kingdom. These processes can take many years and require the expenditure of substantial resources. Delays in obtaining regulatory approvals could adversely affect the development and commercialization of our pharmaceutical product candidates and could have a material adverse impact on our business, financial condition and results of operations. Although we intend to make use of fast-track and abbreviated regulatory approval programs when possible, we cannot be certain that we will be able to obtain the clearances and approvals necessary for clinical testing or for manufacturing and marketing our pharmaceutical products candidates.

Our research and development efforts will be seriously jeopardized if we are unable to attract and retain key personnel and cultivate key academic and scientific collaborations

We are a small company with only 40 full-time employees. Our success is highly dependent on the continued contributions of our principal management and scientific personnel and on our ability to develop and maintain important relationships with leading academic institutions and scientists. Competition among biotechnology and pharmaceutical companies for qualified employees is intense, and we cannot be certain that we will be able to continue to attract and retain qualified scientific and management personnel critical to our success. We also have relationships with leading academic and scientific collaborators who conduct research at our request or assist us in formulating our research and development strategies. These academic and scientific collaborators are not our employees and may have commitments to, or consulting or advisory contracts with, other entities that may limit their availability to us. In addition, these collaborators may have arrangements with other companies to assist such companies in developing technologies that may prove competitive to ours.

We may not be able to keep pace with technological change or with the advances of our competitors

The biotechnology and pharmaceutical industries are subject to rapid and significant technological change. Our competitors in Australia and elsewhere are numerous and include, among others, major pharmaceutical companies, biotechnology firms, universities and other research institutions. These competitors may develop technologies and products that are more effective than any that we are developing, or which would render our technology and products obsolete or non-competitive. Many of these competitors have greater financial and technical resources and manufacturing and marketing capabilities than we do. In addition, many of our competitors have much more experience than we do in preclinical testing and human clinical trials of new or improved drugs, as well as in obtaining FDA, TGA and other regulatory approvals.

We know that competitors are developing or manufacturing various technologies or products for the treatment of diseases that we have targeted for product development. Some of these competitive products use therapeutic approaches that compete directly with some of our product candidates. Our ability to further develop our products may be adversely affected if any of our competitors were to succeed in obtaining regulatory approval for their competitive products sooner than us.

Acceptance of our products in the marketplace is uncertain, and failure to achieve market acceptance will negatively impact our business and operations

We cannot make any assurances that our products will achieve market acceptance even if they are approved by the TGA and the FDA. The degree of market acceptance of our products will depend on a number of factors, including:

- The receipt and timing of regulatory approvals for the uses that we are studying;

- The establishment and demonstration in the medical community of the safety, clinical efficacy and cost-effectiveness of our product candidates and their potential advantages over existing therapeutics and technologies; and
- The pricing and reimbursement policies of governments and third-party payors.

Physicians, patients, payors or the medical community in general may be unwilling to accept, use or recommend any of our products.

We may need to establish our sales, marketing and distribution capability

We currently have no experience in marketing, sales or distribution of pharmaceutical products. If we develop any commercially marketable pharmaceutical products and decide to perform our own sales and marketing activities, we will require additional management, will need to hire sales and marketing personnel, and will require additional capital. We cannot make any assurances that qualified personnel will be available in adequate numbers or at a reasonable cost, that additional financing will be available on acceptable terms, or at all, or that our sales staff will achieve success in their marketing efforts. Alternatively, we may be required to enter into marketing arrangements with other parties who have established appropriate marketing, sales and distribution capabilities. We cannot make any assurances that we will be able to enter into marketing arrangements with any marketing partner or that if such arrangements are established, our marketing partners will be able to commercialize our products successfully. Other companies offering similar or substitute products may have well-established and well-funded marketing and sales operation in place that will allow them to market their products more successfully. Failure to establish sufficient marketing capabilities may have a material adverse impact on our business, financial condition and results of operations.

Healthcare insurers and other organizations may not pay for our products, or may impose limits on reimbursement

The drugs we hope to develop may be rejected by the marketplace due to many factors, including cost. The continuing efforts of governments, insurance companies, health maintenance organizations and other payors of healthcare costs to contain or reduce healthcare costs may affect our future revenues and profitability and those of our potential customers, suppliers and collaborative partners, as well as the availability of capital. In Australia and certain foreign markets, the pricing or profitability of prescription pharmaceuticals is already subject to government control. We expect initiatives for similar government control at both the state and federal level to continue in the United States. The adoption of any such legislative or regulatory proposals could have a material adverse effect on our business, financial condition and results of operations.

Our ability to commercially exploit our products successfully will depend in part on the extent to which reimbursement for the cost of our products and related treatment will be available from government health administration authorities, private health coverage insurers and other organizations. Third-party payors, such as government and private health insurers, are increasingly challenging the price of medical products and services. Although the Australian government continues to provide a subsidy to certain prescribed prescription pharmaceutical products through the Pharmaceutical Benefits Scheme, which, pending development, could include PI-88 and PI-166,

uncertainty exists as to the reimbursement status of newly approved health care products and in foreign markets, including the United States. If third-party coverage is not available to patients for any of the products we develop, alone or with collaborators, the market acceptance of these products may be reduced which may adversely affect our future revenues and profitability. In addition, cost containment legislation and reductions in government insurance programs may result in lower prices for our products and could materially adversely affect our ability to operate profitably.

Our business and operations may be negatively impacted if we fail to comply with government regulations applicable to our current revenue generating business

We import biological products into Australia under existing permits from the Australian Quarantine and Inspection Service that require us to declare incoming biological materials and to ensure that such products contain labels as to their use and disposal under approved methods. Any potential violation of Australian import laws or modification or revocation of our permits could be significant and may negatively impact our business and operations. Our contract manufacturing operations include some manufacturing processes that are required to comply with the applicable cGMP requirements of the TGA, the Australian Office of Gene Technology Regulator and the Australian National Registration Authority (agricultural and veterinary chemicals), which govern the methods, controls, facilities and quality assurance procedures used in manufacturing, packing and storing biological and pharmaceutical products. In addition, certain international markets have quality assurance and manufacturing requirements that may be more or less rigorous than those in Australia. Our manufacturing facilities are also subject to biennial inspections by the TGA and the Australian National Registration Authority. Any potential failure to comply with cGMP requirements or with any other international requirements could have a material adverse impact on our business, financial condition and results of operations.

We may have product liability exposure

The importation of biological products entails the risk of product and manufacturer's liability under present Australian law. We currently have limited product and manufacturer's liability insurance coverage related to our current sales activities. We cannot be certain that this coverage will be adequate to protect us in the event of a successful product or manufacturer's liability claim or that the insurance will continue to be available on commercially reasonable terms.

The testing, marketing and sale of human health care products also entails an inherent risk of product liability. We may incur substantial liabilities or be required to limit development or commercialization of our products if we cannot successfully defend ourselves against product liability claims. In addition, product liability claims or product recalls, regardless of the ultimate outcome, could require us to spend significant time and money in litigation and to pay significant damages. We cannot be certain that our current limited product liability coverage will adequately protect us in the event of a successful product liability claim or that such insurance will continue to be available on commercially reasonable terms.

We may be liable for damages for any accidental contamination or injury from our use of biological and hazardous materials or our failure to comply with applicable laws and regulations

Our research and development activities and manufacturing processes involve the use or sale of potentially harmful biological materials and hazardous substances. As a result, we are subject to federal, state and local laws and regulations in Australia governing the use, manufacture, storage, handling and disposal of potentially harmful biological materials and hazardous substances and certain waste products. We are also subject to applicable Australian environmental laws and regulations. Although we believe that our safety procedures for handling and disposing of such materials comply in all material respects with the standards prescribed by applicable laws and regulations, we cannot completely eliminate the risk of accidental contamination or injury from these materials. In the event of such an accident, we could be held liable for any resulting damages and any such liability could exceed our resources. We also believe that we are in compliance in all material respects with applicable environmental laws and regulations. However, any potential violation of these and other applicable laws and regulations could be significant and may negatively impact our business and operations.

Changes in government legislation and policy may adversely affect us

While we do not anticipate in the near future any specific material changes in government legislation that may adversely affect us, any material changes in interest rate, exchange rate, relevant taxation and other legal regimes and government policies may adversely affect us and the market price of our ordinary shares.

Exchange rate fluctuations will continue to affect our reported results of operations

Substantially all of our revenues are realized, and substantially all of our operating costs are incurred, in Australian dollars. Because our financial statements included elsewhere in this annual report are presented in U.S. dollars, any significant fluctuation in the currency exchange rates between the Australian dollar and the U.S. dollar will affect our reported results of operations.

Our stock price may be volatile and the U.S. trading market for our ordinary shares is limited

The market price for our ordinary shares, like that of the securities of other pharmaceutical and biotechnology companies, has fluctuated substantially and may continue to be highly volatile in the future. We believe that the following factors, in addition to other risk factors described above and elsewhere in this annual report, will continue to significantly affect the market price of our ordinary shares:

- The results of preclinical testing and clinical trials by us and our competitors;
- Developments concerning research and development, manufacturing, and marketing alliances or collaborations by us and our competitors;
- Announcements of technological innovations or new commercial products by us and our competitors;

- Determinations regarding our patent applications and those of others;
- Publicity regarding actual or potential results relating to medicinal products under development by us and our competitors;
- Proposed governmental regulations and developments in Australia, the U.S. and elsewhere;
- Litigation;
- Economic and other external factors; and
- Period-to-period fluctuations in our operating results.

In addition, stock markets have experienced extreme price and volume fluctuations. These fluctuations have especially affected the stock market price of many high technology and healthcare-related companies, including pharmaceutical and biotechnology companies, and, in many cases, are unrelated to the operating performance of the particular companies. We believe that these broad market fluctuations may continue to negatively affect the market price of our ordinary shares.

From time to time, there has been limited trading volume with respect to our ordinary shares quoted on the Nasdaq SmallCap Market, but we cannot make any assurances that there will continue to be a trading market in our ordinary shares.

ITEM 4. INFORMATION ON THE COMPANY

Item 4.A. History and Development of the Company

We were incorporated in September 1989 as Almagest Pty. Ltd. in the State of Queensland, Australia, and changed our name to Progen Industries Pty. Ltd. in April 1990. In 1991, we converted to a public limited liability company under the name Progen Industries Limited and introduced our first life sciences products to the Australian market for use in DNA recombinant research.

Since October 1993, we have been engaged in the research and development of small molecule pharmaceuticals, including heparanase inhibitors, that are potent and selective inhibitors of carbohydrate-protein interactions implicated in a range of disease states. Our research and development activities are conducted in collaboration with private industry and academic and research institutions in Australia, the United States and elsewhere.

As part of our focused strategy towards drug discovery and development, we sold our Life Sciences division in November 2003 and intend to pursue selective strategic alliances to complete product development and move our product candidates into the market place.

We have incurred significant losses since our inception and as of June 30, 2004, our accumulated deficit was approximately \$39.0 million. We expect to incur additional operating losses for at least the next several years as we accelerate our drug discovery research, expand our development and preclinical activities, conduct additional clinical trials with PI-88 and PI-166, and advance into later stages of development. We may need to raise additional funds in the future to continue our operations.

To date, we have funded our operations primarily through sales of equity and debt securities, including an Australian initial public offering in 1995 for approximately A\$7.7 million (\$5.7 million) in net proceeds, and an Australian and overseas institutional placement underwritten by UBS Warburg in March 2000 for approximately A\$10.6 million (\$6.7 million) in net proceeds. In November 2000, we raised A\$10.5 million (\$5.5 million) by the issue of 2.75 million ordinary shares to Medigen Biotechnology Corporation, our collaborative partner for PI-88 clinical trials. In June 2003, we raised approximately A\$3.5 million (\$2.35 million) in net proceeds under an Australian and New Zealand share purchase plan and Australian placement, and in November 2003, we raised approximately A\$5.3 million (\$3.8 million) in net proceeds under an Australian placement to institutional and sophisticated investors. As of December 2, 2004, we have raised approximately A\$1.29 million (\$0.92 million) in net proceeds through the exercise of bonus options granted to our shareholders on a one for eight pro rata basis in November 2003.

Corporate Information

Our principal executive offices are located at 2806 Ipswich Road, Darra, Queensland 4076, Australia. Our web site is located at www.progen.com.au. Information contained on our web site is not incorporated by reference into and does not form a part of this annual report.

Progen is a registered trademark of Progen Industries Limited. Trademarks, tradenames or service marks of other companies appearing in this annual report are the property of their respective

owners.

Item 4.B. Business Overview

Progen Industries Limited is an Australian-based, globally-focused biotechnology company committed to the discovery, development and commercialization of small molecule therapeutics for the treatment of cancer and other serious diseases. Our lead product candidate, PI-88, is one of a new class of multi-functional, multi-targeted cancer therapeutics inhibiting both angiogenesis, or tumor promoting factors such as Vascular Endothelial Growth Factor, Fibroblast Growth Factor 1, Fibroblast Growth Factor 2, and also heparanase, an enzyme implicated in metastasis (tumor spread). PI-88 completed two Phase I trials in January and February 2004 and is currently being studied in three Phase II clinical trials in the U.S., Australia and Taiwan under an active Investigational New Drug application, or IND, with the United States Food and Drug Administration, or FDA. In May 2004, PI-88 was designated an orphan drug by the FDA for the treatment of high risk Stage II, Stage III and Stage IV melanoma.

Preliminary results of the Phase I solid tumor trial, as well as results of the completed multi-center Australian Phase II clinical trial of PI-88 in patients with multiple myeloma (bone marrow cancer) have shown:

- Disease control in 15 out of 38 (39%) evaluable patients in the Phase I advanced solid tumor monotherapy study (includes one partial response and 14 disease stabilizations for periods greater than three months up to 38 months);
- 42% of melanoma patients in the Phase I advanced solid tumor monotherapy study showed disease control (includes one partial response and seven disease stabilizations for periods greater than three months);
- Disease stabilization in seven out of 18 patients (39%) with refractory or relapsed multiple myeloma treated with PI-88, in a Phase II study, with one patient still receiving PI-88 after 32 months; and
- PI-88 has an acceptable safety and tolerability profile in clinical trials to date.

Our second oncology product candidate, PI-166, is undergoing a Phase I clinical trial in patients with inoperable primary liver cancer (hepatocellular carcinoma or HCC). PI-166 is a potential novel treatment modality that serves a patient population, which is particularly difficult to treat and whom are suffering from a disease that is resistant to current therapies.

Through our internal drug discovery research program and academic collaborations, we are developing small molecule drug candidates that modulate the interaction between carbohydrates (sugars) and disease-related protein targets as potential therapeutics for cancer and other serious diseases. Our research team and academic collaborators have identified a portfolio of heparan sulfate binding proteins that are involved in different diseases, and we are now designing, synthesizing and screening small molecule compounds that disrupt heparan sulfate binding.

We also provide contract manufacturing and bioprocess technology development services to the Australian Code of Good Manufacturing Practice, or cGMP, standards through our Commercial Services division. This division serves Australian and U.S.-based clients and has shown revenue growth over each of the past four years.

Our Business Strategy

We intend to develop and commercialize therapeutics for cancer and other serious diseases. To achieve this objective, we are concentrating on the following key initiatives:

- *Leveraging in-house expertise and capabilities in Product Development.* We believe that our core scientific and management team has significant and demonstrated expertise in drug discovery and in selecting and advancing promising product candidates into early stage human clinical trials to demonstrate proof of efficacy. We intend, as necessitated by our existing and in-licensed programs, to expand our in-house capabilities in molecular modeling, biochemistry, cell biology, crystallography, medicinal and synthetic chemistry, pharmacology and clinical trial management.
- *Discovering and developing novel small molecule therapeutics using our proprietary drug discovery technology platform.* We will continue to focus our drug discovery research programs on the discovery and development of small molecule therapeutics for cancer and other serious diseases, that will feed our product candidate pipeline and leverage our drug development infrastructure over time.
- *Expanding our product candidate pipeline through in-licensing.* In addition to our internal drug development efforts, we intend to selectively in-license lead compounds and new therapies for cancer and other serious diseases at early stages of development and other new therapies for cancer and other serious diseases and undertake early stage clinical development.
- *Establishing strategic collaborations for the development and commercialization of our product candidates.* We intend to complement our internal capabilities by selectively entering into collaborations with pharmaceutical and biotechnology companies to complete product development and move our product candidates into the marketplace as well as to improve our ability to move new compounds into the clinic.
- *Leveraging our in-house manufacturing capabilities to support the development and commercialization of our product candidates.* We manufacture PI-88 and PI-166 for preclinical and clinical trials at our manufacturing facility. We intend to leverage our experience in bioprocess manufacturing technologies to support the development and commercialization of our present and future product candidates.
- *Establishing and maintaining a strong intellectual property portfolio.* We plan to continue to aggressively pursue patent protection in Australia, the United States and other significant markets, as well as protect trade secrets and know-how, as our drug

discovery technologies uncover additional small molecule product candidates or as necessitated by our in-licensed development programs.

Development Programs

Cancer Therapeutics

PI-88 - Novel Angiogenesis and Heparanase Inhibitor

PI-88 is our most advanced compound within our oncology pipeline. Our principal objective is to commercialize PI-88 as a cytostatic anti-cancer therapy applicable to a broad range of cancer types. All PI-88 clinical trials to date are being conducted under an active Investigational New Drug application, or IND, with the United States Food and Drug Administration, or FDA. Specifically, the Phase II trial program has been purposely designed to;

- Evaluate the efficacy and safety of PI-88 as a single agent therapy in patients with advanced melanoma
- Evaluate the efficacy and safety of PI-88 combination with a standard chemotherapy, docetaxel (taxotere), in non-small cell lung cancer.
- Evaluate the potential of PI-88 to reduce recurrence and increase survival in post-operative liver cancer patients as an adjuvant to surgery.
- Evaluate the efficacy and safety of PI-88 as a single agent in hematological (blood) malignancies, notably multiple myeloma.

PI-88 has been developed to attack the life support system of cancer in a two-fold manner:

- Inhibition of new blood vessel growth (angiogenesis) which is essential to promote tumor growth; and
- Reduction in the spread of secondary tumors (metastasis).

It is expected that attacking these processes will lead to the development of a cytostatic therapeutic approach that may reduce the toxic side effects associated with current therapies such as irradiation, chemotherapy, or other cytotoxic drugs. By inhibiting angiogenesis, it is possible to starve the tumor of nutrients and oxygen. This process has been shown to stop tumor growth in animal models. Anti-angiogenic therapeutics, including PI-88, specifically targeted at cancerous tumors may result in additive and/or synergistic efficacy when combined with other agents without significantly increasing side effects since angiogenesis occurs only in specific instances in healthy adults (wound healing, fetal development and menstrual cycle). In addition, anti-angiogenic drugs developed are expected to have broader application in a range of cancers. The concept of halting the growth of cancer and “living with the disease” is becoming a more accepted paradigm and is reflected in the design of anti-angiogenic clinical trials, including our clinical program for PI-88. Ultimately, it is hoped that cocktails of these anti-angiogenic drugs may have the potential for co-treatment with other therapies and halt the progression of cancer and grant patients many years of additional quality life.

Angiogenesis Background

Angiogenesis (the development of new vasculature to provide blood supply) is an important process in the progression of cancer. All tumors require blood supply to grow and survive. The vascularization of the tumor also promotes the spread of tumor cells throughout the body, which results in the formation of metastases (secondary tumors).

Tumor angiogenesis involves the following key steps:

- The tumor produces enzymes, including heparanase, that degrade the basement membrane of blood vessels and the extracellular matrix surrounding the endothelial cells that line blood vessel walls. Specifically, heparanase degrades heparan sulfate in the basement membrane where growth factors are stored.
- The release of growth factors provides the angiogenic stimulus to the endothelial cells lining the nearby blood vessels. The growth factors that are released interact with heparan sulfate and with receptor molecules located on the surface of the endothelial cells, both of which are bound to the cell surface. As a result, the endothelial cells begin proliferating. Three important growth factors in this process are Vascular Endothelial Growth Factor, or VEG-F, Fibroblast Growth Factor 1, or FGF-1, and basic Fibroblast Growth Factor, or FGF-2.
- Heparanase degradation of the extracellular matrix and basement membrane also allows the proliferating endothelial cells to migrate and form new blood vessels and the remodeling of the basement membrane.
- The new blood vessels supply the tumor with the essential nutrients and oxygen required for growth.

Metastasis Background

The spread of cancer beyond an initial tumor (metastasis) is a major contributing factor to the accelerated progression of cancer. In the process of metastasis, tumor cells confront the extracellular matrix that surrounds the endothelial cells lining blood vessel walls and the basement membrane of blood vessels. Tumor cells confront these blood vessels and membranes at least twice and must penetrate them using degradative enzymes including heparanase. Metastasis occurs in the following sequence:

- Tumor cells detach from the primary tumor site and invade the blood vessel. This invasion requires enzymatic degradation of the extracellular matrix and basement membrane of blood vessel walls. Heparanase is a key enzyme in this process.
- Tumor cells enter into the circulation and migrate to other sites in the body where they lodge in small capillaries. As with invasion, tumor cells secrete heparanase to degrade the basement membrane of the blood vessel, thus allowing the tumor cells to cross the wall into the nearby tissue.
- At the distant site the tumor cells divide and form a secondary tumor.

PI-88 – A Multi-Functional Therapeutic Solution

Our lead cancer product candidate, PI-88, is being developed as a small molecule inhibitor of both angiogenesis and metastasis. In preclinical studies, PI-88 shows applicability to both a range of solid tumors and hematological tumors (blood-related malignancies) and has been shown to retard the growth of primary tumors by inhibiting new blood vessel growth (angiogenesis) and the spread of secondary tumors (metastasis). The anti-angiogenic activity is manifest in three distinct ways:

- Inhibition of heparanase, which prevents the release of angiogenic growth factors which are resident in the extracellular matrix;
- Direct interaction with the heparan sulfate-binding domains of angiogenic growth factors Vascular Endothelial Growth Factor, or VEG-F, basic Fibroblast Growth Factor 1, or FGF-1, and basic Fibroblast Growth Factor, or FGF-2, which reduces their functional activity; and
- Stimulation of the release of Tissue Factor Pathway Inhibitor, or TFPI, an endogenous protein that has anti-angiogenic and anticoagulation properties.

PI-88's anti-metastatic activity is attributable to the inhibition of heparanase, as heparanase is required to break down vasculature to allow tumor cells to spread.

PI-88 Clinical Development Program

All clinical trials of PI-88 are being conducted under an active IND with the FDA. In preclinical and clinical studies, PI-88 has shown an acceptable safety and tolerability profile in clinical trials to date. PI-88 is also showing early signs of clinical efficacy in the multinational clinical development program. 195 patients with various cancers have been treated and continuing treatment for some patients range from 3 months to beyond three years. Since PI-88 is an anti-angiogenic agent, the primary and relevant efficacy endpoint for these early stage clinical trials is stabilization of disease. This is an important difference from traditional cytotoxic anti-cancer therapies, where more toxic agents (cytotoxics) maybe used to eradicate cancer cells, often with adverse consequences to normal cells and to the patient.

The following chart summarizes the results of our ongoing, recently completed and currently planned clinical trials for PI-88.

PHASE II TRIALS		
Indication	Treatment	Status & Key Points
Advanced Melanoma	PI-88 monotherapy (subcutaneous self administration)	Phase II component of this Phase I/II trial commenced January 2004. Completed the recruitment of 46 patients.
Advanced Lung Cancer (NSCLC)	PI-88 + taxotere (docetaxel) combination therapy. (subcutaneous self administration)	Trial commenced February 2004. 90 patients to be recruited.
Multiple Myeloma	PI-88 monotherapy (subcutaneous self-administration)	Completed. Disease marker study – 19 patients. Disease Stabilisation (SD) 39% of evaluable patients.
Liver Cancer (primary)	PI-88 as adjuvant treatment post surgery (subcutaneous self administration)	Trial commenced July 2004. 340 patients to be recruited. Trial conducted and funded by Medigen Biotechnology Corporation.
PHASE I TRIALS		
Indication	Protocol	Status & Key Points
Melanoma + other advanced solid tumors	PI-88 dose and safety determination study of PI-88 subcutaneous self administration.	Completed. Thirty-eight (38) evaluable patients. 15/38 patients with disease control SD/PR (39% rate, SD (n=14) and PR (n=1) 8/19 (42%) melanoma patients with SD/PR Maximum tolerated dose determined to be 250mg 4 consecutive days per week.
Advanced Cancers Solid tumors	PI-88 + taxotere (docetaxel) dose and safety determination study of combination treatment.	Completed. 17 evaluable patients recruited. Confirmed safety and tolerability profile of PI-88 in combination with docetaxel.
Advanced Cancers	PI-88 dose and safety determination study of PI-88 intravenous (IV) administration.	Completed. 14 patients recruited. Highest dose 2.28mg/kg continuous dosing 14 consecutive days.

PI-88 is being investigated under an active IND with the FDA. Ongoing and recently completed clinical trials for PI-88 are as follows:

- In August 2003, we completed an Australian multi-center Phase II trial in Multiple Myeloma. 19 patients with refractory or relapsed multiple myeloma, a bone marrow cancer, were enrolled at three Australian hospitals, The Alfred Hospital in Melbourne under Dr. Andrew Spencer, The Mater Misericordiae in Newcastle under Dr. Arno Enno, and The Wesley Clinical Research Centre in Brisbane under Dr. John Bashford. The endpoint of the study, stabilization of serum disease markers, was achieved in seven, of the 18 evaluable patients (39%) in the study. One patient continues to receive PI-88 post-study under a special access scheme after 32 months.

- In January 2004 we concluded the Phase I component of a Phase I/II clinical trial at the University of Colorado Health Sciences Center in Denver, Colorado, in which PI-88 was self-administered subcutaneously (injected under the skin) to patients with advanced malignancies (including melanoma and renal-cell carcinoma) in order to determine the appropriate safe dose of PI-88 for the Phase II component of this study. 15 out of 38 evaluable patients with advanced tumors (39%) have had disease stabilization ranging from three to 38 months, including one partial response. This trial examined the dosing and investigated the safety and tolerability of PI-88 as a single-agent therapy. Following completion of the Phase I component of this study, the Phase II component, investigating advanced melanoma specifically, was launched in four sites across Australia with advanced melanoma patients and at the University of Colorado Health Sciences Center in Denver, Colorado. Recruitment into this Phase II component of this study has concluded with 46 patients enrolled on the study.
- In February 2004 we concluded a Phase I trial at the University of Colorado Cancer Center in Denver, Colorado, of PI-88 in combination with taxotere, a frequently used chemotherapy treatment, in patients with advanced solid tumors. This trial was designed to determine the appropriate safe dose of PI-88 when combined with weekly doses of taxotere, and was conducted as a precursor to a planned multi-center Australian Phase II trial of the combination in patients with advanced non-small cell lung cancer. 16 patients were recruited into this Phase I study and the trial met its objectives of determining the safety and tolerability of PI-88 in combination with taxotere. Following the completion of the Phase I component a multi-center Australian Phase II trial of PI-88 in combination with taxotere in patients with advanced non-small-cell lung cancer was launched utilizing the dose established from the Phase I combination study.
- In July 2004 a Phase II trial of PI-88 as post-operative (following surgery) adjuvant treatment in patients with primary liver cancer (hepatocellular carcinoma or hepatoma) was launched in 4 Taiwan clinical centers by our alliance partner and clinical collaborator, Medigen Biotechnology Corporation (MBC) an emerging Taiwanese biotechnology company.

Other earlier PI-88 clinical trials include:

- Completion of a Taiwanese Phase Ib clinical trial in advanced cancer patients to assess the safety and tolerability of PI-88 given intravenously in Asian patients suffering from advanced forms of cancer, by our alliance partner and clinical collaborator, Medigen Biotechnology Corporation.
- Completion of a Phase I clinical trial in healthy volunteers in Manchester, the United Kingdom in March 1999. This first-time-in-man clinical trial was designed to evaluate the safety, tolerability and pharmacokinetic profile (concentration in the blood over time) of PI-88 when administered intravenously.
- Completion of a multi-center Phase Ib clinical trial in patients with advanced solid tumors at the Royal Melbourne Hospital and the Peter MacCallum Cancer Institute in

Melbourne, Australia in November 2000. The clinical trial was designed to assess the safety and tolerability of PI-88 when administered intravenously.

- Completion of a Phase I clinical trial in healthy volunteers in Manchester, the United Kingdom in October 2000. The clinical trial was designed to evaluate the safety, tolerability and pharmacokinetic profile of PI-88 when administered subcutaneously.

Preclinical Studies of PI-88

Preclinical studies confirm that PI-88 significantly reduces the growth of primary human tumors and inhibits metastasis in animal models. We have conducted extensive preclinical pharmacology in animal models that approximate the human clinical condition. In one such experiment, mammary tumor cells were injected into a foot pad of mice and allowed to grow for seven days until a palpable tumor could be detected. The mice were then treated with PI-88 by continuous subcutaneous infusion over a 24-day period. At the conclusion of the treatment period, mice that had received PI-88 had a reduction in lung metastases of up to 75%. In another experiment, PI-88 reduced the growth of pancreatic tumors in transgenic mice by 80% of the size of tumors in control animals. Moreover, PI-88 was shown to be most effective at preventing small but highly vascularized tumors from developing into large tumors. This is consistent with PI-88's action as an angiogenesis inhibitor. In additional experiments, the growth of human colon carcinoma xenografts in nude (athymic) mice was reduced by up to 28% in animals treated with PI-88 twice daily by injection for 22 to 26 days.

Microscopic examination of primary tumors in animals treated with PI-88 has shown a significant reduction in vascularization both within and surrounding the tumor. This has been confirmed by measurement of hemoglobin content in tumors removed from animals treated with PI-88 and untreated animals.

Additional preclinical studies have shown that PI-88 in combination with chemotherapeutic agents, such as 5-fluorouracil, is significantly more effective than either compound alone in reducing tumor growth in mice.

Several independent assessments of PI-88 have been completed, including single dose, two-week dose ranging, four-week and 13-week toxicology studies in rats; a single dose, two-week, four-week and 13-week dosing studies in primates; and a safety pharmacology study for cardiovascular and respiratory functions with dogs. Results of these studies have been comparable between species. In rat toxicology studies, minimal effects were observed at low dosages with toxicities observed only at high dosages. In monkey toxicology studies, a no-effect level was achieved at low dosage. In the dog safety pharmacological study, a no-effect level was observed at low dosage.

Results of our 1999 United Kingdom Phase I trials of PI-88 in healthy volunteers indicate that at escalating dosages administered as single two-hour intravenous infusions, PI-88 does not cause any immediate adverse reactions within the human body except for transient elevations of activated partial thromboplastin time (the time for blood to clot under defined *in vitro* conditions). In addition, results of our 2000 United Kingdom Phase I trial of PI-88 in healthy volunteers indicate

that, at escalating dosages administered subcutaneously (injected under the skin), PI-88 was well tolerated with minimal local effects and 98% bioavailability.

Development Strategy

We have retained worldwide commercial rights to PI-88. At the appropriate time, we will select collaborators for later-stage clinical development and commercialization of PI-88 as a cancer therapeutic.

PI-166 – Novel Anti-Cancer Agent

PI-166, our second oncology product candidate, is a novel combination of an active small organic chemical molecule and a delivery vehicle that directs and retains the active drug constituent at the tumor site. PI-166 is being developed for potential application in the treatment of advanced hepatocellular carcinoma (primary liver cancer).

Preclinical Studies of PI-166

Preclinical studies of PI-166 indicate that this treatment modality has antiproliferative activity against hepatocellular carcinoma (liver cancer) cells *in vitro* (within an artificial environment) and anti-tumor activity *in vivo* against the Novikoff hepatoma in rats, a model of primary liver cancer in humans that like human hepatoma, is known to be highly resistant to standard chemotherapeutic agents.

Development Strategy for PI-166

A Phase I clinical trial with PI-166 was initiated at the St. George Hospital in Sydney in 2003. Due to slower than expected recruitment from this center additional sites have recently been added (Princess Alexandra Hospital, Brisbane and Monash Hospital, Melbourne). The primary objective of this trial is to investigate the safety and tolerability of escalating doses of PI-166 in patients with advanced stage primary liver cancer where surgical intervention is no longer an option (unresectable). Based on interim data to date, no drug-related side effects of PI-166 have been observed in patients enrolled in the trial.

We have retained worldwide commercial rights to PI-166. At the appropriate time, we will select collaborators -to conduct later-stage clinical trials and commercialization of PI-166 as a cancer therapeutic.

Cardiovascular Therapeutics

PI-88 has been shown in preclinical models to have potential as an anti-thrombotic and inhibitor of restenosis. In light of our focus on developing novel cancer therapeutics, recent competitive developments and the high cost of development in the cardiovascular disease area, we do not presently plan to initiate a PI-88 cardiovascular clinical trial program.

Drug Discovery Research

The goal of our drug discovery research is to discover and develop small molecule drug candidates that modulate the interaction between carbohydrates (sugars) and disease related protein targets as potential therapeutics for cancer. Our current drug discovery research involves the ongoing collaboration with the academic laboratory of Professor Martin Banwell of the Research School of Chemistry at the Australian National University in Canberra, Australia. The company funded three-year collaborative heparanase program with Prof. Mark von Itzstein at the Griffith University's Institute of Glycomics came to a conclusion in March 2004. The proprietary core technology for our drug discovery research, out of which PI-88 was developed, emanates from our previous collaborative research on heparan sulfate mimics and related polysaccharides with Professor Christopher Parish of The John Curtin School of Medical Research at the Australian National University, Canberra, Australia. Our drug discovery research program is partially funded by a A\$3.1 million Australian federal government AUSIndustry START grant awarded in August 2001.

Our internal research program, augmented by the work of our academic collaborators, has led to the identification of a portfolio of heparan sulfate binding proteins that are involved in different diseases, and we are designing, synthesizing and screening small molecule compounds that disrupt heparan sulfate binding.

We believe our advanced understanding of the role of carbohydrates in disease processes combined with our clinical development expertise in advancing promising product candidates into early stage clinical trials to demonstrate proof of efficacy enables us to discover novel therapeutics as well as identify and license product candidates. We intend to enter into collaborations with pharmaceutical and biotechnology companies that will allow us to build on our in-house expertise and capabilities, including acquiring additional product candidates, as well as improve our ability to move new compounds into the clinic.

Background

Carbohydrate-Protein Interactions and Disease. Most diseases involve complex interaction between proteins and many of these interactions also involve carbohydrates. Different classes of proteins in which many members are known to be dependent on a carbohydrate sequence for function are cytokines, chemokines, infectious agents such as viruses, selectins, and proteases. Incorrect functioning of any of these processes can lead to disease states including cancer, inflammation, cardiovascular disease and infection.

Carbohydrates. Carbohydrates constitute a third class of bioinformatic molecules after DNA and proteins. While the nutritional and structural roles of carbohydrates have long been understood,

an appreciation of their function as information carriers and recognition molecules has occurred only recently. Carbohydrates play an important role in a wide range of biological processes as diverse as cellular differentiation, hormone-cell regulation, and cell-to-cell interaction, especially viral-host cell and bacteria-host cell recognition. Historically, the potential for carbohydrates as targets for therapeutics and therapeutic agents was limited, one limiting factor being the lack of cost effective and scaleable synthetic processes. While synthesis is feasible on a small scale, large-scale manufacture is prohibitively expensive with current technology.

Small Molecule Drugs. The advantage of small molecule drugs over therapeutic proteins includes their potential for oral administration, applicability to a wider range of disease targets, including those inside the cell, improved effectiveness, reduced side effects and greater ease of manufacture compared to carbohydrates. Small molecule drugs are particularly appropriate for the treatment of chronic diseases that require daily administration over many years. Historically, the opportunity to commercialize small molecule drugs has been limited by the difficulty of discovering safe and effective small molecules.

Our solution

We are initially focusing on the role of heparan sulfate, a complex sugar that belongs to a class of carbohydrates called glycosaminoglycans, or GAGs. GAGs are sulfated polysaccharides (long sugar chains) that are generally found linked to core proteins in a complex known as a proteoglycan. Proteoglycans are found on the surface of all cells where they act as receptors, participate in cell-to-cell interactions, and promote or inhibit cell growth. In addition, GAGs play a structural role by forming a major component of the extracellular matrix surrounding endothelial cells as well as the basement membrane of blood vessels. GAG-binding proteins have been implicated in a range of different diseases including cancer, cardiovascular diseases, inflammation, infectious diseases, amyloid diseases, diabetic retinopathy, macular degeneration and xenotransplantation.

Our goal is to produce lead molecules that inhibit the binding of heparan sulfate to different proteins. Our rational drug design approach analyzes the binding of specific regions of heparan sulfate to target proteins by computer modeling to aid the design of very selective drugs that bind to the same protein and block heparan sulfate. We have been able to identify a significant number of heparan sulfate binding proteins and many are shown to be involved in different diseases including cancer, infectious disease, cardiovascular disease and inflammatory disease such as multiple sclerosis. Previous work done by our research collaborators and others has demonstrated that if these targets are blocked, disease can be halted.

Using a comparative database of the three dimensional structures of a number of heparan sulfate-binding proteins, we have been able to design, synthesize and screen several first generation classes of molecules (scaffolds) that bind to the protein targets and inhibit their heparan sulfate-binding ability. We have also been able to chemically modify these scaffolds to dramatically increase their specificity for specific protein targets. We believe that these new small molecule compounds produced by our proprietary synthetic procedures can also potentially incorporate chemical groupings to aid detection and oral delivery. Our initial primary targets include Vascular Endothelial Growth Factor, or VEG-F, and a family of cell signaling molecules called Fibroblast Growth Factors, or FGFs, and include FGF-1 and FGF-2.

We have exclusive proprietary rights to a class of small molecules. These small molecules are semi-synthetic oligosaccharides (short sugar chains) that we have screened as inhibitors of specific functions of heparan sulfate-binding proteins targets such as heparanase, growth factors that stimulate angiogenesis and proteins involved in the coagulation pathway. PI-88, our lead product candidate is a heparan sulfate mimetic that has been shown at the cellular level to prevent the binding of growth factors to target receptors and to inhibit heparanase. We are also developing novel manufacturing techniques to synthesize low molecular weight glycomimetics to increase the variety of carbohydrate and carbohydrate-like molecules for screening as potential therapeutics.

Additional Research Programs

Additional research programs supported through collaborations with academic institutions and industry include:

Heparanase Technologies. Technologies are being developed for the heparanase enzyme as a diagnostic and therapeutic target, including a more sensitive assay to distinguish heparanase levels in various disease states, such as malignant versus benign tumors, metastatic versus non-metastatic cancers and various cardiovascular diseases.

Inflammation Disease Therapeutics. Based on research results on agents that target and restrict the activity of heparanase, the same small molecule sulfated oligosaccharides that inhibit cancer spread (including PI-88) are also potentially effective prophylactic anti-inflammatory agents. Furthermore, heparanase inhibitors constitute a prospective new class of drugs for use in the treatment of inflammatory disease (such as inflammatory bowel disease and multiple sclerosis).

Carbohydrate-Based Anti-Viral Technologies. An important function of polysaccharides in the human body is the facilitation of cell-to-cell interactions and cell adhesion. These molecules act as specific identifiers at the surface of different cells and play a role in the physical adhesion between two cells. Carbohydrates have also been associated with the attachment of many parasites, as well as a number of viruses. Screening of small molecule sulfated oligosaccharides as inhibitors of viral infection is continuing.

Research and Clinical Collaborations

In the course of conducting our research and clinical studies, we maintain collaborations with private industry and a number of academic and research institutions in Australia, the U.S. and elsewhere.

We support, or have supported, pivotal research at the following institutions:

- The Research School of Chemistry at the Australian National University, Canberra, Australia, is developing a combinatorial chemistry approach to the synthesis of molecules that mimic the structure of sugars. This chemistry will enable synthesis of defined structures to overcome the limitations in commercial synthesis of oligosaccharides and plays a pivotal supporting role to our in-house drug discovery research program funded in part by an Australian Federal Government research grant.
- Griffith University's Institute of Glycomics in Brisbane, Australia through a three-year collaborative heparanase program funded by us. This collaboration came to a conclusion in March 2004. This program sought to design an inhibitor to the enzyme heparanase that is implicated in inflammatory diseases such as multiple sclerosis and inflammatory bowel disease. We may extend the program depending on the availability of alternative external funding. Our investment in the program is protected by the application of two patents.

At various times, we have also conducted collaborative research with The John Curtin School of Medical Research at the Australian National University in Canberra, Australia, the Institute of Medical and Veterinary Sciences, Adelaide, Australia, the University of Otago in Otago, New Zealand, the Gothenburg University in Gothenburg, Sweden, the University of California in Davis, California, the University of California in San Francisco, California, the University of Nebraska in Lincoln, Nebraska, the University of L'Aquila in L'Aquila, Italy, and The Royal North Shore Hospital, Sydney, Australia.

Our clinical collaborators include:

Phase I/II melanoma monotherapy study:

- The University of Colorado Health Sciences Center (Denver, Colorado)
- Sir Charles Gairdner Hospital (Perth, Australia);
- Princess Alexandra Hospital (Brisbane, Australia);
- The Alfred Hospital (Melbourne, Australia); and
- The Queen Elizabeth Hospital (Adelaide, Australia).

Phase II Non-Small Cell Lung (NSCL) cancer studying PI-88 in combination with taxotere:

- Royal Prince Alfred Hospital (Sydney, Australia);
- Sir Charles Gairdner Hospital (Perth, Australia);
- Border Medical Oncology (Wodonga, Australia);
- Mater Adult Hospital (Brisbane, Australia);
- Prince Charles Hospital (Brisbane, Australia);
- The Alfred Hospital (Melbourne, Australia);
- Royal North Shore Hospital (Sydney, Australia);
- The Queen Elizabeth Hospital (Adelaide, Australia);
- Prince of Wales Hospital (Sydney, Australia);
- Newcastle Mater Hospital (Newcastle, Australia); and
- Sydney Haematology and Oncology Clinic (Sydney, Australia).

Phase I trial of PI-166 in patients with unresectable hepatocellular carcinoma is being conducted at:

- St George Hospital (Sydney, Australia);
- Princess Alexandra Hospital (Brisbane, Australia); and
- Monash Medical Centre (Melbourne, Australia).

Medigen Biotechnology Corporation in Taipei, Taiwan, is conducting a Phase II clinical trial with PI-88 in patients with post-resection hepatoma at:

- The National Taiwan University Hospital (Taipei, Taiwan);
- Chang Gung Memorial Hospital (Linkou, Taiwan);
- Veterans General Hospital (Taichung, Taiwan); and
- China Medical University Hospital. (Taipei, Taiwan).

The collaboration between us and Medigen is described in the following section.

In August 2003, we completed an Australian multi-center Phase II study of PI-88 in multiple myeloma patients at The Alfred Hospital in Melbourne, The Mater Misericordiae Hospital in Newcastle and the Wesley Clinic Research Centre in Brisbane. In 2001, clinical testing of intravenous PI-88 in Phase Ib clinical trials in advanced stage cancer patients at the Peter MacCallum Cancer Institute and at the Royal Melbourne Hospital was concluded under the auspices of the Center for Developmental Cancer Therapeutics.

Collaboration with Medigen Biotechnology Corporation

In May 2000, we entered into a strategic alliance agreement with Medigen Biotechnology Corporation, or MBC, a biotechnology company based in Taiwan. The collaboration relates to early stage clinical trials of PI-88. Under the agreement:

- We have retained all intellectual property rights to PI-88;
- MBC will receive a percentage of our future revenues received from PI-88 in cancer and cardiovascular disease provided MBC successfully completes all clinical trials agreed to be conducted and funded by MBC under the agreement;
- We will use reasonable endeavors to complete one Phase II trial with PI-88 in an oncology indication, one Phase II trial of PI-88 in a cardiovascular indication, and two proof of principle trials in oncology indications;
- We will supply PI-88 to MBC, at no charge, for the conduct of all trials funded by MBC;
- We have agreed to supply to MBC, at MBC's cost, technical assistance, including the services of trained personnel and technical training, for the conduct of clinical trials by MBC;

- We have agreed to assist MBC, at MBC's cost, to establish a manufacturing plant that can produce potential human therapeutics in accordance with cGMP and FDA requirements if so requested; and
- MBC has the right to negotiate the funding and conduct of Phase III trials with PI-88, subject to any agreements that we may enter into with strategic partners to further develop and commercialize PI-88.

In return, MBC:

- Will fund and conduct one Phase II cancer trial with PI-88 and one Phase II cardiovascular trial with PI-88;
- Will fund and conduct two Phase II proof of principle cancer trials with PI-88;
- Has issued to us a 19.9% equity stake in MBC with certain anti-dilution rights; and
- Has paid to us A\$11 million for 2.75 million of our ordinary shares.

Commercial Services Businesses

Life Sciences

Prior to the sale of our life sciences division to Global Science and Technology Limited in November 2003 we were the Australian and New Zealand distributor of a wide range of life sciences research products manufactured by a number of U.S. and European life sciences companies. We also offered our own range of fine chemical products sold under the Progen brand name. Our life sciences products were marketed to research and diagnostic laboratories in private and government institutions, including universities, hospitals and biotechnology companies, by our own sales staff and under sub-distributor arrangements in New Zealand and Western Australia.

Contract Manufacturing

We provide contract manufacturing services to cGMP standards for various human clinical trial and therapeutic products and veterinary pharmaceuticals, as well as non-cGMP bioproducts contract manufacturing services. We also provide bioprocess technology development services and consulting services in quality and regulatory management systems. Contract and consulting services revenues constituted approximately 34.9%, 37.6% and 56.0% of our sales revenue for the fiscal years ended June 30, 2002, 2003 and 2004, respectively.

Following the sale of our life sciences division in November 2003 contract manufacturing services contributes 100% of our sales revenue.

Government Regulation

Contract Manufacturing

Our contract manufacturing operations include some manufacturing processes that are required to comply with the applicable cGMP requirements of the TGA and the National Registration Authority, which govern the methods, controls, facilities and quality assurance procedures used in manufacturing, packing and storing biological and pharmaceutical products. In addition, certain international markets have quality assurance and manufacturing requirements that may be more or less rigorous than those in Australia. Our manufacturing facilities are also subject to biennial inspections by the TGA. We cannot make any assurances that we will continue to be in compliance with cGMP requirements. Failure to comply with cGMP requirements or with any other international requirements could have a material adverse effect on our business, financial condition and results of operations.

Research and Development

The research and development, manufacture and commercialization of our pharmaceutical products will be subject to regulation by governmental entities in Australia and other countries including the United States. Pharmaceutical products are subject to rigorous regulation by the TGA under the Australian Therapeutic Goods Act, by the FDA in the United States, and by similar health authorities in foreign countries under laws and regulations that govern, among other things, the testing, clinical trials, manufacture, safety, efficacy, labeling, storage, record keeping, advertising, promotion, export, marketing and distribution of such products. Product development and approval within this regulatory framework is uncertain and can take a number of years and require the expenditure of substantial resources. Any failure to obtain regulatory approval or any delay in obtaining such approvals could have a material adverse effect on our business, financial condition and results of operations.

Australian Government Regulation

The steps required before a drug may be approved for marketing in Australia generally include:

- Preclinical laboratory and animal testing;
- Submission to the TGA of a clinical trial notification, or CTN, or a clinical trial exemption, or CTX, application for human trials;
- Submission of an investigators' brochure and clinical protocols to the independent ethics committee, or IEC, of each institution at which the trial is to be conducted;
- Adequate and well-controlled clinical trials to demonstrate the safety and efficacy of the product;
- Development of a Drug Masterfile, which demonstrates that the manufacture of the product conforms to GMP guidelines;

- Submission of the manufacturing, preclinical and clinical data to the TGA; and
- Approval by the TGA for inclusion in the Australian Register of Therapeutic Goods.

The testing and approval processes for a drug require substantial time, effort and financial resources. Furthermore, post-market surveillance must be carried out, and any adverse reactions to the drug must be reported to the TGA. We cannot make any assurances that any approval will be granted on a timely basis, if at all.

Preclinical studies include laboratory evaluation of the product as well as animal studies to assess the potential safety and efficacy of the product. The results of the preclinical studies are submitted to each investigator's IEC and, in some instances, to the TGA. Approval by each IEC and by the TGA is necessary before clinical trials can commence. An IEC is a review committee at each institution at which a study is conducted and is set up under guidelines of the Australian National Health and Medical Research Council. The role of an IEC is to review proposals for clinical trials, and approve and subsequently monitor the clinical trials. The IEC will consider, among other things, ethical factors and the safety of human subjects. We cannot make any assurances that submission to the applicable IECs and the TGA will result in authorization to commence clinical trials.

Clinical trials involve administering the investigational product to healthy volunteers or patients under the supervision of a qualified principal investigator. The TGA has developed guidelines for a CTN and a CTX, the two classes of clinical trials in Australia. Under the CTN scheme, under which most clinical trials in Australia are conducted, the TGA is formally notified by submission of a CTN application but is not obliged to review the safety of the drug or any aspect of the proposed trial. However, the TGA can request safety information or halt a trial on the basis of safety issues. Primary responsibility for all aspects of the trial conducted under a CTN application remains with the IEC of each investigator's institution and with us. A CTX application requires submission of a summary of preclinical and manufacturing data to the TGA, in addition to submission of an investigator's brochure and protocol to the applicable IEC. In cases where an IEC is unsure of the safety or efficacy of a product, a CTX application is submitted. Approval by both bodies is necessary before the trials can commence. The role of the TGA is primarily to assess safety issues.

Clinical trials are typically conducted in three sequential phases that may overlap:

- Phase I clinical trials that involve the initial introduction of the drug into human subjects and the exploration of its safety (adverse effects), dosage tolerance, absorption, metabolism, excretion and pharmacodynamics;
- Phase II clinical trials that (i) evaluate the efficacy of the drug for specific, targeted indications, (ii) determine dosage tolerance and optimal dosage, and (iii) identify possible adverse effects and safety risks. Phase II trials usually involve studies in a limited patient population; and

- Phase III clinical trials that generally further evaluate clinical efficacy and further test for safety within an expanded patient population sufficient to provide statistically significant data.

In the case of products with a high risk of toxicity, the initial clinical trials are sometimes conducted in patients rather than in healthy volunteers. Since these patients are already afflicted with the target disease, it is possible that such clinical trials may provide evidence of efficacy traditionally obtained in Phase II clinical trials. We cannot make any assurances that Phase I, Phase II or Phase III testing will be completed successfully within any specific time period, if at all, with respect to any of our product candidates. Furthermore, the TGA and/or the applicable IEC may suspend clinical trials at any time on various grounds, including a finding that the subjects or patients are being exposed to an unacceptable health risk.

We successfully completed our first Phase I clinical trial with PI-88 given as an intravenous infusion in healthy volunteers in Manchester, the United Kingdom, in March 1999, and our first Phase Ib clinical trial with PI-88 given intravenously in cancer patients in November 2000. The multi-center oncology Phase Ib clinical trial was conducted at the Royal Melbourne Hospital and the Peter MacCallum Cancer Institute, Melbourne, Australia, under the auspices of the Centre for Developmental Cancer Therapeutics pursuant to an IND application with the FDA, a CTN application with the TGA and IEC approvals.

All completed and ongoing PI-88 patient clinical trials are/have been conducted under an active IND application with the FDA, under a CTN application with the TGA for Australian sites and other health authority jurisdictions where relevant.

In January 2003, a Phase I clinical trial with PI-166 in patients with unresectable primary liver cancer, was initiated at the St. George Hospital in Sydney, Australia. This Phase I trial is being conducted under a separate CTN application with the TGA.

In order to obtain Australian marketing approval for a drug, the results of the preclinical studies and clinical trials, together with detailed information on the manufacture and composition of the product, are submitted to the TGA with a request for registration of the product in the Australian Register of Therapeutic Goods. The TGA may delay approval if applicable regulatory criteria are not satisfied, require additional testing or information, and/or require post-marketing testing and surveillance to monitor the safety or efficacy of a product. We cannot make any assurances that approval by the TGA will be granted on a timely basis, if at all. Also, if regulatory approval of a product is granted, such approval may entail limitations on the indicated uses for which such product may be marketed.

U.S. Government Regulation

FDA approval to market our drug products in the U.S. is expected to be undertaken by us or in conjunction with a commercial partner. The approval process of the FDA and TGA are similar, with substantial requirements for preclinical research, conduct of clinical trials, and manufacture of the product. Human clinical testing of a new drug requires the submission of an IND that must include the results of preclinical studies, together with manufacturing information and analytical data. We cannot make any assurances, however, that submission of an IND will allow us to

commence clinical trials. Furthermore, once trials have commenced, the FDA may stop the trials, or particular types of trials, by placing a "clinical hold" on such trials because of, for example, concerns regarding the safety of the product being tested. Such holds can cause substantial delay and, in some cases, may require abandonment of a product. In addition, in the U.S., Phase IV clinical trials are conducted after approval by the FDA to gain additional experience from the treatment of patients in the intended therapeutic indication and to document a clinical benefit in the case of drugs approved under accelerated approval regulations. If the FDA approves a product while a company has ongoing clinical trials that were not necessary for approval, a company may be able to use the data from these clinical trials to meet all or part of any Phase IV clinical trial requirement. These clinical trials are often referred to as "Phase III/IV post-approval clinical trials." Failure to promptly conduct Phase IV clinical trials could result in withdrawal of product approval under accelerated approval regulations.

The results of preclinical studies and clinical trials, together with detailed information on the manufacture and composition of the product, are submitted to the FDA in the form of a New Drug Application, or NDA, requesting approval to market the product. Before approving an NDA, the FDA will inspect the facilities at which the product is manufactured and will not approve the product unless the manufacturing facility is in GMP compliance. The FDA may delay an NDA if applicable regulatory criteria are not satisfied, require additional testing or information, and/or require post-marketing testing and surveillance to monitor the safety or efficacy of a product. We cannot make any assurances that FDA approval of any NDA submitted by us will be granted on a timely basis, if at all. Also, if regulatory approval of a product is granted, such approval may entail limitations on the indicated uses for which the product may be marketed.

The FDA has implemented accelerated review and approval procedures for therapies that have been studied for their safety and effectiveness in treating serious life-threatening or severely debilitating diseases, and which provide a meaningful therapeutic benefit to patients over existing treatments. Sponsors of such products may request to meet with the FDA-reviewing officials early in the drug development process to review and reach agreement on the design of necessary preclinical and clinical studies. We believe that PI-88 may ultimately qualify for this expedited review and approval process. Depending on the results of our current PI-88 clinical trial program, some of our later stage clinical trials may be designed with the objective of securing accelerated approval by the FDA. Significant uncertainty exists as to whether, and the extent to which, accelerated review and approval will be granted. The FDA also retains considerable discretion in determining eligibility for accelerated review and approval and is not bound by discussions that an applicant may have with FDA staff. Accordingly, the FDA could employ such discretion to deny eligibility of PI-88 as a candidate for accelerated review or require additional clinical trials or other information before approving PI-88. In addition, the approval of a product under the expedited approval procedures is subject to various conditions, including the requirement to verify clinical benefit in post-marketing studies and the authority on the part of the FDA to withdraw approval under streamlined procedures if such studies do not verify clinical benefit, or under various other circumstances. We cannot predict the ultimate impact, if any, of the new approval process on the timing or likelihood of FDA approval of PI-88 or any of our other potential products.

We are currently conducting the Phase II component of a Phase I/II clinical trial of PI-88 as a single agent therapy in patients with melanoma in a multi-center study in Australia and the U.S. in addition a Phase II multi-center combination study of PI-88 and taxotere in Australia in NSCL

cancer patients under our IND with the FDA and separate CTN applications with the TGA. We may seek FDA and TGA approval for independent Phase II trials of PI-166 in the U.S. and Australia upon successful completion of the Phase I trial in Australia. We cannot make any assurances that our submissions to the FDA or the TGA will be successfully reviewed, that the requisite approvals will be granted, that accelerated approvals will apply, or that clinical trials will commence.

Orphan Drug Status

PI-88, our lead product candidate, has been designated as an orphan drug by the FDA for treatment of high risk Stage II, Stage III and Stage IV melanoma. If our other product candidates meet the criteria, we may also apply for orphan drug status for such product candidates.

The FDA may grant orphan drug status to drugs intended to treat a rare disease or condition, which is generally a disease or condition that affects fewer than 200,000 individuals in the United States. Orphan drug status does not convey any advantage in, or shorten the duration of, the regulatory review and approval process, and the FDA may grant orphan drug status to multiple competing product candidates targeting the same indication. A product that has been designated as an orphan drug that subsequently receives the first FDA approval for the indication for which it has received such designation is entitled to orphan drug exclusivity and the FDA may not approve any other applications to market the same drug for the same indication, except in very limited circumstances, for seven years from the date of FDA approval. A supplier of a designated orphan product may also seek certain tax benefits.

Patent Rights; Licenses and Proprietary Technology

Generally

Our success will depend in large part on whether we can:

- Obtain patents to protect our own products;
- Obtain licenses to the patented technologies of third parties;
- Operate without infringing on the proprietary rights of third parties; and
- Protect our trade secrets and know-how.

For a discussion of the risks and uncertainties associated with our intellectual property position, see “Risk Factors – Our success depends upon our ability to protect our intellectual property and our proprietary technology.”

Patents

We own or have exclusive rights to 26 granted patents (including those accepted for grant) and a further 28 patent applications worldwide that relate to our proprietary technology in Australia, the United States and other foreign countries, of which three are issued Australian patents and nine are corresponding issued United States patents with expiration dates between 2013 and 2018. We

also have exclusive licenses to approximately 11 families of patent applications and have been assigned a further 2 families of patent applications.

The availability and breadth of claims allowed in biotechnology and pharmaceutical patents is highly uncertain and generally involves complex legal and factual questions. We cannot make any assurances that any of our pending or future patent applications will be approved, or that we will develop additional proprietary products or processes, or be able to license any other patentable products or processes. We also cannot make any assurances that others will not independently develop similar products or processes, duplicate any of the products or processes developed or being developed by or licensed to us, or design around the patents owned or licensed by us, or that any patents owned or licensed by us will provide us with competitive advantages. Furthermore, patents held by third parties may prevent the commercialization of products incorporating the technology developed by or licensed to us, and third parties may challenge or seek to narrow, invalidate or circumvent any or all of the issued, pending or future patents owned or licensed by us.

If it were determined that we were infringing any third party patents, we could be required to pay damages, alter our products or processes, obtain licenses or cease certain activities. We cannot make any assurances that the licenses required under patents held by third parties would be made available to us on acceptable terms, or at all. To the extent that we are unable to obtain such licenses, we could be foreclosed from the development, manufacture or commercialization of the product requiring such license or encounter delays in product introductions while we attempt to design around such patents.

We also believe that because of the differences in patent laws, foreign patents, if obtained, and the protection afforded by such foreign patents and foreign intellectual property laws may be more limited than that provided under Australian or United States patents and intellectual property laws. Litigation, which could result in substantial costs and diversion of effort on our part, may also be necessary to enforce any patents issued or licensed to us or to determine the scope and validity of third party proprietary rights. We may have to participate in opposition proceedings before the Australian Patent and Trademark Office or another foreign patent office, or in interference proceedings declared by the United States Patent and Trademark Office, to determine the priority of the invention for patent applications filed by competitors. Any such litigation, interference or opposition proceeding, regardless of outcome, could be expensive and time consuming, and adverse determinations in any such proceedings could have a material adverse effect on our business, financial condition and results of operations.

Licenses

PI-88. We have an exclusive worldwide license from the Australian National University in Canberra, Australia, to five families of patents and patent applications relating to PI-88, our sulfated oligosaccharide heparanase inhibitor. Our license rights terminate on November 4, 2018 or ten years after the expiration of the last patent related to the PI-88 technology, whichever is later. Our license with the Australian National University requires us to pay the University a portion of PI-88 related payments that we receive including royalties on sales of PI-88 as well as on any fees we receive from sublicensing this technology. In addition we are the assignee to a sixth patent application.

PI-166. We also have an exclusive worldwide license from the University of New South

Wales in Sydney, Australia, to PI-166, a novel drug and delivery technology that is a potential new therapy for the treatment of hepatocellular carcinoma (primary liver cancer). Our license rights terminate on expiration of the last patent forming part of the technology or, if no patent issues, in 2012 with an option to extend until 2022. Our license with the University of New South Wales requires us pay the University a portion of PI-166 related payments that we receive including royalties on sales of PI-88 as well as on any fees we receive from sublicensing this technology.

Drug Discovery Technology. We also have an exclusive worldwide license from the Australian National University to our patent application covering the synthesis of potential drug intermediaries. Our license rights terminate at the expiration of the last patent related to the synthesis technology. Our license with the Australian National University requires us pay the University a portion of product related payments that we receive including royalties on sales of products arising from the synthesis technology as well as on any fees we receive from sublicensing this technology, and to make periodic payments on the achievement of certain milestones. In addition we are the assignee to a further patent application.

Proprietary Technology

In addition to patent protection, we rely on unpatented trade secrets and know-how and proprietary technological innovation and expertise, all of which are protected in part by confidentiality and invention assignment agreements with our employees, advisors and consultants. We cannot make any assurances that these agreements will not be breached, that we will have adequate remedies for any breach, or that our unpatented proprietary intellectual property will not otherwise become known or independently discovered by competitors. We also cannot make any assurances that persons not bound by an invention assignment agreement will not develop relevant inventions.

Competition

Drug Development

We face competition in each of our target product markets. The pharmaceutical and biotechnology industries are also intensely competitive. Our anti-cancer pharmaceutical product candidates would be subject to significant competition from existing drugs and therapies, as well as from products and therapies utilizing alternative or similar technologies. There are many pharmaceutical and biotechnology companies, and public and private academic institutions and research organizations actively engaged in the research and development of alternative products and therapies for the treatment of diseases that we have targeted for product development. Many of these organizations have greater financial, technical, manufacturing and marketing resources.

We are aware of certain products that are being developed by competitors that modulate tumor-related angiogenesis, including heparanase inhibitors, FGF-2, VEG-F and other signal protein inhibitors, and inhibitors of certain matrix metalloproteases, a family of enzymes known to be involved in processes through which tumors invade tissues, metastasize and grow. Other competitors are developing technologies that interfere with endothelial cells directly. Several of these product candidates are in advanced stages of clinical trials and being marketed. Competitors that are marketing products or developing technologies that compete with PI-88, our lead oncology product

candidate, include Genentech, Inc., Entremed, Inc., Imclone Systems, Onyx Pharmaceuticals, Genaera Corporation, Genzyme Corporation, Aeterna Zentaris, MedImmune Inc. and Celgene Corporation. We are also aware of several agents that are being developed by competitors that are intended for the treatment of hepatocellular carcinoma. These agents are in various stages of clinical development and comprise small synthetic organic molecules and biologicals, as well as targeted radiotherapy and hyperthermia treatments. These competitors include Maxim Pharmaceuticals, Onyx Pharmaceuticals and SIRTEx Medical.

Some of our competitors may succeed in developing products earlier than us, obtain governmental approvals more rapidly than us, or develop products that are safer and more effective than those under development by us. Other companies may also develop products or therapies that render our technology and products obsolete or non-competitive. We also cannot make any assurances that any therapy developed by us will be preferred to any existing or newly developed technologies. Some of our competitors may succeed in developing treatments that are superior to any therapy or product developed by us. Our ability to successfully compete with these and other companies will also depend to a considerable degree on the continuing availability of capital to us, as well as our ability to recruit and retain highly qualified scientific personnel and consultants, and to compete with the established manufacturing and marketing capabilities of our competitors.

Contract Manufacturing

Our contract manufacturing division's clients are mostly from the Australasia region with a limited number also from the United States. Competitors offering a similar service or facility to us within Australia include BresaGen Ltd. and CSL Ltd. Our ability to compete with these and other companies located elsewhere in the world will depend on our ability to remain cost competitive and to recruit and retain qualified personnel.

Item 4.D. Property, Plants and Equipment

We maintain and operate an 11,200 square foot fully-integrated pharmaceutical raw material manufacturing facility in Darra, Australia. Our principal offices are also located on the premises. The facility has the capability to develop and manufacture therapeutic products for worldwide markets and consists of 15 modular laboratories, each with a designated function. There are two independent and eight integrated laboratory modules that comply with the Code of Good Manufacturing Practice, or cGMP, and five non-cGMP laboratory modules. The cGMP laboratory modules have specific functions including media preparation, cell culture, fermentation, harvest, purification, pack and fill, and bioprocessing. The non-cGMP laboratories have functions in fermentation, research and development, and analytical services covering microbiology, biochemistry, protein and carbohydrate analysis and processing, and quality control testing.

The facility is used to manufacture a range of biological products, including PI-88 active ingredient and preparation of PI-166 for preclinical and clinical trials. It is equipped for the genetic manipulation of micro-organisms, cell culture, small and large-scale fermentation of micro-organisms, purification and downstream processing, freeze-drying, and sterile packing and filling.

Our manufacturing facility is licensed by the Australian Therapeutic Goods Administration, or TGA, for the manufacture of biological-based starting materials for human therapeutics to cGMP standards and by the Australian Office of Gene Technology Regulator for the manufacture of large scale genetically modified organisms. The TGA is a division of the Australian Department of Health and Aged Care in Canberra and a member of the International Pharmaceutical Inspection Convention. The TGA regulates the manufacture of compounds intended as starting materials for human therapeutics. In addition, the facility is licensed by the Australian National Registration Authority for manufacture of sterile and immunobiological veterinary products to cGMP standards and by the Australian Quarantine and Inspection Service as a quarantine facility.

The building in which our principal offices and manufacturing facilities are located is leased. Under a lease agreement expiring in March 2007, we pay a current rental of approximately \$68,800 per annum, subject to annual review, based on the movement in the consumer price index.

ITEM 5. OPERATING AND FINANCIAL REVIEW AND PROSPECTS

The following discussion and analysis should be read in conjunction with our financial statements and the related notes included elsewhere in this annual report.

This discussion may contain forward-looking statements based on current expectations that involve risks and uncertainties. Our actual results and the timing of selected events could differ materially from those anticipated in these forward-looking statements as a result of several factors, including those set forth in “Item 3. Key Information – Risk Factors” above and elsewhere in this annual report.

Overview

We are an Australian-based biotechnology company committed to the discovery, development and commercialization of small molecule therapeutics for the treatment of cancer and other serious diseases.

Our two cancer product candidates are PI-88 and PI-166. PI-88, our lead candidate, has completed two Phase I clinical trials in the U.S. as a single agent therapy for solid tumor cancers and as a combination therapy with the chemotherapy drug docetaxel, or taxotere. In August 2003, we completed an Australian multi-center Phase II clinical trial of PI-88 as a single agent therapy for multiple myeloma (bone marrow cancer). PI-166, our second oncology product candidate, is in a Phase I clinical trial for unresectable primary liver cancer.

Our drug discovery research program has identified a portfolio of therapeutic targets that play key roles in cancer and other serious diseases, and we are designing, synthesizing and screening small molecule compounds directed at these targets. This research program is partially funded by an AusIndustry START grant.

We operate a cGMP certified pilot manufacturing facility that provides contract manufacturing services to the biotechnology industry earning revenues on a fee for service basis. The facility has manufactured PI-88 and prepared PI-166 for all clinical trials to date.

As part of our focused strategy toward drug discovery and development, we divested our life sciences division in November 2003 and intend to pursue selective strategic alliances to complete product development and move our product candidates into the market place.

We have incurred significant losses since our inception and as of June 30, 2004, our accumulated deficit was approximately \$39.0 million. We devote a substantial portion of our financial resources to fund the development our two cancer product candidates and our drug discovery research efforts. We expect to incur additional operating losses for at least the next several years as we accelerate our drug discovery research and conduct additional clinical trials with PI-88 and PI-166, and advance into later stages of development. We may need to raise additional funds in the future to continue our operations.

Our operations have historically been financed by the issuance of capital stock because it is generally difficult to fund pharmaceutical research via borrowings due to the lack of revenues to service debt and the significant inherent uncertainty as to results of this research and the timing of those results.

Critical Accounting Policies

The following discussion and analysis of our operating and financial review and prospects are based upon our financial statements, which have been prepared in accordance U.S. generally accepted accounting principles. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of revenue, assets, liabilities and expenses. We re-evaluate our estimates on an on-going basis. Our estimates are based on historical experience and on various other assumptions that are believed to be reasonable under the circumstances. Actual results may differ from these estimates under different assumptions or conditions.

We believe the following are our critical accounting policies that affect our more significant judgments and estimates used in the preparation of our financial statements.

Revenue Recognition

Revenue is recognized when the four basic criteria of revenue recognition are met: (1) a contractual agreement exists; (2) services have been rendered; (3) the fee is fixed or determinable; and (4) collectibility is reasonably assured. For each source of revenue Progen complies with the above revenue recognition criteria in the following manner:

Revenue from the sale of services is recognized as the service is performed, and no additional services or products are required to be provided. Such revenue is predominantly derived from supplying Contract Manufacturing services and formal contracts. It is typical for us to receive upfront payments under the terms of these contracts, before performance of the contract is commenced. In these cases we defer revenue and recognize it over the periods that the contracted services are delivered.

We recognize Australian federal government grant income when research and development expenditure to which the particular grant relates has been incurred. Under the conditions of these grants the Australian government contributes 50% of eligible project expenditure up to predetermined maximums.

We recognize interest income as it is earned and when collectibility is reasonably assured.

Research and Development Expense

Research and development expense, which includes personnel costs, manufacturing and administration expenses consists of expenditures for research we conduct. We expense research and development costs as they are incurred.

In addition, although we believe that our patents and underlying technology have continuing value, the future benefits to be derived therefrom are uncertain. We, therefore, include patent costs under research and development expenses rather than capitalizing them.

Discontinued Operations

On November 11, 2003, we entered into an agreement to sell our Life Sciences business. This sale was consummated on November 28, 2003. The assets and liabilities sold have been classified in the June 30, 2003 balance sheet as held for sale, as an active plan to sell the business had been initiated prior to June 30, 2003 and we were engaged in marketing the business to potential buyers. The assets and liabilities of this business have been measured at their carrying values, which are considered to be less than their fair values. Fair value has been determined based on the proceeds from the sale of the business. In addition, the results of operations for the 2002, 2003 and 2004 fiscal years from our Life Sciences business are presented in the statement of operations as discontinued operations.

Item 5.A. Operating Results

Years ended June 30, 2004, 2003 and 2002

Revenue from Operations

Until the sale of our Life Sciences business in November 2003 we derived revenue from the following two sources:

- The sale of life science research products; and
- The provision of contract manufacturing services.

Our revenue from sales and provision of services for fiscal 2002, 2003 and 2004 is as follows (in thousands):

	Years Ended June 30,		
	2002	2003	2004
Sale of life science research products	\$1,314	\$1,742	\$1,097
Revenue from provision of contract manufacturing	704	1,052	1,394
Total revenue from sales and provision of services	\$2,018	\$2,794	\$2,491

Despite the sale of the Life Science business in November 2003 total sales only decreased 10.8% to \$2,491,486 in fiscal 2004 from \$2,793,901 in fiscal 2003 due to continued strong growth in revenue from the contract manufacturing sector.

Revenues from the provision of contract manufacturing services grew 32.5% to \$1,394,589 in fiscal 2004 from \$1,051,695 in fiscal 2003. Further, fiscal 2003 contract manufacturing revenues grew 49.4% over fiscal 2002 revenues. In Australian dollars (the Company's functional currency) revenues only grew by 8.6% in fiscal 2004 over fiscal 2003 and by 33.9% in fiscal 2003 over fiscal 2002. The increase over the past three fiscal years is due to a focused effort in gaining contract manufacturing work to utilize idle manufacturing capacity. We cannot be certain that we will be able to continue to secure new manufacturing contracts. Additionally, growth in contract manufacturing revenue will be limited by current capacity constraints at our manufacturing facility since production of PI-88 is expected to increase as both we and Medigen Biotechnology Corporation, our clinical collaborator, expand recruitment into our respective PI-88 clinical trials.

As a result of the sale of our Life Sciences business, our revenue is presently wholly-derived from the provision of contract manufacturing services. We ultimately expect to derive additional revenue from the out-licencing of our product candidates currently under development in return for milestone payments and royalties on commercial sales.

Research and Development Expenses

Our research and development expenses for compounds under development and discovery are as follows (in thousands):

	Years Ended June 30,		
	2002	2003	2004
PI-88	\$945	\$709	\$1,155
PI-166	-	64	46
Drug discovery	473	1,118	1,308
General research and development	767	544	674
Total research and development	\$2,185	\$2,435	\$3,183

Costs for PI-88 and PI-166, our two oncology compounds under development, include external direct costs such as principal investigators fees, patient recruitment fees, data monitoring charges as well as our personnel costs for preclinical, clinical and regulatory activities associated with preparing compounds for submission of new drug applications to the FDA and TGA or similar agencies. General research and development expenses include research and development management personnel costs and general laboratory costs that cannot be allocated to a specific compound or our drug discovery effort. Drug discovery costs include our personnel and associated costs incurred in relation to this effort as well as external sponsored research costs

Total research and development expenditures were \$3,183,278 for fiscal 2004 compared to \$2,435,896 for fiscal 2003 and \$2,185,066 for fiscal 2002. Research and development expenses for fiscal 2004 increased 34.4% in US dollars, however in Australian dollars the increase was only 7.1%. This increase was primarily due to PI-88 with the increased costs associated with conducting phase II human clinical trials. Investment in our drug discovery efforts has increased over the past three fiscal years with the Company being awarded an AusIndustry Start Grant which partially funds this activity. The increase of 136.4% in drug discovery costs from 2002 to 2003 coincided with the award of the AusIndustry START Grant and this increase explains the overall increase in research and development expenses between these two years.

We expect our research and development expenses to decrease in fiscal 2005 as the collaboration agreement with the Griffith University has concluded, preclinical studies of PI-166 have been completed and our PI-88 Phase I human clinical trials have finished recruiting patients. Off-setting this somewhat is the expected increase in recruitment into our PI-88 Phase II human clinical trials.

Selling, General and Administrative Costs

Selling, general and administrative costs were \$2,494,570 for fiscal 2004 compared with \$1,958,355 for fiscal 2003 and \$1,214,771 for fiscal 2002. The 27.4% increase in selling, general and administrative costs in fiscal 2004 was primarily due to movements in the exchange rate between the US dollar and the Australian dollar which is the Company's functional currency. In Australian dollars selling, general and administrative costs increased 4.3% due to a further strengthening of our business development department with an additional headcount. The increase of \$743,584 from fiscal year 2002 to fiscal year 2003 was primarily due to \$229,767 of funding for the scientific development division, responsible for the licensing of PI-166 and associated in-licensing fees, insurance costs increased by \$54,957, foreign exchange loss of \$75,420, increase in salaries \$90,400 and consulting fees of \$63,142 paid for corporate initiatives.

Other Costs of Operations

Other costs of operations fell 33.3% in fiscal 2004 over 2003 following a 66.8% fall in 2003 over 2002. These costs are the overheads of our Contract Manufacturing division that are not recovered against cost of sales and have been decreasing over the past three fiscal years as the revenue derived by this division increased. A majority of these costs are fixed and therefore as the manufacturing facility is utilized more frequently a greater portion of these costs are recovered against revenue and are shown as cost of sales.

The costs are primarily salaries and wages and repairs and maintenance.

Depreciation expense

Depreciation expense increased by \$6,673 in fiscal 2004, however in Australian dollars (our functional currency) depreciation actually reduced by A\$132,140. The decrease in depreciation (in Australian dollars) was due primarily to assets being fully depreciated. In fiscal 2003 depreciation expense increased \$151,695 due to depreciation on equipment purchases made at the end of fiscal 2002. Depreciation expense is expected to decline further in fiscal 2005 as assets continue to be fully depreciated and depreciation on our estimated capital expenditure requirements will not be sufficient to off-set that decline.

Other Income (Expenses)

We realized total net other income of \$1,078,787 in fiscal 2004 compared with \$537,991 in fiscal 2003 and \$417,658 in fiscal 2002. The components of Other Income (Expenses) as shown in our statements of operations included elsewhere in this annual report are (in thousands):

	Years Ended June 30,		
	2002	2003	2004
Share of net (losses) gains of associate accounted for using the equity method	\$(510)	\$-	\$-
Interest income	380	288	475
Interest expense	(3)	(7)	(12)
Grant income	124	435	596
Other income	74	28	20
Unrealised (loss) gain on investments	102	-	-
Realised (loss) gain on investments	251	(206)	-
Total other income	\$418	\$538	\$1,079

Interest income received varies from year to year depending on the amount of cash we have available to invest and the interest rate prevailing at that time.

Grant income relates to the funding we receive for our drug discovery program under the AusIndustry START grant. The grant is based on a 50% re-imbusement of eligible expenditure, and therefore is directly related to level of expenditure incurred on this program. The amount of the grant is capped at A\$3.1 million. The term of the grant has been extended to now expire in June 2005 when previously it was due to expire in December 2004. It is therefore anticipated that grant income will remain at similar levels in fiscal 2005.

Income Taxes

As at June 30, 2004, we had net operating loss carry forwards of approximately \$44.5 million, resulting in a deferred tax asset of approximately \$13.4 million. We had net operating loss carry forwards of \$39.7 million as at June 30, 2003. Since re-coupment of the carried loss forward is not reasonably assured, a valuation allowance has been established to offset in full the deferred tax asset resulting in a net deferred asset of \$nil.

Item 5.B. Liquidity and Capital Resources

Sources of Liquidity

Since inception, we have financed our operations primarily through public and private sales of equity and debt securities totaling approximately \$49.0 million in net proceeds. As at June 30, 2004, cash and cash equivalents totaled approximately \$9.9 million and consisted primarily of highly liquid interest bearing investments with maturities of one month or less. We believe that these investments do not constitute any material market risk exposure.

Cash Flows

We expended approximately \$3.8 million in cash and cash equivalents during the twelve months ended June 30, 2004 to finance our net operating activities. This compares to \$1.6 million and \$2.1 million for fiscal 2003 and 2002, respectively. The increase in net cash expended in fiscal

2004 over fiscal 2003 was primarily due to the \$1.2 million received from the proceeds of an investment in fiscal 2003. Payments to suppliers and employees increased in each of the last three fiscal years to June 30, 2004 as the Company's investment into its various clinical trials increased.

Cash and cash equivalents held as at June 30, 2002, 2003 and 2004 was \$6.4 million, \$8.0 million and \$9.9 respectively. The balance of cash and cash equivalents increased each fiscal year due to investments maturing and/or the raising of cash through the sale of our equity securities.

Funding Requirements

We currently have no material commitments for capital expenditures. However, we expect to incur substantial future commitments in light of our oncology clinical program and our drug discovery program. We are presently funding two Phase II multi-center clinical trials of PI-88 and one Phase Ib clinical trial of PI-166. These three ongoing trials of PI-88 and PI-166 are expected to cost approximately \$1.46 million over the next two years. In addition in September 2002, we extended our agreement with ANUTECH Pty. Ltd. agreeing to fund further research projects relating to the synthesis of heparinoid mimetics and development of the heparanase enzyme as a diagnostic and therapeutic target over a further three-year period. Our total estimated commitment under this agreement is \$159,690.

Our future cash requirements will depend on a number of factors, including: the scope and results of preclinical studies and clinical trials, continued progress of our research and development programs, including our in-licensing activities, our ability to successfully expand our contract manufacture services; our ability to generate revenue from the commercialization of PI-88, PI-166 and our drug discovery platform, and the availability of other financing.

Based upon current and expected levels of cash expenditures, we believe that our existing cash and investments resources, approximately \$11.0 million at November 30, 2004, will be adequate to satisfy the requirements of our current and planned operations through March 2006. Thereafter, to the extent that we are unable to generate cash from our operating or commercialization activities, we will be required to seek additional funding through the public or private sale of debt or equity securities. We may require additional financing before such time and we cannot be certain that we will have access to the capital markets for the sale of our securities on acceptable terms, or at all. Any shortfall in funding could result in our having to curtail our operations, including our research and development activities which could have a material adverse effect on our business, financial condition and results of operations.

Item 5.E. Off-Balance Sheet Arrangements

We have not entered into any off-balance sheet transactions, agreements or other contractual arrangements (including contingent obligations) with any unconsolidated entity that have or are reasonably likely to have a current or future effect on our financial condition, changes in financial conditions, revenues or expenses, results of operations, liquidity, capital expenditures or capital resources.

Item 5.F. Tabular Disclosure of Aggregate Contractual Obligations

The following table sets forth our aggregate contractual obligations for the three years following June 30, 2004 (in thousands):

<u>Contractual obligations</u>	Payments Due by Period		
	Total	< 1 year	1-3 years
Operating leases (principal office and manufacturing)	\$189	\$69	\$120
Sponsored research and clinical trial obligations	1,625	1,281	344
Total	\$1,814	\$1,350	\$464

We do not have any contractual obligations that extend beyond the next three years.

ITEM 6. DIRECTORS, SENIOR MANAGEMENT AND EMPLOYEES

Item 6.A. Directors and Senior Management

The following table sets forth certain information about our directors and executive officers:

<u>Name</u>	<u>Age</u>	<u>Position</u>
Stephen Chang	55	Executive Chairman
Lewis J. Lee	46	Managing Director
Prof. John R. Zalberg	52	Non-Executive Director
Patrick O. Burns	67	Non-Executive Director (1), (2)
Dr. Malvin L. Eutick	55	Non-Executive Director (1), (2)
Dr. Stanley S.C. Chang	48	Non-Executive Director
Dr. Robert H. Don	48	Vice President Research and Development
Dr. Darren M. Schliebs	36	Vice President Business Development
Linton W. P. Burns	39	Company Secretary and Chief Financial Officer
Gregory M. Orders	47	General Manager Contract Manufacturing

(1) Member of Audit Committee

(2) Member of Remuneration Committee

Stephen Chang is a founding Director and has served as Chairman from 1989 to 1994 and again since 1999. Mr. Chang is also a director of Capac International Pty. Ltd., a private import/export firm. From 2000 to 2001, Mr. Chang served as chairman of Medigen Biotechnology Corporation, and from 1977 to 2001, was a director of Australia Pacific Electric Cables Pty. Ltd. and Australia Pacific Electric Cables (Holdings) Pty. Ltd. Mr. Chang holds a B.Sc. in mechanical engineering from the National Taiwan College of Marine Science and Technology. There is no family relationship between Mr. Chang and Dr. Stanley Chang.

Lewis J. Lee has served as our Managing Director since February 2000. Prior to joining us, Mr. Lee held a number of senior management positions with F. Hoffmann-La Roche Limited, Switzerland, and its various international subsidiaries, serving respectively over a ten-year period since 1989 as the global business leader for PEGASYS™, a major Roche drug, global brand manager for Roferon-A, biotechnology division head of Roche Products Ltd., Taiwan, product manager of Roche Products Ltd. Sydney and headquarter country manager for several emerging markets in the Middle-East and Far East. Mr. Lee is also a director of Xenome Ltd., a public, non-listed Australian biotechnology company. Mr. Lee holds a B.Sc. in engineering and an M.B.A. from the University of Queensland, Australia.

Professor John R. Zalberg, M.D., Ph.D. joined as a Non-Executive Director in May 1995. He is Professor/Director of the Division of Haematology and Medical Oncology at the Peter MacCallum Cancer Institute in Melbourne, Australia. Among his numerous professional positions, Prof. Zalberg is the chairman of the Australasian Gastrointestinal Trials Group and a board member of the New South Wales Cancer Institute and Cancer Trials Australia. Prof. Zalberg was the past president of the Clinical Oncology Society of Australia from 2000 to 2001, a member of the Committee of Management of the University of Sydney Cancer Research Fund from 1997 to 1999,

and a past member of the Global Oncology Advisory Board of Pharmacia & Upjohn. Prof. Zalberg is a member of the editorial boards of Investigational New Drugs, Annals of Oncology, European Journal of Cancer, Journal of Clinical Oncology, and American Journal of Drugs. He has been the recipient of numerous research grants and has published extensively in scientific journals. Prof. Zalberg holds a Ph.D. from the University of Melbourne and is a fellow of the Royal Australian College of Physicians (Medical Oncology).

Patrick O. Burns was appointed a Non-Executive Director in March 1999. Mr. Burns is vice chairman of Euclid Systems Corporation, a private eye care company, and the chairman of its 66% subsidiary Stable Eyes Inc. He is also a director of and senior advisor to Firm View Inc a company providing computer programming to brokerage business's. He is also a senior consultant to Airline Capital Associates, Inc., a private aviation consulting company and of Ophthalmic Laboratories Pty. Limited a private Australian pharmaceutical company. Previously, Mr. Burns served as a director of Synbiotics Corp., a public company specializing in animal health care, from 1997 to 2002, a senior consultant to Early Stage Enterprises, a New Jersey venture capital fund investing primarily in developing technology growth companies, from 1997 to 2003, vice president/principal of R&D Funding Corp., the general partner of four research and development funds and an affiliate of Prudential Securities Incorporated, from 1986 to 1997, and Senior Vice President of Prudential Securities from 1991 until 1997. Mr. Burns holds an B.A. in Government from Dartmouth College and an L.L.B. from Harvard Law School. There is no family relationship between Mr. Burns and Mr. Linton W. P. Burns our Company Secretary and Chief Financial Officer.

Dr. Malvin L. Eutick, Ph.D. was appointed a Non-Executive Director in March 1999. He is a director of TUTA Healthcare Pty. Ltd. and TUTA Pharmaceuticals Pty. Ltd., which are private Australian suppliers of plastic medical devices and pre-filled pharmaceutical systems for home care, and director and chief executive officer of Ophthalmic Laboratories Pty. Limited a private Australian pharmaceutical company. Previously, Dr. Eutick served as the Chairman of Bioquest Limited, a non-listed public Australian biotechnology company specializing in the supply of molecular biology products, equipment and training, and a director of Starrate Australia Pty. Ltd., a private Australian biotechnology company. Dr. Eutick holds a B.Sc. and a Ph.D. in biochemistry from the University of Sydney, Australia and was awarded the Medal of the Order of Australia for services to biotechnology.

Dr. Stanley Chang, M.D., Ph.D. was appointed a Non-Executive Director in February 2001, and is the chief executive officer and managing director of Medigen Biotechnology Corporation, a Taiwan-based biotechnology company. Dr. Chang also serves as a director of MediGreen Biotechnology Corp., a 40% Taiwanese subsidiary of Medigen Biotechnology Corporation, and GeneTrol Biotherapeutics, Inc., a private U.S. biotechnology company. Dr. Chang is also the president and executive director of ACM Medical Technologies LLC and a director of The New Century Health Care Promotion Foundation. Previously, Dr. Chang was chairman of the Faculty of Medicine of Tzu Chi College of Medicine and Humanities, Taiwan, from 1996 to 2000, and a consultant urologist at the Department of Urology of Tzu Chi General Hospital from 1988 to 2000. Dr. Chang served on the editorial board of *The Journal of Ultrasound in Medicine* from 1996 to 1998 and from 1998 to 2000, and is a fellow of the Association of Urology, Taiwan and the Society of Ultrasound in Medicine, Taiwan. Dr. Chang is the recipient of numerous research grants and has published many scientific articles. He holds an M.D. from the College of Medicine at the National Taiwan University and a Ph.D. from the Department of Surgery, University College London

Medical School at the University of London, United Kingdom. There is no family relationship between Dr. Chang and Mr. Stephen Chang, our Chairman.

Dr. Robert H. Don, Ph.D. joined us in 1994 as Vice President of Research and Development. Prior to joining us, Dr. Don was a program leader at the Center for Molecular Biology and Biotechnology at the University of Queensland, Australia, from 1989 to 1994, leading a research group in the study of molecular genetics of embryonal development. Previously, Dr. Don was a research scientist at the Commonwealth Scientific and Industrial Research Organization, or CSIRO, in Brisbane where he worked on development of animal vaccines as part of a collaborative research program with CSL Ltd., a senior scientific officer at the Oncology Research Center, Prince of Wales Hospital in Sydney, and a research fellow of the Department of Medical Biochemistry at the University of Geneva, Switzerland, in collaborative research with the Bayer AG. Dr. Don has published numerous articles on molecular genetics. He holds a B.Sc. and a Ph.D. in microbiology from the University of Queensland, Australia.

Dr. Darren M. Schliebs, Ph.D. joined us in May 2003 as Vice President of Business Development. Prior to joining us, Dr. Schliebs served from 1998 to 2003 in various business development and scientific positions for Alchemia Limited, an Australian public biotechnology company, and its U.S. business development subsidiary, where he was most recently based in the San Francisco Bay Area as business development manager. Dr. Schliebs is an inventor of a patent relating to carbohydrate-based drug discovery, and has published several articles on carbohydrate and natural product chemistry in scientific journals and magazines. Dr. Schliebs holds a B.Sc. in organic chemistry from the University of Adelaide, Australia, and a Ph.D. in organic chemistry from The Australian National University, Canberra, Australia.

Linton W. P. Burns joined us in August 2004 as Chief Financial Officer and Company Secretary. Prior to joining us, Mr. Burns spent 5 years as chief financial officer and company secretary for ASX listed biotechnology company BresaGen Limited. Preceding that role Mr. Burns was the New Zealand general manager for the information solutions company, Equifax Ltd. Prior to that he held senior financial positions with Equifax in Australia and the United Kingdom. Mr. Burns holds a Bachelor of Arts in Accountancy from the University of South Australia, Adelaide, Australia and is a member of the Australian Institute of Chartered Accountants.

Gregory M. Orders joined us in April 2001 as Quality Assurance Manager, served as the Acting General Manager of Contract Services from October 2001 until August 2002, at which time he was appointed General Manager Contract Manufacturing. From 1995 to 2001, Mr. Orders held various positions in quality assurance and pharmaceutical manufacture for Sigma Pharmaceuticals Pty. Ltd, an Australian-based contract pharmaceutical manufacturer. From 1993 to 1995, he worked at the virology and bacteriology laboratories of Fernz Corporation, a New Zealand manufacturer of interferon tablets. Mr. Orders holds a B.Sc. and a Masters in molecular science from LaTrobe University in Melbourne, Australia.

Alternate Director

Eugene Cheng was appointed the alternate director for Dr. Stanley Chang on March 24, 2003 and is the chief operating officer of Medigen Biotechnology Corporation. From 2000 to 2003 Mr. Cheng was a partner of E-telint Capital Partners, a Silicon Valley based venture capital firm. From 2000 to 2001, Mr. Cheng was the president of Advanced Semiconductor Engineering, Inc., a publicly held Taiwanese corporation and one of the largest global providers of semiconductor manufacturing services. From 1987 to 1999, Mr. Cheng occupied various management positions with Acer Inc., a publicly held Taiwanese corporation and one of the world's top branded PC vendors, serving from 1995 to 2000 as chief of staff of Acer Information Products Group. Mr. Cheng holds a B.E. in chemical engineering from the Chung Yuan College of Science and Engineering, Chung Li, Taiwan, and an M.B.A. from the Management School of the National Sun Yat-sen University, Kaohsiung, Taiwan.

Our executive officers are appointed by, and serve at the pleasure of, our board of directors. There are no family relationships among our directors or executive officers. No director has a contractual right to serve as a member of our board of directors.

Item 6.B. Compensation

The following table sets forth certain information concerning the compensation that we paid to our directors and our five most highly compensated executive officers, both individually and as a group, during the fiscal year ended June 30, 2004:

<u>Name and Principal Position</u>	<u>Annual Compensation</u>					<u>TOTAL</u>
	<u>Salary</u> (1)	<u>Directors' Fees</u>	<u>Superannuation Contributions</u> (2)	<u>Automobile Allowance</u>	<u>Stock Options</u> (3)	
Stephen Chang Chairman and Executive Director	\$134,786	-	\$12,131	-	\$58,892	\$205,809
Lewis J. Lee Executive Director and Managing Director	179,470	-	16,152	12,122	58,893	266,637
Prof. John R. Zalberg Non-Executive Director	-	28,154	2,534	-	23,557	54,245
Patrick O. Burns Non-Executive Director	-	30,688	-	-	23,557	54,245
Dr. Malvin L. Eutick Non-Executive Director	-	28,154	2,534	-	23,557	54,245
Dr. Stanley S.C. Chang Non-Executive Director	-	30,688	-	-	23,557	54,245
Dr. Robert. H. Don Vice President Research and Development	84,607	-	7,615	-	18,846	111,068
Dr. Darren M. Schliebs Vice President Business Development	78,523	-	7,067	-	14,134	99,724
Milton S. McColl Company Secretary and Chief Financial Officer (4)	71,715	-	6,454	7,627	23,557	109,353
Gregory M. Orders General Manager Contract Manufacturing	69,590	-	6,263	-	18,846	94,699

Rodney A. Stewart Sales and Marketing Manager (Life Sciences) until November 28, 2003	36,079	-	2,313	-	-	38,392
All directors and executive officers as a group (11 persons)	\$654,770	\$117,684	\$63,063	\$19,749	\$287,396	\$1,142,662

- (1) No part of the compensation shown was paid pursuant to a material bonus or profit-sharing plan.
- (2) We are obligated to contribute to various superannuation plans to provide pension, retirement or similar benefits under the Australian Superannuation Guarantee Legislation. Contributions are at set percentages of salaries and wages. We have no responsibility for the administration or performance of the superannuation plans. We have not established any superannuation plans.
- (3) During the 2004 fiscal year stock options were granted to all directors and executive officers under our 2003 directors and employee incentive plan. The grant of options to all directors and executive officers followed shareholder approval of the issue of stock options under this plan at the 2003 annual general meeting of shareholders. The options were issued free of charge. Each option entitles the holder to subscribe for one fully paid ordinary share in the Company at an exercise of A\$2.50. The options expire on May 31, 2005. The estimated value of these options is calculated at the date of grant using the Black-Scholes option pricing model.
- (4) Mr. McColl resigned in August 2004.

Item 6.C. Board Practices

We currently have six directors. Our constitution provides that at least one-third of our directors (except our managing director) must retire at each annual general meeting of shareholders. As a result, only a portion of our board of directors will be elected each year. Prof. Zalberg was re-elected at the 2002 annual general meeting of shareholders and Dr. Eutick was re-elected at the 2003 annual general meeting of shareholders. Mr. Stephen Chang, Dr. Stanley Chang and Mr. P Burns were re-elected at our 2004 annual general meeting of shareholders. The terms of Prof. Zalberg and Dr. Eutick will expire at our 2005 annual general meeting of shareholders.

No termination benefits are provided to directors other than statutory superannuation.

Audit Committee. Our audit committee currently consists of Mr. P. Burns and Dr. Eutick (Chair), both of whom are non-management members of our board of directors. The authority and responsibilities of our audit committee are set forth in its charter and includes:

- The appointment, compensation, retention, and oversight of the work of the independent auditors who report directly to the audit committee;
- The approval of all audit and non-audit engagements and fees with the independent auditors;
- The authority to engage, without board approval, independent legal counsel and other advisors, at the Company's expense, as deemed necessary to carry out its duties;
- Reviewing and monitoring the framework of our internal controls and the objectivity of our financial reporting;

- Oversight of the internal audit function including the adequacy and effectiveness of the Company's internal controls over financial reporting and disclosure controls and procedures;
- Reviewing, prior to filing, our unaudited interim or audited annual financial statements and discussing the statements and reports with our management and the independent auditors, including any significant adjustments, management judgments and estimates, new accounting policies and disagreement with management;
- Reviewing and discussing with management the Company's interim and year-end earnings press releases prior to the release being issued; and
- Establishing and reviewing procedures for complaints received by us regarding accounting matters.

Remuneration Committee. Our remuneration committee currently consists of Dr. Eutick and Mr. P. Burns, who are non-management members of our board of directors. The function of our remuneration committee includes:

- Reviewing and, as it deems appropriate, recommending to our board of directors, policies, practices and procedures relating to the compensation arrangements for management and other personnel, including the granting of options under our option plans;
- Establishing and reviewing general compensation policies with the objective to attract and retain superior talent, reward individual performance and achieve our financial goals; and
- Advising and consulting with our executive officers regarding managerial personnel and development.

Item 6.D. Employees

As of June 30, 2004, we had a workforce of 40 full-time employees, of whom 13 hold Ph.D. degrees, and 9 hold other advanced degrees. Of our total workforce, 17 are engaged in research and development, 9 in manufacturing operations, 4 in quality assurance, seven in sales and marketing, and 10 in business development, finance and administration. None of our employees are represented by a labor union, nor have we experienced work stoppages. We believe that our relations with our employees are good. We also maintain consulting agreements with a number of scientists at various universities and other research institutions.

Item 6.E. Share Ownership

Information about the share ownership and option holdings of our directors and executive officers is disclosed below in "Item 7.A. Major Shareholders."

Option Plans

In September 1995, our shareholders approved an employee option plan. All our employees (including directors) who are at least 18 years of age are eligible to participate in the plan. Pursuant to the plan, we will not grant any option if, after such issuance, the number of options issued to non-executive directors and non-executive employees during the previous five years whether or not exercised and which have not yet terminated or expired would exceed 5% of the then total number of outstanding ordinary shares. All grants of options to directors pursuant to the plan require the prior approval from our shareholders. As of December 2, 2004, there were no outstanding options to purchase ordinary shares under the 1995 employee option plan.

In November 1999, our shareholders approved the executive directors' option plan. Only our directors who hold salaried employment are eligible to participate in the plan. Our board of directors may impose any conditions upon the vesting or exercise of any options granted under the plan. As of December 2, 2004, there were outstanding options under the executive 1999 directors' option plan to purchase a total of 400,000 ordinary shares at a weighted average exercise price of A\$6.46 per share expiring on February 8, 2005.

In October 2000, our board of directors approved an employee option plan. In accordance with Australian law, we will not grant any option if, after such issuance, the number of options issued to non-executive directors and non-executive employees during the previous five years whether or not exercised and which have not yet terminated or expired would exceed 5% of the then total number of outstanding ordinary shares. All our employees and our executive and non-executive directors are eligible to participate in the plan. As approved by our shareholders in November 2000, all grants of options under the plan to employees who are not directors may be made without shareholder approval. However, in accordance with Australian Stock Exchange Listing Rules all grants of options to directors require the prior approval from our shareholders. The plan also provides that the minimum exercise price must be A\$4.00 per share for initial grants under the plan and, thereafter, must equal the greater of A\$4.00 or 125% of the weighted average market price of our ordinary shares as quoted on the Australian Stock Exchange for the ten business days prior to the option grant. As of December 2, 2004, there were outstanding options under the 2000 employee option plan to purchase an aggregate of 178,820 ordinary shares at an exercise price of A\$4.00 per share of which options to purchase a total of 350,000 ordinary shares expire on December 22, 2005 and options to purchase a total of 232,020 ordinary shares expire on February 28, 2006.

In October 2003, our shareholders approved the directors and employee incentive scheme and the allotment thereunder of options issuable for a total of 900,000 ordinary shares to our directors and options issuable for a total number of 900,000 ordinary shares to our employees. All our directors and all employees, whether full time or part time, are eligible to participate in the scheme. Options to purchase a total of 900,000 ordinary shares were subsequently issued to directors and options to purchase a total of 900,000 ordinary shares were issued to our employees. In accordance with Australian Stock Exchange Listing Rules, all grants of options to directors under the scheme require the prior approval from our shareholders. The scheme also provides that all options granted under the scheme have an exercise price of A\$2.50 per share and will expire on May 31, 2005. As of December 2, 2004, there were 1,398,221 outstanding options to purchase ordinary shares under the 2003 directors and employees incentive scheme.

In November 2004, our shareholders approved the directors and employee option incentive plan. All our directors and all employees, whether full time or part time, are eligible to participate in this plan. Pursuant to the plan, we will not grant any options if, after issuance and subject to limited exceptions, the number of ordinary shares issuable upon exercise of such options together with the number of ordinary shares issuable upon exercise of options granted under our other employee shares schemes and the number of ordinary shares issued during the previous five years in accordance with an employee share scheme exceeds 5% of the then total number of outstanding ordinary shares. All grants of options to directors under the plan require the prior approval from our shareholders. The minimum exercise price of options granted under this plan shall not be less than the average closing share price as recorded on the Australian Stock Exchange in the five business days preceding the grant of those options. The expiry date of options issued under this plan can not exceed 10 years from the date of grant. As of December 2, 2004, no options have been issued under this plan.

ITEM 7. MAJOR SHAREHOLDERS AND RELATED PARTY TRANSACTIONS

Items 7.A. Major Shareholders

The following table sets forth as of December 2, 2004, certain information with respect to the ownership of our outstanding ordinary shares and options to purchase ordinary shares by:

- Each person who is known to us to be the beneficial owner of 5% or more of our ordinary shares;
- Each of our directors and executive officers; and
- All our directors and executive officers as a group.

<u>Name</u>	<u>Number of Issued Ordinary Shares</u>	<u>Percentage of Issued Ordinary Shares (1)</u>	<u>Number of Ordinary Shares Issuable Pursuant to Options</u>
Medigen Biotechnology Corporation	1,961,350	5.5%	-
Stephen Chang (2)	432,377	*	379,047
Lewis J. Lee (3)	-	-	610,000
Prof. John R. Zalcborg (4)	15,849	*	175,000
Patrick O. Burns (5)	500	*	175,062
Dr. Malvin L. Eutick (6)	-	-	175,000
Dr. Stanley S.C. Chang (7)	-	-	100,000
Dr. Robert H. Don (8)	-	-	102,000
Dr. Darren M. Schliebs (9)	2,000	*	62,000
Milton S. McColl (10)	-	*	-
Linton W. P. Burns (10)	-	*	-
Gregory M. Orders (11)	-	-	80,000
All directors and executive officers As a group (10 persons) (12)	450,726		1,858,109

* Represents less than 1%.

(1) Based on 35,510,121 issued ordinary shares as of December 2, 2004. Excludes ordinary shares issuable pursuant to options granted under our 1995 employee option plan, 1999 executive directors' option plan, 2000 employee option plan and 2003 directors and employee incentive scheme, which are more fully described above in "Item 6. Directors, Senior Management and Employees – Option Plans."

(2) Includes (a) 432,377 ordinary shares held of record by Mr. Stephen Chang and Mrs. Lisa Chang Super Fund, (b) 75,000 ordinary shares issuable upon exercise of an option granted under our 2000 employee option plan exercisable at any time on or before December 22, 2005 at an exercise price of A\$4.00 per share, (c) 250,000 ordinary shares issuable upon exercise of an option granted under our 2003 directors and employee incentive scheme at any time on or before May 31, 2005 at an exercise price of A\$2.50 per share, and (d) 47,077 ordinary shares issuable upon exercise of an option held of record by Mr. Stephen Chang and Mrs. Lisa Chang Super Fund and 6,970 ordinary shares issuable upon exercise of an option held of record by Capac International Pty. Ltd. of which Mr. Chang is a director and majority shareholder granted under our 2003 one for eight Bonus Option issue exercisable at any time on or before May 31, 2005 at an exercise price of A\$2.50 per share.

(3) Includes (a) 100,000 ordinary shares issuable upon the exercise of an option granted under our 1999 executive directors' option plan exercisable at any time on or before February 8, 2005 at an exercise price of A\$4.46 per share, (b) 200,000 ordinary shares issuable upon the exercise of an option granted under our 1999 executive directors' option plan exercisable at any time on or before February 8, 2005 at an exercise price of A\$6.24 per share, (c) 100,000 ordinary shares issuable upon the exercise of an option granted under our 1999 executive directors' option plan exercisable at any time on or before February 8, 2005 at an exercise price of A\$8.91 per share, (d) 50,000 ordinary shares issuable upon exercise of an option granted under our 2000 employee option plan exercisable at any time on or before December 22, 2005 at an exercise price of A\$4.00 per share, and (e) 160,000 ordinary shares issuable upon exercise of an option granted under our 2003 directors and employee incentive scheme at any time on or before May 31, 2005 at an exercise price of A\$2.50 per share

(4) Includes (a) 75,000 ordinary shares issuable upon exercise of an option granted under our 2000 employee option plan exercisable at any time on or before December 22, 2005 at an exercise price of A\$4.00 per share, and (b) 100,000 ordinary shares issuable upon exercise of an option granted under our 2003 directors and employee incentive scheme at any time on or before May 31, 2005 at an exercise price of A\$2.50 per share.

(5) Includes (a) 75,000 ordinary shares issuable upon exercise of an option granted under our 2000 employee option plan exercisable at any time on or before December 22, 2005 at an exercise price of A\$4.00 per share, (b) 100,000 ordinary shares issuable upon exercise of an option granted under our 2003 directors and employee incentive scheme at any time on or before May 31, 2005 at an exercise price of A\$2.50 per share, and (c) 62 ordinary shares issuable upon exercise of an option granted under our 2003 one for eight Bonus Option issue exercisable at any time on or before May 31, 2005 at an exercise price of A\$2.50 per share

(6) Includes (a) 75,000 ordinary shares issuable upon exercise of an option granted under our 2000 employee option plan exercisable at any time on or before December 22, 2005 at an exercise price of A\$4.00 per share, and (b) 100,000 ordinary shares issuable upon exercise of an option granted under our 2003 directors and employee incentive scheme at any time on or before May 31, 2005 at an exercise price of A\$2.50 per share.

(7) Includes 100,000 ordinary shares issuable upon exercise of an option granted under our 2003 directors and employee incentive scheme at any time on or before May 31, 2005 at an exercise price of A\$2.50 per share. Dr. Chang is the chief executive officer of Medigen Biotechnology Corporation and disclaims beneficial ownership of the ordinary shares held by Medigen Biotechnology Corporation.

(8) Includes (a) 22,000 ordinary shares issuable upon exercise of an option granted under our 2000 employee option plan exercisable at any time on or before February 28, 2006 at an exercise price of A\$4.00 per share, and (b) 80,000 ordinary shares issuable upon exercise of an option granted under our 2003 directors and employee incentive scheme at any time on or before May 31, 2005 at an exercise price of A\$2.50 per share.

(9) Includes (a) 22,000 ordinary shares issuable upon exercise of an option granted under our 2000 employee option plan exercisable at any time on or before February 28, 2006 at an exercise price of A\$4.00 per share, and (b) 40,000 ordinary shares issuable upon exercise of an option granted under our 2003 directors and employee incentive scheme at any time on or before May 31, 2005 at an exercise price of A\$2.50 per share.

(10) Mr. McColl resigned as Company Secretary and Chief Financial Officer in August 2004 and was replaced by Mr. L. Burns.

(11) Includes 80,000 ordinary shares issuable upon exercise of an option granted under our 2003 directors and employee incentive scheme at any time on or before May 31, 2005 at an exercise price of A\$2.50 per share.

(12) On a fully-diluted basis that takes into account 1,858,109 ordinary shares issuable pursuant to options granted under either our 1999 executive directors' option plan, 2000 employee option plan or 2003 directors and employee incentive scheme, all directors and executive officers as a group would have an interest in 6.2% of our issued and outstanding ordinary shares. This total excludes Mr. M. McColl who resigned in August 2004.

As of December 2, 2004, a total of 3,485,232 ordinary shares (or 9.81% of the total number of our ordinary shares then outstanding) were held by seven holders with registered addresses in the United States. We believe we have approximately 1,175 beneficial shareholders in the United States.

To the best of our knowledge, we are not owned or controlled, directly or indirectly, by another corporation, by any foreign government or by any other natural or legal persons severally or jointly, and we disclaim control by the companies, entities or individuals listed in the table above. We do not know of any arrangements in place that could result in a change in control of our company.

Item 7.B. Related Party Transactions

Except as disclosed herein and elsewhere in this annual report, there were no material transactions to which we were a party and in which any of our directors, executive officers or major shareholders (or any of their affiliates, associates or enterprises) were involved since July 1, 2003.

None of our directors, executive officers or major shareholders (or any of their affiliates, associates or enterprises) was indebted to us at any time since July 1, 2003.

ITEM 8. FINANCIAL INFORMATION

Item 8.A. Consolidated Statements and Other Financial Information

Our audited financial statements and related notes for our fiscal years ended June 30, 2002, 2003 and 2004 are contained on pages F-1 through F-24 of this annual report.

Export Sales

The following table indicates the percent of revenues derived from export.

	For the Years Ended June 30,		
	2002	2003	2004
Contract manufacture	55.5%	74.3%	18.2%

The percentage of contract manufacturing revenues derived from customers outside Australia fluctuates as these contracts are typically adhoc in nature. We entered into a significant contract with another Australian based biotechnology company in fiscal 2003. We earned \$786,000 in revenue from this contract in fiscal 2004, or 56.3% of total revenue. As a result, our export revenues declined as we have limited manufacturing capacity.

Legal Proceedings

There is no litigation of a material nature pending or threatened against our property or the Company.

Dividend Policy

We have never declared cash dividends on our ordinary shares and have no present intention of declaring such cash dividends in the foreseeable future. Our board of directors will not be able to recommend the payment of any dividends until we make a profit. Future profitability will depend on future earnings and our working capital requirements. Our board of directors currently intends to reinvest income in the continued development and operations of our business. We expect to continue to generate operating losses on our research and development projects until products arising from our research and development activities are successfully commercialized. Factors beyond our control, such as market competition, exchange rate fluctuations and changing government policy may also affect profitability and our capacity to pay dividends.

Item 8.B. Significant Changes

Except as disclosed elsewhere in this annual report, no significant change has occurred since the date of the annual financial statements included in this annual report.

ITEM 9. THE OFFER AND LISTING

Item 9.C. Markets

The principal non-United States trading market for our ordinary shares is the Australian Stock Exchange, or the ASX, on which our ordinary shares have been trading under the code "PGL" since December 1995. Prior to that time, there was no established public trading market for our ordinary shares. Our ordinary shares are also quoted on the Nasdaq SmallCap Market under the symbol "PGLAF."

Price Range of Ordinary Shares

Australian Stock Exchange (ASX)

The following table sets forth the high and low closing sales prices in Australian dollars and the trading volume of our ordinary shares as reported on the ASX during the periods indicated:

	High	Low	Trading Volume
<u>Yearly Data:</u>			
Fiscal year 2000	A\$ 5.55	A\$ 1.75	6,436,562
Fiscal year 2001	2.83	1.02	9,081,542
Fiscal year 2002	2.02	0.75	5,385,169
Fiscal year 2003	1.25	0.50	3,310,777
Fiscal year 2004	3.76	0.72	25,976,500
<u>Quarterly Data:</u>			
Third Quarter 2002	1.25	0.96	284,203
Fourth Quarter 2002	1.00	0.75	359,780
First Quarter 2003	0.95	0.72	348,846
Second Quarter 2003	1.18	0.48	2,317,800
Third Quarter 2003	2.27	0.72	4,937,400
Fourth Quarter 2003	1.70	1.40	2,886,700
First Quarter 2004	3.45	1.49	10,320,200
Second Quarter 2004	3.76	2.75	7,832,200
Third Quarter 2004	4.75	3.25	5,403,317
Fourth Quarter 2004 (through November 30, 2004) ...	6.46	4.66	5,061,054
<u>Monthly Data:</u>			
June 2004	3.63	3.20	1,580,300
July 2004	3.90	3.25	1,766,900
August 2004	4.25	3.80	1,815,200
September 2004	4.75	4.09	1,821,217
October 2004	6.46	4.66	2,494,840
November 2004	5.90	4.90	2,566,214

Nasdaq SmallCap Market

The following table sets forth the high and low closing sales prices in United States dollars and the trading volume of our ordinary shares as reported on the Nasdaq SmallCap Market during the periods indicated:

	<u>High</u>	<u>Low</u>	<u>Trading Volume</u>
<u>Yearly Data:</u>			
Fiscal year 2000	\$4.063	\$1.000	4,223,100
Fiscal year 2001	1.688	0.563	3,112,300
Fiscal year 2002	0.990	0.410	948,645
Fiscal year 2003	0.880	0.300	2,478,639
Fiscal year 2004	3.240	0.510	18,534,500
<u>Quarterly Data:</u>			
Third Quarter 2002	0.650	0.530	65,014
Fourth Quarter 2002	0.570	0.370	209,095
First Quarter 2003	0.550	0.340	27,600
Second Quarter 2003	0.880	0.300	2,176,930
Third Quarter 2003	1.250	0.510	2,887,600
Fourth Quarter 2003	1.330	0.910	3,147,700
First Quarter 2004	3.110	1.120	7,084,100
Second Quarter 2004	3.240	1.750	5,415,100
Third Quarter 2004	3.370	2.250	1,205,500
Fourth Quarter 2004 (through November 30, 2004) ...	5.140	3.310	1,205,800
<u>Monthly Data:</u>			
June 2004	2.550	2.200	465,200
July 2004	2.700	2.250	468,500
August 2004	3.030	2.570	392,300
September 2004	3.370	2.730	344,700
October 2004	5.140	3.310	841,900
November 2004	4.440	3.700	363,900

On December 2, 2004, the closing sales price in U.S. Dollars of the ordinary shares as reported on the ASX and the Nasdaq SmallCap Market was \$3.78 and \$3.76, respectively.

ITEM 10. ADDITIONAL INFORMATION

Item 10.B. Memorandum and Articles of Association

The following description of our ordinary shares, including brief summaries of the rights of our shareholders as conferred by our constitution and Australian law, and certain matters respecting directors, is not complete and is qualified by reference to Australian law and our constitution. Our constitution may be inspected and copied at the Public Reference Section of the Securities and Exchange Commission at 450 Fifth Street, N.W., Washington, D.C. 20549.

General

Our issued capital is made up of 35,510,121 ordinary shares. All our ordinary shares are fully paid and non-assessable. Holders of our ordinary shares have no preemptive or conversion rights, and there are no redemption or sinking fund provisions applicable to our ordinary shares.

Other than the provisions contained in the Foreign Acquisitions and Takeovers Act 1975 as briefly described below under “Exchange Controls – Foreign Acquisitions and Takeovers Act of 1975,” there are no restrictions on overseas residents from holding our ordinary shares. In addition, there are no restrictions either at law or in our constituent documents, which limit the right of nonresident shareholders to vote at our general meetings.

Directors

One third of our directors (except the managing director) must retire at each annual general meeting of shareholders. Retiring directors are eligible for re-election at the annual general meeting at which the retirement occurs. Any person under the age of 72 may be appointed or reappointed as a director, unless otherwise permitted by a special resolution of our shareholders at a general meeting. There is no share qualification for directors. At any meeting of our directors, a director who has a direct or indirect material personal interest in a matter may not vote on or in relation to such matter, unless otherwise permitted by ordinary resolution of our shareholders at a general meeting. Remuneration of non-executive directors is determined by ordinary resolution at a general meeting of shareholders. Our constitution does not limit the borrowing powers of the company exercisable by our directors.

General Meetings of Shareholders

We must convene an annual general meeting of shareholders within five months after the end of each fiscal year and may convene other general meetings of shareholders when necessary or at the request of a shareholder holding at least 5% of our paid up capital carrying voting rights. The annual general meeting of our shareholders is generally convened by our company secretary pursuant to resolution of our board of directors.

Ordinary resolutions, such as the election of directors, may be passed by simple majority of the votes cast. Special resolutions, such as amendments to our constitution, a change of our corporate name, a reduction in our share capital or the voluntary winding-up of our company, require the affirmative vote of at least 75% of the votes cast.

Written notice setting out the agenda of general meetings must be given to all shareholders of record at least 28 days prior to a general meeting. A quorum for a general meeting is the presence of at least three shareholders in person.

Voting Rights

Every registered holder of our ordinary shares is entitled to attend general meetings of our shareholders in person or by proxy and has one vote on a show of hands unless a poll is demanded. If a poll is demanded, each registered holder present in person or by proxy is entitled to one vote for each fully paid ordinary share held.

Dividend Rights

Our board of directors may declare final dividends and interim dividends. No dividend may be paid except out of our profits.

Under Queensland law, dividends that are not claimed by the person entitled cannot be forfeited. After six years, we must enter the amount in a register that we will maintain. If the monies are not claimed after one year of entry on the register, we must pay such amounts to the Queensland Public Trustee from whom the person entitled may claim the monies. Both we and the Queensland Public Trustee are obligated to advertise the existence of unclaimed monies in the Queensland Government Gazette.

Liquidation Rights

On a winding-up or other return of capital, holders of our ordinary shares have the right to the payment of any capital paid up on the ordinary shares and are entitled to participate in any surplus assets, if any, in proportion to their shareholdings.

Variation of Rights

The rights attaching to our ordinary shares can be varied only by a special resolution of our shareholders and, if a distinct class of shares with different rights is established, by both a special resolution of shareholders of the class and our shareholders generally.

Change in Control

Our constitution does not contain any specific provisions that would have an effect of delaying, deferring or preventing a change in control in our company or that would operate only with respect to a merger, acquisition or corporate restructuring involving our company.

Disclosure of Shareholder Ownership Thresholds

Our constitution does not contain any provision relating to the disclosure of shareholder ownership thresholds. However, under the Australian Corporations Act, a person who holds at least 5% of the shares of an Australian company listed on the Australian Stock Exchange is required to give us certain information relating to such ownership.

United States Transfer Agent and Registrar

The United States transfer agent and registrar for our ordinary shares is Computershare Investor Services US.

Item 10.C. Material Contracts

Information about material contracts, other than contracts entered into in the ordinary course of business, to which we are a party and which we have entered into during the two immediately preceding fiscal years are disclosed above in “Item 4. Information on the Company”.

Items 10.D. Exchange Controls

In the early 1980s, the Australian Government began a program of deregulation of the Australian financial sector. This led to the introduction of competition from foreign banks and, perhaps more notably, the deregulation of foreign exchange controls. Deregulation has been at the forefront of Australian Government policy since the early 1980's and, except as discussed below, there are no laws or regulations in Australia that restrict the export or import of capital or affect the remittance of dividends or other payments to holders of our ordinary shares who are nonresidents of Australia, subject to withholding taxes under Australian law with respect to remittances of dividends (to the extent the taxes on the dividends are not paid by us) and interest payments. See "Taxation" below.

The Foreign Acquisitions and Takeovers Act 1975

The Foreign Acquisitions and Takeovers Act 1975 is an act of the Parliament of the Commonwealth of Australia which seeks to regulate overseas investment in Australia. By and large, the Government's policy is to encourage foreign investment provided that it is consistent with the needs of the Australian community. Although restrictions are applied in certain areas, in the majority of industry sectors, proposals are approved unless they are judged contrary to the national interest. The Act requires compulsory notification of certain proposed acquisitions of Australian assets and makes other proposed acquisitions and arrangements subject to prohibition or divestiture after they have been examined and found to be contrary to the national interest.

The Financial Transactions Reports Act 1988

The Financial Transactions Reports Act 1988 is an act of the Parliament of the Commonwealth of Australia, designed to facilitate the administration and enforcement of Australia's revenue laws. It provides for the reporting of certain financial transactions and transfers, including the export or import of currency exceeding A\$10,000 to the Cash Transactions Reporting Agency.

The Income Tax Assessment Act of 1936 and the Income Tax Assessment Act of 1997 (collectively, the "Tax Act")

The Tax Act is the principal law of the Commonwealth of Australia, concerning the collection and administration of taxes (except goods and services tax). Under the Tax Act, overseas residents are obliged to pay income tax in Australia on income derived from Australian sources.

Item 10.E. Taxation

The following is a summary of the current tax laws of Australia as they relate to us and our shareholders, including United States and other non-Australian shareholders. The summary is based upon laws and relevant interpretations thereof in effect as of the date of this annual report, all of which are subject to change, possibly on a retroactive basis. The discussion does not deal with all possible tax consequences relating to an investment in the ordinary shares. In particular, the discussion does not address estate and gift tax issues or the tax consequences under state, local and other non-federal systems of tax.

Prospective purchasers of ordinary shares are advised to consult their own tax advisors with respect to the specific tax consequences to them of the purchase, ownership and disposition of ordinary shares, including, in particular, the effect of any foreign, state or local taxes.

Non-Australian residents are liable to pay tax on income derived from Australian sources. The mechanism by which that tax is paid (for nonresidents who have no permanent establishment in Australia or where the income is not connected with a permanent establishment) is known as withholding tax. Dividends paid by a resident Australian company to a resident of the United States of America are subject to withholding tax at the rate of 15%. The rate of withholding tax on dividends is normally 30%, but since the United States has concluded a double tax treaty agreement with Australia, the rate is reduced to 15%. It should be noted, however, that under Section 128B(3) of the Tax Act, to the extent that dividends paid to nonresidents have been franked (generally where a company pays tax itself), such dividends are exempt from withholding tax. Franked dividends is the expression given to dividends when the profits out of which those dividends are paid have been taxed in our hands. Accordingly, an Australian company paying fully franked dividends to a nonresident is not required to deduct any withholding tax. Dividends on which withholding tax has been paid are not subject to any further Australian tax. In other words, the withholding tax represents the final Australian tax liability in relation to those dividends.

The pertinent provisions of the double tax treaty between Australia and the United States provide that dividends are primarily liable for tax in the country of residence of the beneficial owner. However, the source country, in this case Australia, may also tax them, but in such case the tax will be limited to 15%. Where the beneficial owner is a United States resident company that holds at least 10% of us, the tax will be limited to 5%. The 15% limit does not apply to dividends derived by a resident of the United States of America who has a permanent establishment or fixed base in Australia, if the holding giving rise to the dividends is effectively connected with that establishment or base. Such dividends are taxed in the normal way as business profits or independent personal services income as the case may be.

We have not paid any cash dividends since our inception and we do not anticipate the payment of cash dividends in the foreseeable future. Additionally, we expect to incur additional operating losses until products arising from our research and development programs are successfully commercialized. See "Item 8.A. Consolidated Statements and Other Financial Information—Dividend Policy."

Capital gains tax in Australia is payable on real gains over the period in which the shares have been held, that is, the difference between the selling price and the original cost price. The cost

price is indexed for inflation if the shares have been held for more than one year, and individual taxpayers can, with respect to shares held for more than one year, elect to forego indexation of the cost base in exchange for being taxed on 50% of the realized gain. Capital losses are available as deductions but only against other capital gains.

Queensland Stamp Duty

Effective July 1, 2001, ordinary shares traded on the Australian Stock Exchange and Nasdaq will not be subject to stamp duty.

ITEM 11. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

The primary objective of our investment activities is to preserve principal and, at the same time, maximize income without significantly increasing risk. At June 30, 2004, our cash and cash equivalents consisted primarily of highly liquid investments with maturities of one month or less. We believe that these investments do not constitute any material market risk exposure.

In fiscal 2004 the majority of our operating expenses were denominated in Australian dollars. With the sale of our Life Sciences division operating expenditure is now predominantly in Australian dollars. From time to time, in order to reduce our exposure to foreign currency exchange rate risks, we buy and hold foreign currencies to cover our operating expenses denominated in those currencies. We also, from time to time, attempt to hedge our currency exchange risk. At June 30, 2004, we were not a party to any foreign currency hedging or other derivative financial instruments.

The Australian dollar is our functional currency. Our assets and liabilities are translated into U.S. dollars at the exchange rate prevailing on the balance sheet date, and our revenues, expenses, gains and losses are translated into U.S. dollars at the average exchange rate for the relevant period. In general, fluctuations between the U.S. dollar and the Australian dollar may affect our operating results as reported in U.S. dollars.

ITEM 12. DESCRIPTION OF SECURITIES OTHER THAN EQUITY SECURITIES

Not applicable.

PART II

ITEM 13. DEFAULTS, DIVIDEND ARREARAGES AND DELIQUENCIES

None.

ITEM 14. MATERIAL MODIFICATIONS TO THE RIGHTS OF SECURITY HOLDERS AND USE OF PROCEEDS

None.

ITEM 15. CONTROLS AND PROCEDURES

Disclosure Controls and Procedures

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in the reports that we file or submit under the Securities Exchange Act of 1934 is recorded, processed, summarized and reported within the time periods specified in the rules and forms of the Securities and Exchange Commission. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed in our reports filed or submitted under the Securities Exchange Act of 1934 is accumulated and communicated to management, including our managing director and chief financial officer, as appropriate, to allow timely decisions regarding required disclosure.

Our management, under the supervision and with the participation of our managing director and chief financial officer, have evaluated the effectiveness of our disclosure controls and procedures as of June 30, 2004 and, based on that evaluation, our managing director and chief financial officer have concluded that such disclosure controls and procedures were effective as of such date.

Management's Annual Report on Internal Control over Financial Reporting

Not applicable.

Attestation Report of the Registered Public Accounting Firm

Not applicable.

Changes in Internal Control over Financial Reporting

In connection with the audit of our fiscal year ended June 30, 2004, Ernst & Young, the Company's independent auditors, informed our audit committee that they consider the following matters represent material weaknesses in the operation of our internal control over financial reporting:

- The financial statement close process and knowledge of US GAAP; and
- Adequate segregation of duties

In order to address the weakness in our knowledge of US GAAP, our senior finance staff are committed to attending targeted US GAAP and SEC reporting courses and subscribing to additional information publications and updates of SEC and US GAAP releases and rule changes and of information about the requirements of the Public Company Accounting Oversight Board. We will also consider mitigating this weakness by conferring and/or hiring outside accounting advisers with respect to the technical requirements applicable to our financial statements.

Our management and audit committee continually assess the level of segregation of duties existing within the financial reporting function and are committed to segregating duties where practically possible. Given the number of staff employed in our finance department it is sometimes not practicable to segregate all duties.

Limitations on the Effectiveness of Controls

Our management, including our managing director and chief financial officer, does not expect that our disclosure controls and procedures or our internal control over financial reporting will assure that all appropriate information will, in fact, be communicated to management to allow timely decisions to be made or prevent all error and fraud. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Additionally, the design of a control system must reflect the fact that there are resource constraints, and the benefit of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within the company have been detected or that our control system will operate effectively under all circumstances. Moreover, the design of any system of controls is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions.

ITEM 16. [RESERVED]

ITEM 16A. AUDIT COMMITTEE FINANCIAL EXPERT

The Company's board of directors has determined that audit committee member Mr. P. Burns is an audit committee financial expert as defined under the rules and regulations of the Securities and Exchange Commission.

ITEM 16B. CODE OF ETHICS

We have adopted a code of ethics that applies to our executive directors and chief financial

officer. The code is filed as Exhibit 11 to this annual report. The code is posted under the Investors section of our website at www.progen.com.au.

ITEM 16C. PRINCIPAL ACCOUNTANT FEES AND SERVICES

The aggregate fees and expenses billed for professional services rendered by our principal accountant, Ernst & Young, for the audit of our annual financial statements for the years ended June 30, 2003 and 2004 and for other listed services rendered in those years are set forth in the following table:

	2003	2004
Audit Fees	\$55,249	\$83,520
Audit-Related Fees (1)	-	-
Tax Fees (2)	-	-
All Other Fees (3)	8,595	12,314
Total Fees	\$63,844	\$95,834

- (1) There were no assurance and related services rendered by our principal accountant related to the performance of the audit or review of our financial statements which have not been disclosed under audit fees above.
- (2) There were no professional services rendered by our principal accountant for tax compliance, tax advice or tax planning.
- (3) This category comprises services provided by our principal accountant other than audit fees, audit-related fees and tax fees set forth above. The services consist of the audit of our AUSIndustry START grant as required under the funding agreement and training in relation to new accounting standards and pronouncements.

Audit Committee Pre-Approval Policies and Procedures

All audit and non-audit services performed by our independent auditors must be specifically pre-approved by our audit committee. Consistent with this policy, for the year ended June 30, 2004, all audit and non-audit services initiated by Ernst & Young were pre-approved by our audit committee.

ITEM 16D. EXEMPTIONS FROM THE LISTING STANDARDS FOR AUDIT COMMITTEES

Not applicable.

**ITEM 16E. PURCHASES OF EQUITY SECURITIES BY THE ISSUER AND
AFFILIATED PURCHASERS**

Not applicable.

PART III

ITEM 17. FINANCIAL STATEMENTS

Not Applicable.

ITEM 18. FINANCIAL STATEMENTS

Financial Statements - Index to Financial Statements

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ITEM 19. EXHIBITS

<u>Exhibit Number</u>	<u>Description</u>
4(b)(iv)	2004 addendum to Lease 2806 Ipswich Road Darra
4(c)(1)	Employment agreement dated May 21, 2003 between Progen Industries Limited and Darren Schliebs
4(c)(2)	Employment agreement dated August 5, 2004 between Progen Industries Limited and Linton Burns
4(c)(3)	Progen Industries Limited Directors and Employee Option Incentive Plan Rules for the directors and employees incentive scheme approved by a resolution of shareholders at the annual general meeting of the Company held on November 30, 2004
11	Code of Ethics for Executive Directors and Chief Financial Officer
12.1	Certification of Lewis J. Lee under Rule 13a-14(a)
12.2	Certification of Linton W. P. Burns under Rule 13a-14(a)
13	Certification of Lewis J. Lee and Linton W. P. Burns under Section 1350 of Chapter 63 of Title 18 of the United States Code

SIGNATURES

The registrant hereby certifies that it meets all of the requirements for filing on Form 20-F and that it has duly caused and authorized the undersigned to sign this annual report on its behalf.

PROGEN INDUSTRIES LIMITED

By: /s/ Lewis J. Lee
Lewis J. Lee
Managing Director

Dated: December, 16 2004

CERTIFICATIONS

I, Lewis J. Lee, certify that:

1. I have reviewed this annual report on Form 20-F of Progen Industries Limited;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the company as of, and for, the periods presented in this report;
4. The company's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rule 13a-15(e) and 15d-15(e)) for the company and have:
 - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the company, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - (b) Evaluated the effectiveness of the company's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (c) Disclosed in this report any change in the company's internal control over financial reporting that occurred during the period covered by the annual report that has materially affected, or is reasonably likely to materially affect, the company's internal control over financial reporting; and
5. The company's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the company's auditors and the audit committee of the company's board of directors:
 - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the company's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the company's internal control over financial reporting.

Date: December, 16 2004

/s/ Lewis J. Lee
Managing Director

CERTIFICATIONS

I, Linton W. P. Burns, certify that:

1. I have reviewed this annual report on Form 20-F of Progen Industries Limited;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report; and
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the company as of, and for, the periods presented in this report;
4. The company's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rule 13a-15(e) and 15d-15(e)) for the company and have:
 - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the company, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - (b) Evaluated the effectiveness of the company's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (c) Disclosed in this report any change in the company's internal control over financial reporting that occurred during the period covered by the annual report that has materially affected, or is reasonably likely to materially affect, the company's internal control over financial reporting; and
5. The company's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the company's auditors and the audit committee of the company's board of directors:
 - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the company's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the company's internal control over financial reporting.

Date: December 16, 2004

/s/ Linton W. P. Burns
Chief Financial Officer

Certification
Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
(Subsections (a) and (b) of Section 1350, Chapter 63 of Title 18, United States Code)

Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (subsections (a) and (b) of section 1350 of title 18, United States Code), each of the undersigned officers of Progen Industries Limited, a company organized under the laws of the State of Queensland, Australia (the “Company”), does hereby certify to such officer’s knowledge that:

The Annual Report on Form 20-F for the year ended June 30, 2004 (the “Form 20-F”) of the Company fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 and the information contained in the Form 20-F fairly presents, in all material respects, the financial condition and results of operations of the Company.

A signed original of this written statement required by Section 906 has been provided to Progen Industries Limited and will be retained by Progen Industries Limited and furnished to the Securities and Exchange Commission or its staff upon request.

Dated: December 16, 2004

 /s/ Lewis J. Lee
Lewis J. Lee
Managing Director (Chief Executive
Officer)

Dated: December 16, 2004

 /s/ Linton W. P. Burns
Linton W. P. Burns
Chief Financial Officer