pharmaxis

Quarterly Report to Shareholders

Issue 23 | April – June 2009

The large scale production of Bronchitol involves a high precision manufacturing process.

Pharmaxis Ltd ABN 75 082 811 630

pharmaxis

Producing human healthcare products to treat and manage respiratory diseases

Overview

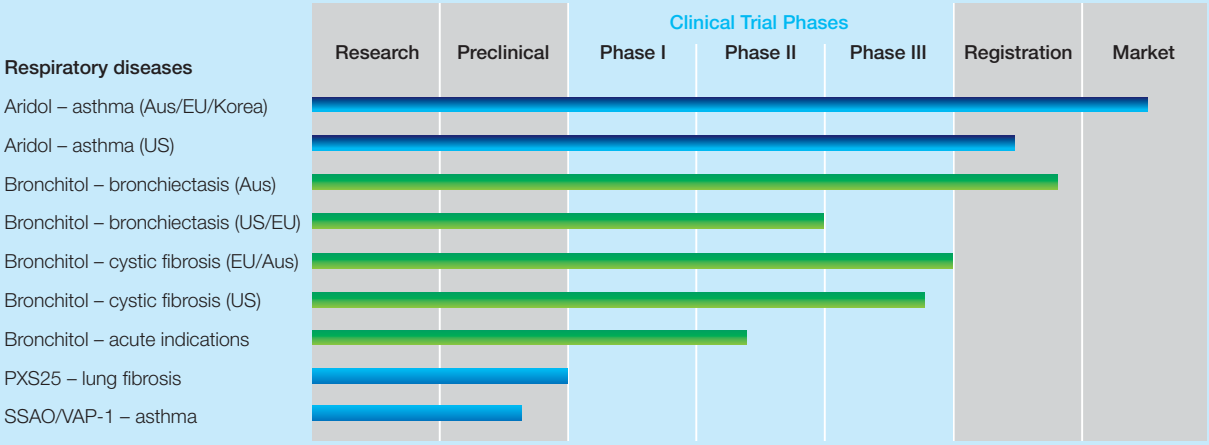
Pharmaxis is a specialty pharmaceutical company with activities spanning product research & development through to manufacture, sales and marketing.

Our therapeutic interests include lung diseases such as cystic fibrosis, asthma, bronchiectasis and chronic obstructive pulmonary disease.

Our first product, Aridol, is now registered for sale in Australia, Europe and South East Asia and a request for marketing has been filed in the United States. Aridol is designed to assist in the management of both asthma and chronic obstructive pulmonary disease. Our second product, Bronchitol, has completed the first regulatory Phase 3 trials in both cystic fibrosis and bronchiectasis.

Our research group is developing two new potential therapies for chronic and debilitating lung conditions such as asthma and pulmonary fibrosis.

Pharmaxis Product Development at June 2009



CEO Report

At the close of the 2008 financial year we reflect on a period of unprecedented changes in the capital markets with flow through consequences that are only now being fully appreciated. In the midst of the turmoil, Pharmaxis has focused its resources on those critical areas of the business that will get us to profitability as quickly as possible, and we have prioritised some projects in favour of others. During the quarter just passed, we reported the results of a major Phase 3 clinical trial and I was privileged to meet some of the patients who had participated in that trial. In the face of an overflowing sea of spreadsheets, it was a short discussion with a family living with cystic fibrosis which brought the data and analysis to life. In Bronchitol, we have a product that passed a high clinical hurdle set by the European regulators, and one that has a clear competitive edge, and that provides a new level of freedom for the patient. Our full commitment is now being applied to bringing this product to patients and our efforts intensify in transforming Pharmaxis from a development stage company to an operating business.

Cystic fibrosis affects 30,000 people in the U.S. and 25,000 in the top five countries in Europe. In the second half of next year, we anticipate having Bronchitol approved for marketing in Europe and in the first half of next year we will have the results of our second Phase 3 trial for the U.S. market. That Bronchitol provides a clinical benefit in the most intensely treated patients provides us with confidence that it will be well accepted by both the CF community and those responsible for pharmaceutical reimbursement. We have engaged both these groups and will continue to seek their support as Bronchitol gets closer to the market.

This report contains details of our progress for the second quarter of 2009.

Alan D Robertson, Chief Executive Officer

2009 first quarter highlights

Phase 3 CF clinical trial reports

- A pivotal Phase 3 trial with Bronchitol in patients with cystic fibrosis demonstrated that Bronchitol is safe and effective as a treatment for cystic fibrosis
- Oral presentation of the cystic fibrosis Phase 3 trial results at the European annual cystic fibrosis scientific meeting
- Constructive meetings were held with the European regulators outlining the review path for Bronchitol in cystic fibrosis
- The Aridol New Drug Application was accepted for review by the U.S. FDA
- PXS25 presented at the 2009 American Thoracic Society meeting in San Diego

Forthcoming Events

2nd Phase 3 CF trial to complete enrolment

- Completion of enrolment for the second Phase 3 cystic fibrosis trial with Bronchitol
- Submission of marketing authorization application for Bronchitol in Europe
- Response from FDA on Aridol New Drug Application

Corporate News

Communication

An important part of the business is ensuring that clinical trial results and company progress is communicated effectively to stakeholders. During the quarter, the Phase 3 clinical trial results for Bronchitol in cystic fibrosis were presented at the European CF meeting in Brest, France. This type of activity is an integral part of educating the physicians on Bronchitol and it is these physicians that eventually make decisions about prescribing the drug. Further presentations at important scientific meetings are planned, as is a peer reviewed publication. In a similar vein, the results of the Phase 3 trial with Bronchitol in bronchiectasis were presented at the American Thoracic Society in San Diego along with a number of presentations concerning Aridol and its role in diagnosing and managing asthma.

International exposure for Pharmaxis

When the CF trial data initially became available, a press conference was hosted by The Children's Hospital at Westmead where more detailed results of the trial were announced by the respected cystic fibrosis physician, Dr Peter Cooper.

PXS25 presented at international meeting

In a separate area of research, the potential for PXS25 in the treatment of pulmonary fibrosis was presented by a team from the prestigious Mayo clinic at the American Thoracic Society meeting in June. A forthcoming presentation looks at the role of PXS25 in the progression of kidney fibrosis.

In addition, the business of the company was presented to investors and analysts at the 8th Annual JMP Securities Research Conference in May 2009 in New York and an updated investor presentation was posted on the website.

Facilities

New factory completed on budget

The construction of the new purpose built Pharmaxis factory and company headquarters at 20 Rodborough Road, Frenchs Forest in Sydney has been completed on time and on budget. Equipment installation and factory commissioning is well advanced and it is planned to have the facility fully operational by the second quarter of 2010. The factory has been designed with the option of doubling capacity when required. After commissioning is complete, the factory will be able to supply sufficient Bronchitol to treat 40,000 patients per year. We took occupancy of the facility in late May 2009.

The factory is the subject of a 15 year lease agreement.

Equity Offering

Capital raised ahead of Bronchitol launch

During the month of June the company raised $54.2 million through the issuance of shares to new and existing investors. The placement represented approximately 10% of the currently issued shares of the company and was well supported. As a result, the company is in a healthy cash position from which to prepare for the launch of Bronchitol in the U.S. and Europe. Shares were primarily issued to investors in Australia, Europe and the U.S. and brings the number of shares on issue to 218 million.

Publications

Diagnostic and therapeutic value of airway challenges in asthma. Cockcroft DW, Davis BE. Curr Allergy Asthma Rep. 2009 May;9(3):247-53. Review.

Mannitol and exercise challenge tests in asthmatic children. Kersten ET, Driessen JM, van der Berg JD, Thio BJ. Pediatr Pulmonol. 2009 Jul;44(7):655-61.

Clinical and Medical News

Phase III CF trial report positive

Bronchitol promises a new treatment option for CF

There are currently two products approved for the treatment of cystic fibrosis to help address the loss of lung function which is the main clinical problem that has to be overcome by those affected by the disease. One of those is an inhaled antibiotic (tobramycin) and one is a drug (rhDNase) that liquefies mucus in the lung. The combined sales of these two products in 2008 were over A$1 billion.

Bronchitol will enter this market as the first drug designed to improve mucus clearance through activation of the normal lung protection mechanism.

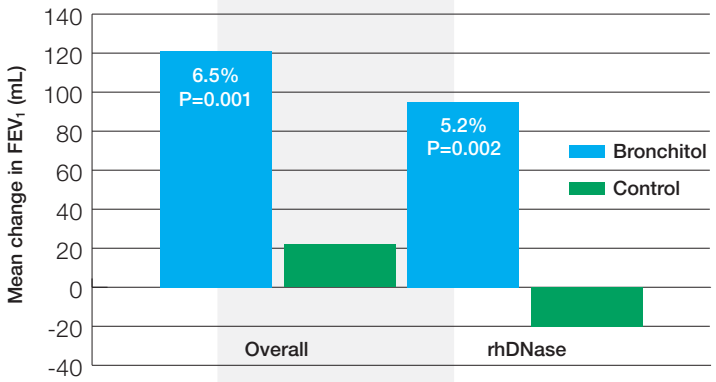
Loss of lung function is rapidly fatal

Cystic fibrosis is a progressive condition in which pulmonary disease is the main determinant of morbidity and mortality. The progressive decline in pulmonary function with time is a key symptom of cystic fibrosis and seems to be inevitable. The annual rate of decline in lung function as measured by forced expiratory volume in 1 second (FEV_1) is a significant predictor of the risk of death.

A Bronchitol Phase 3 trial involving 325 patients with cystic fibrosis reported in early May 2009. The main purpose of the trial was to determine if Bronchitol, delivered twice daily for six months, improved lung function (FEV_1) when measured against control. The trial took place across 40 clinical centres in Australia, New Zealand, the United Kingdom and Ireland, and enrolled patients aged 6 years and older who were variously affected by the disease; from mild through to severely affected. The trial aimed to determine if Bronchitol could be added to current best clinical practice in the subject group.

Bronchitol safe and effective in cystic fibrosis

The trial achieved its pre-specified end point. After six months patients with cystic fibrosis had not only experienced no lung function deterioration but had, in fact, shown lung function improvement of 6.5%. For those patients taking rhDNase, the lung function improvement was more than 5%. On average, a person with cystic fibrosis may lose 2% of lung function each year.



Lung function changes after 6 month Bronchitol treatment

Lung function improved with Bronchitol

This trial was designed with the assistance of the European Medicines Agency (EMEA) and Bronchitol has been given orphan drug designation in Europe. The EMEA was particularly interested to learn if Bronchitol could be used in patients that were on a number of concomitant medications, including rhDNase, and it was particularly reassuring to see that it can. Not only is an additional clinical benefit derived but there are no additional safety issues associated with its use.

US cystic fibrosis trial actively recruiting

Second Phase 3 cystic fibrosis trial

A second Phase III trial in patients with cystic fibrosis is in progress and is aimed at the U.S. market. The U.S. regulatory agency, the FDA usually requires a second clinical trial to be completed before a marketing application can be submitted. This second trial was not required by the European regulators but provides an excellent opportunity for clinicians and patients in the U.S. to experience the benefits of Bronchitol first hand. The trial is recruiting over 300 volunteers and involves more than 65 clinical centres in Argentina, the USA, France, Belgium, Canada, The Netherlands and Germany.

The trial design is similar to the first Phase 3 trial with the same primary objective of improving lung function. The trial is actively recruiting, with more than 66% of the required subjects already enrolled. Data from the trial is expected during the first quarter of 2010.

Marketing application to be filed in Europe

Regulatory matters and cystic fibrosis

A series of meetings with the regulatory agencies in Europe over the past month has resulted in agreement on the path to gaining a marketing authorisation for Bronchitol. The marketing application will now be submitted as soon as possible with a decision on the application due during the second half of 2010. Bronchitol has orphan drug designation in Europe which affords up to 12 years market exclusivity.

Bronchitol has been granted fast track designation by the FDA. The FDA's Fast Track programs are designed to facilitate and expedite the development of new drugs that are intended to treat serious or life-threatening conditions and that demonstrate the potential to address unmet medical needs. Following reporting of the Phase 3 trial early next year, the marketing application for the U.S. can be submitted.

Bronchitol has orphan drug status in the U.S. which affords 7 years market exclusivity.

First dry powder for CF

Marketing matters and cystic fibrosis

The two drugs specifically developed for cystic fibrosis, tobramycin and rhDNase, have to be stored in a refrigerator, and delivered to the patient by the use of a nebulizer and a compressor. Tobramycin is an antibiotic to help fight lung infections and rhDNase is designed to make the mucus in the lung less sticky and easier to clear. While both drugs are effective they do carry with them a heavy treatment and social burden on the patient, which often leads to poor compliance. Bronchitol, which can be used in conjunction with both of these drugs is a dry powder, delivered to the lungs by a small, breath activated inhaler that does not require set up, a power source, or cleaning and is stable at room temperature.

We believe that Bronchitol will be well received by the CF community.

Bronchitol Phase III trial to begin

Second Bronchitol Phase 3 trial in bronchiectasis

A second Phase 3 trial in bronchiectasis will commence recruitment shortly and is expected to report in 2011. Bronchiectasis is an acquired, incurable condition of the lung with features similar to cystic fibrosis. This trial will determine the effects of Bronchitol following twelve months treatment and the design has been agreed with the U.S. FDA and the EMEA. 54 hospitals are participating in the trial from Germany, the UK, the U.S., Australia, Argentina and New Zealand. The objective is to show that people treated with Bronchitol will have fewer periods of acute sickness and require less hospitalisation than people not taking Bronchitol.

Marketing and Regulatory Activities

Aridol supplied to two new European countries

Aridol is now being marketed in Australia and throughout Scandinavia, Denmark, The Netherlands, Greece, Portugal, Switzerland, Spain, Italy and the United Kingdom. It has received consistent support and is becoming the test of choice in these markets. Our objective now is to stimulate market growth and open up the important markets of Germany, the U.S and Korea.

The marketing application for the USA was submitted electronically to the FDA at the end of February and accepted by the FDA for review at the end of April. The date whereby the FDA is expected to provide a complete response to the application is 27 December 2009. In the meantime, we have commenced communicating the clinical results with representation and presentations at the American Thoracic Society meeting in May.

Korea is one of the most attractive markets for Aridol in Asia. Pricing and re-imbursement discussions are now reaching a conclusion and our distributor in Korea is already test marketing the product and running small experience studies to familiarise physicians with the test.

The Aridol shelf life has recently been extended to 18 months.

Early Stage Research Activities

PXS25 Phase I trials to commence

PXS25 inhibits the function of a key protein involved in scar formation and wound repair. This protein is useful if it is required to repair a wound in the skin but can cause difficulties if it inadvertently tries to repair the lung. This can cause scarring and loss of lung function and eventually death from respiratory failure.

Phase 1 clinical studies of PXS25 are scheduled and aim to determine the behaviour of PXS25 in healthy subjects, as a prelude to evaluation in patients with lung fibrosis.

Financial Overview of the Quarter

Cash at 30 June of $125 million

At 30 June 2009, Pharmaxis had $125 million in cash. During the quarter, capital expenditure in relation to our new facility was approximately A$1.8 million. Remaining capital expenditure in relation to the facility is approximately A$ 2.8 million, including $1.3 million accrued at 30 June 2009.

For the June 2009 quarter, Aridol sales of A$141,000 compared to A$197,000 in 2008. Sales for the year were A$595,000 compared to A$527,000 in 2008. Interest income of $763,000 is earned primarily on commercial bills, compares to $2.2 million in 2008, reflecting lower interest rates and a lower average balance of funds invested.

Research and development expenditure of A$8.5 million for the June 2009 quarter compares to A$6.0 million in the June 2008 quarter, and A$7.2 million in the March 2009 quarter. Additional expenditure on clinical trials, regulatory filings and preclinical development accounted for the change.

Commercialization expenditure increases

Commercial expenditure of A$1.9 million compares to A$1.5 million in the June 2008 quarter and A$1.5 million in the March 2009 quarter. The increase reflects initial commercialisation costs for Aridol in the U.S. and Bronchitol in the E.U.

Administration expenditure of A$1.5 million compares to A$1.5 million in the June 2008 quarter and A$1.4 million in the March 2009 quarter.

Finance expenses represent the ongoing finance charge associated with the capitalised finance lease of our new facility at Frenchs Forest.

Financial Statement Data – Unaudited
(International Financial Reporting Standards)

('000 except per share data)

Income Statement Data

	Three months ended		Twelve months ended	
	30-Jun-09	30-Jun-08	30-Jun-09	30-Jun-08
	A$	A$	A$	A$
Revenue from sale of goods	141	197	595	527
Cost of sales	(35)	(36)	(153)	(129)
Gross profit	106	161	442	398
Interest	763	2,233	5,347	7,402
Other income	246	654	523	1,576
Expenses				
Research & development	(8,531)	(5,995)	(29,308)	(19,996)
Commercial	(1,865)	(1,452)	(6,202)	(4,557)
Administration	(1,541)	(1,446)	(5,800)	(5,231)
Finance expenses	(122)	–	(122)	–
Total expenses	(12,059)	(8,893)	(41,432)	(29,784)
Loss before income tax	(10,944)	(5,845)	(35,120)	(20,408)
Income tax expense	(24)	(15)	(51)	(32)
Loss for the period	(10,968)	(5,860)	(35,171)	(20,440)
Basic and diluted earnings (loss) per share – $	(0.055)	(0.030)	(0.180)	(0.108)
Depreciation & amortisation	475	252	1,265	1,023
Fair value of options issued under employee plan	631	829	2,432	3,433

Balance Sheet Data

	As at	
	30-Jun-09	30-Jun-08
	A$	A$
Cash and cash equivalents	124,993	111,842
Property, plant & equipment	32,698	3,668
Intangible assets	1,193	1,227
Total assets	163,997	125,049
Total liabilities	(26,306)	(5,928)
Net assets	137,691	119,121

Cash Flow Data

	Three months ended		Twelve months ended	
	30-Jun-09	30-Jun-08	30-Jun-09	30-Jun-08
	A$	A$	A$	A$
Cash flows from operating activities	(10,143)	(2,179)	(26,422)	(18,853)
Cash flows from investing activities	(1,800)	(2,233)	(11,542)	(5,059)
Cash flows from financing activities	51,104	1	51,115	59,572
Net increase (decrease) in cash held	39,161	(4,411)	13,151	35,660

Share Data

	Ordinary Shares as at	
	30-Jun-09	30-Jun-08
Ordinary shares on issue	217,659	194,515
Options over ordinary shares outstanding	15,075	11,536

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Contact Details

Further information on Pharmaxis can be obtained from www.pharmaxis.com.au or by contacting David McGarvey, Chief Financial Officer:

Telephone: +612 9454 7200
david.mcgarvey@pharmaxis.com.au

Pharmaxis Ltd
ABN 75 082 811 630
20 Rodborough Road
Frenchs Forest NSW 2086