DEVELOPING SOLUTIONS

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12-31-03

AR/S

ONCOLOGY, ADVANCED DRUG DELIVERY, ORAL DISEASE

Access

Pharmaceuticals, Inc.

2003 Annual Report

Active Partnering Programs

Innovative Drug Delivery Solutions

"Establishing partnerships with other pharmaceutical companies is important to Access since it provides income and reduces financial and development risks whilst at the same time, endorsing Access' proprietary drug delivery technologies and development projects."

Access Has Executed Significant Collaborative Agreements for its Technologies with the Following International Partners:

Wyeth Consumer Healthcare

Strakan

ESTEVE

CELLTECH

unipharm ltd.

Zambon Group

PLIVA

HYUNDAI PHARM.IND.CO.,LTD

Fujisawa
New Medicines for New Times

MEDA

TaroPharma™

FarmaSel

反華生技醫藥股份有限公司
Orient Europharma Co., Ltd.

MedLink

Designed by R. Jenece Austin

Innovative Drug Delivery Solutions

2003 Highlights

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Access: To Present Polymer Platinate AP5346 Data at AACR Meeting. Enters Research Collaboration on Nanoparticle Aggregate Drug Delivery Technology. Completes $9.7 Million Private Placement. OraDisc™ A NDA Accepted for Filing. Presents at the Roth Capital Partners 16th Annual Growth Stock Conference.

Signs Licensing Agreements for North America with Wyeth Consumer Healthcare. Retains Genesis Select to Spearhead Investor Relations Program. Presenting at Rodman & Renshaw Techvest Healthcare Conference. American Stock Exchange Accepts Access' Plan to Regain Compliance with Continued Listing Standards. Celltech & Access Oral Drug Delivery Research Collaboration. Clinical Trial Results of OraDisc A. Positive Data Reported for 701 Patient Phase III Study.

Generates Revenues from First Product Sales, Royalties, Licensing Payments. Agreements for Zindaclin® Launched in France and Germany.....Approximately $2.5 Million to be Generated.

Technology Applications

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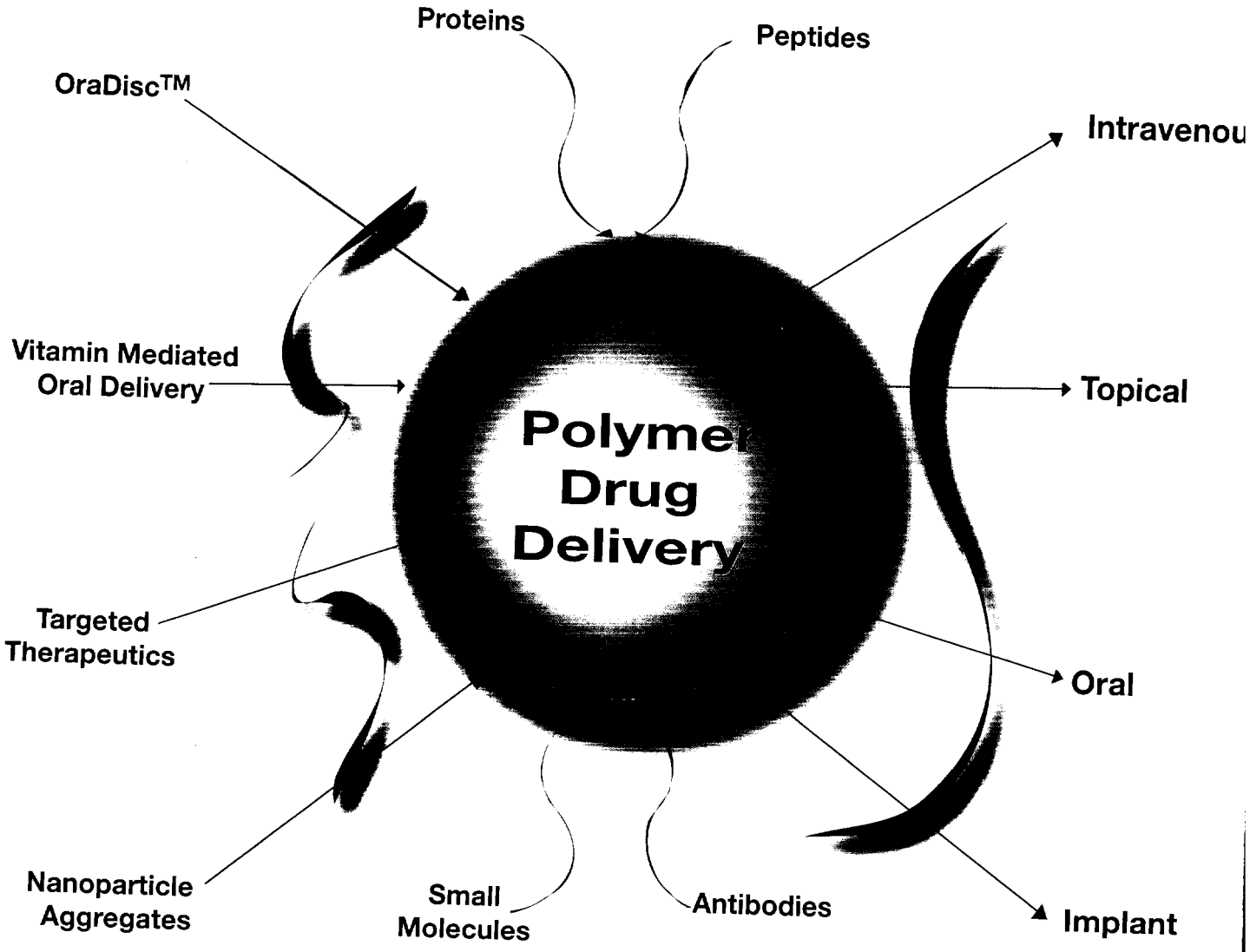

Platform Technologies

Types of Drug Products

Route of Administration

TO OUR SHAREHOLDERS:

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During the past 12 months, Access has continued to make significant progress implementing our business plan. The plan was designed to build a fundamentally sound company capable of generating revenues from lower-risk opportunities to fund our exciting oncology and drug delivery initiatives. Progress has been achieved in several critical areas including the advancement of our clinical development candidates and the generation of data supporting our preclinical initiatives. Significant progress has been made in the implementation of our partnership strategy. Importantly, during 2003 the investment community commenced to recognize the value of our scientific programs and the disparity of the Company's valuation relative to our peer group. We are optimistic that with a further improvement in the investment environment for the healthcare sector and the execution of our strategic plan, the market capitalization of the Company will continue to increase and our technology value will be reflected in our share price.

The achievements during 2003 validate our business model and clearly demonstrate that it is possible to cost-effectively develop new products, and file for regulatory approval, with a small focused team of dedicated employees. The filing of a New Drug Application for OraDisc™ A with the FDA, and having the filing accepted, is a clear confirmation of this approach, as the technology was invented and developed by the company, and five clinical studies were conducted. The preparation of the NDA was completed entirely in-house. Our facility, and that of our contract manufacturer, was prepared for the FDA inspection which accompanies the submission of an NDA.

During the past year, our first collaboration with a major pharmaceutical company was executed, a licensing agreement for an over-the-counter product application of our OraDisc™ technology with Wyeth Consumer Healthcare. Partnerships such as this not only generate revenues for the company but also provide an external validation of our technology. This is a first step in the implementation of our partnership strategy, which is a cornerstone to our business model.

BUSINESS STRATEGY

When Access was formed through the merger of two entities in January 1996, it was our stated objective to build a company with a diverse product portfolio, balanced in terms of timing and development risk, and not to be reliant on one product or technology for the ultimate success of the company. Through the development of the nearer-term, lower-development risk opportunities we have commenced the development of a fundamentally sound business capable of generating profitability and providing the funding for our major initiatives in oncology and polymer drug delivery. I believe that we are now well positioned to benefit from this business strategy as we project having four marketed products generating product revenues within the next 12 months.

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Additionally, several of our product development candidates and preclinical technologies have advanced to the point where revenues could be generated from licensing, research collaborations and product development opportunities.

I believe that our portfolio is well balanced in terms of developed products, clinical candidates and preclinical technologies, which enables us with our focused organization to effectively advance our priority initiatives. Our major product opportunities are receiving the necessary management attention, scientific support and research funding to realize the value of these technologies.

2003 PERFORMANCE

During the past 12 months, there were significant commercial, development and scientific achievements, which included:

- *Filing the OraDisc™ A NDA and having the filing accepted by the FDA.*
- *Execution of a licensing agreement with Wyeth Consumer Healthcare, a division of Wyeth, granting the North American rights, with an option to extend the agreement to a worldwide license, to market an OTC product utilizing our OraDisc™ technology.*
- *Execution of two collaborative research agreements to evaluate our preclinical technologies.*
- *Continued advancement of our polymer platinate program including the clinical advancement of AP5346 and the development of significant preclinical data supporting the program.*
- *Expansion of our OraDisc™ technology with additional development candidates and further technology improvement.*
- *Substantial completion of the development and manufacturing scale-up of OraDisc™ B containing benzocaine.*
- *Significant expansion and advancement of our corporate partnering discussions.*
- *The issuance of two US patents, one covering our polymer platinate technology and the other our OraDisc™ technology.*
- *Significant expansion of the preclinical data base supporting our nanoparticle aggregate technology, vitamin mediated oral delivery and targeted polymer therapeutics program in cancer.*

Additionally, Zindaclin® was launched by our partners in further markets including France and Germany, and the licensing of Zindaclin® was expanded to cover in excess of 30 markets worldwide. We established a new contract manufacturer for Aphthasol® and the necessary production was completed to achieve both US and European approval for this supplier.

During 2003 we commenced a more aggressive program to gain institutional investor awareness and recognition in the financial community. I believe that we are now realizing the benefits of this program and we intend to continue this investor relations program to gain additional visability and expand our shareholder base.

In February 2004, we completed a $9.7 million private placement which was placed with approximately 12 institutions. While it would have been possible to raise significantly greater equity,

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given our anticipated cash flow, this funding is expected to provide us the necessary resources to aggressively advance our product developments, while limiting the dilution of existing shareholders.

DRUG DELIVERY OPPORTUNITY

The market for products utilizing drug delivery systems is growing significantly, in part due to the need of pharmaceutical companies to extend intellectual property protection of their current products by utilizing proprietary drug delivery systems and the increasing number of therapeutics requiring drug delivery solutions to maximize the products' effectiveness. The competitive advantages offered with all four of our drug delivery platforms place us in an advantageous position to capitalize on this market trend. The delivery solutions offered by our technologies address several major needs of the industry: targeted drug delivery, oral delivery of products currently only available by injection and the stabilization and delivery of proteins and peptides. Our commercially-viable broadly-based delivery platforms offer us the opportunity to position the Company as the "Drug Delivery Solution Company."

GROWTH OPPORTUNITIES

We are focused on four core technology platforms to drive our future growth: Targeted Polymer Therapeutics, Vitamin Mediated Oral Delivery, Nanoparticle Aggregates and OraDisc™. While we have four core technology platforms, these technologies are all based on polymer drug delivery, which enables us to leverage our extensive expertise in this field. We believe these advanced drug delivery technologies can provide the Company with a flow of product development candidates over the next five years and beyond.

We believe that OraDisc™ provides Access with the opportunity to develop over-the-counter products to generate near-term licensing and product sales revenues. The licensing agreement with Wyeth Consumer Healthcare is an important validation of this technology and the potential to develop other over-the-counter products. In addition to the near-term potential this technology affords, there exists significant opportunities to develop prescription products utilizing the technology as a buccal delivery device. OraDisc™ is the major component of our near-term objective to establish a sound revenue base for the Company. Third party interest would indicate that there is significant potential in the near-term to develop numerous products in multiple therapeutic areas to achieve this objective.

The polymer platinate program is our most exciting and advanced development utilizing our targeted polymer therapeutics technology. In the past 12 months, not only have we advanced the clinical development of AP5280 and AP5346, we have greatly enhanced the preclinical program supporting this project. Recently presented preclinical data on platinum accumulation in tumors and the formation of Pt-tumor DNA complexes offers strong confirmation in an animal model that our polymer technology can deliver significantly more drug to the target for tumor inhibition. Development work continues to optimize the benefits of targeted polymer therapeutics including utilizing vitamins to target tumors, and to identify the polymer delivery vehicle which will maximize the therapeutic ratio - the balance between effectiveness and toxicity. We have recently developed some exciting data in this area and additional work is ongoing to establish the necessary intellectual property position prior to disclosing these results.

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There is a high level of excitement within the Company regarding our nanoparticle aggregate technology and the potential benefits this technology offers for protein and peptide delivery. Protein and peptide therapeutics are a rapidly expanding area within the pharmaceutical industry that requires a drug delivery approach for maximum effectiveness and patient convenience. The ability to develop sustained delivery forms for products which currently require frequent injections is considered a major opportunity. Extensive preclinical studies have been conducted internally to show that extended delivery and response to the delivered macromolecule can be achieved over periods in excess of 70 days. Access has established a collaboration with a major drug delivery company to evaluate our technology for the delivery of macromolecules and we intend to establish further collaborations in this area. We believe that our nanoparticle aggregate technology represents the most versatile biocompatible material currently available with numerous competitive advantages compared to competing technologies.

During 2003 we formed our first collaboration involving our vitamin mediated oral drug delivery technology with Celltech, a major company in the area of protein therapeutics. The ability to deliver proteins and peptides orally is considered the gold standard in drug delivery. The collaboration with Celltech will evaluate the ability of our technology to deliver monoclonal antibodies or fragments of antibodies. During 2003 further preclinical work was conducted which provides additional support for this technology, confirming the active transport of drug from the gut into the blood stream and the achievement of the desired therapeutic effect. In 2004 we plan to establish additional research collaborations with our vitamin mediated oral drug delivery technology to evaluate the delivery of numerous compounds.

SCIENTIFIC ORGANIZATION

The benefits of the expansion of our scientific organization to include a biological capability were clearly evident in 2003. Our Australian subsidiary with its biological capability, both in vitro and animal, has enabled us to not only more cost effectively and rapidly develop our technologies but also provide additional scientific support for the technologies. The rapid development of our nanoparticle aggregate technology is a clear demonstration of the advantages afforded by having this biological capability.

As our Company matures, product candidates advance towards the market, and additional strategic partnerships are formed, there will be an increasing need to expand our project management and product procurement abilities. Further, in order to accelerate the development of our nanoparticle aggregate technology, additional resources will be required. These areas will be addressed in 2004, however, it is anticipated that our head count will not significantly exceed 40 during the upcoming 12 months.

COLLABORATIONS

The successful advancement of our development programs and product candidates has placed us in a favorable position to significantly expand our partnership programs. An advantage of our business strategy, the development of a broadly-based technology portfolio, is that multiple licensing opportunities are possible. In addition, as Access is developing several drug delivery technologies numerous products are expected to be developed utilizing these technologies.

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Consequently, the possibility exists to enter numerous licensing agreements for all four of our technology platforms. Currently, multiple discussions are ongoing aimed at forming collaborations for product development using all four technologies.

2004 OUTLOOK

During the upcoming 12 months our plans include the achievement of numerous commercial and development milestones, including:

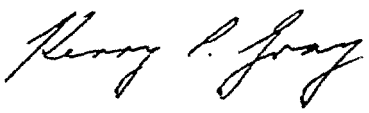
- *Approval of OraDisc™ A in both the US and Europe.*
- *Additional license agreements for a number of our products and technologies.*
- *Research collaborations involving our preclinical technologies.*
- *OTC product development agreements.*
- *Initiation of the next clinical development phase for both polymer platinate and mucositis technology.*
- *Product launches in both the US and Europe for existing approved products and the OraDisc™ products.*

During 2004, we plan to advance several product development candidates towards clinical development utilizing our drug delivery technologies. It is anticipated that this will be achieved through co-development activities with partners as well as Access' internal product development candidates.

In closing, at our inception our long range objective was to become a leader in the drug delivery segment of the industry. We believe that we have now accumulated the technologies through licensing, acquisition and internal developments to achieve our objectives. Our strengths include the dedication of our employees, the quality of our science and the strength and depth of our development pipeline.

Our achievements would not have been possible without the support of our shareholders, the leadership of the Board of Directors and the dedication of our senior management and employees, all of whom I thank.

Sincerely,



Kerry P. Gray

Clinical Candidates

2004

AP5346 — Polymer Linked DACH-Platinum

AP5280 — Polymer Linked Cisplatin

MLT — Mucositis

2005

Targeted Therapeutics — Cancer

2006

Oral Drug Delivery — Protein Delivery

Nanoparticle — Protein Delivery

Innovative Drug Delivery Solution

With the conclusion of the OraDisc™ A clinical development program, Access is currently funding three clinical development candidates; the two polymer platinate compounds and our mucositis program. During 2004 it is anticipated that the polymer platinate program will commence Phase II development and the pivotal study in mucositis will commence.

A major focus of the Company in 2004 is identifying a compound in our targeted therapeutics program in cancer to commence preclinical development with the objective of starting Phase I development in 2005. Furthermore, it is our objective, either in conjunction with a strategic partner or with an internally sponsored program, to commence clinical development of a product candidate in 2006 utilizing both our vitamin mediated oral delivery technology and the nanoparticle aggregate delivery system.

Exclusive of developments utilizing our OraDisc™ technology, commencing in 2005 it is our objective every year to advance at least one new product candidate into clinical development. This assumes that the clinical development responsibility for our outlicensed product opportunities are assumed by a strategic partner, freeing our internal group to focus on our next generation of clinical candidates.

Polymer Platinate

Innovative Drug Delivery Solutions

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Platinum Agents in Cancer Therapy

Platinum agents are used extensively in the treatment of cancer with worldwide sales in 2003 of approximately $2 billion. These compounds have a broad spectrum of activity and are used to treat numerous solid tumors including lung, colorectal, head and neck, ovarian and testicular cancers. Combination therapy utilizing platinum with other chemotherapeutics is being increasingly used in the treatment of numerous cancers.

Oxaliplatin (a DACH-Platinum agent) has recently been approved as a first line therapy in colorectal cancer and in the first calender year on the market in the United States generated sales of approximately $575 million.

Conventional platinum agents have well-defined toxic effects that limit the amount of drug that can be administered as well as the frequency of the dosing. Drug development efforts related to platinum agents in the past decade have focused on identifying analogs with a broader spectrum of anti-tumor activity and reduced toxicities.

Access has implemented an alternative strategy in the development process of platinum drugs by improving the delivery of the active compound to increase the amount of platinum which is delivered to the tumor, and/or decrease the exposure of normal tissue to the drug.

AP5346 Polymer DACH-Platinum

In order to improve the therapeutic index (the ratio of effectiveness to toxicity) of DACH-Platinum, Access has used a rational design approach. AP5346 was designed to deliver more platinum to the tumor while reducing systemic side effects. The polymer approach capitalizes on biological differences in the permeability of the vasculature of tumors versus that of normal tissue as well as increasing the circulation time of the platinum in the blood stream. In addition, the polymer system is designed to limit the release of active drug in the blood stream, increase the availability and uptake of platinum by tumor cells, and finally release the platinum through cellular mechanisms to form platinum-DNA complexes. The polymer DACH-Platinum complex remains inert until platinum is released from the polymer.

Projected Product Benefits

AP5346 has been designed to take advantage of a combination of polymer characteristics, of the tumor vasculature and cellular uptake mechanisms. The projected impact of these properties leads to:

- Enhanced penetration of drug into the tumor.
- Greater retention of platinum in the tumor.
- Greater tumor uptake.
- Reduced uptake of platinum by normal cells.

Data presented on the following pages confirms that in animal models the platinum delivery objectives are being achieved: enhanced tumor uptake, greater amounts of drug reaching the tumor DNA and significantly improved tumor inhibition. The formation of Pt-tumor DNA complexes is believed to be the mechanism by which platinum agents inhibit tumor growth.

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This study indicates that in excess of a 13-fold increase in Pt-tumor DNA complexes are formed with AP5346 compared to the marketed DACH-Platinum drug, oxaliplatin.

Clinical Development Status

A Phase I study is currently being conducted with the following objectives:

- Determine the maximum tolerated dose of 3 weekly 1 hour infusions.
- Identify an appropriate dose for Phase II studies.
- Determine the dose limiting toxicities.
- Study the distribution of the drug.
- Document possible anti-tumor activity.

On completion of the Phase I study a Phase II program will be initiated which is planned for mid-year 2004. It is planned to conduct the initial Phase II study in platinum sensitive ovarian cancer patients to most rapidly determine the activity profile of AP5346. It is anticipated that a second Phase II study utilizing combination therapy in colorectal cancer patients will be conducted in the United States. A meeting has been held with the FDA and it is planned to file an IND to commence clinical testing in the United States.

Polymer Platinate Program

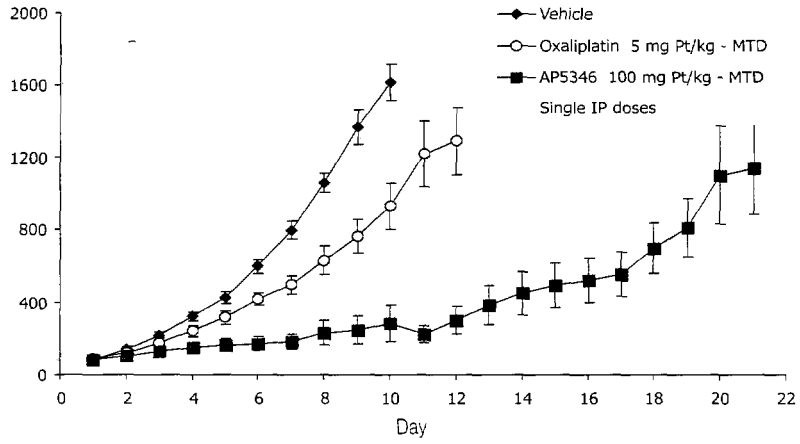
In addition to the AP5346 program we have developed AP5280 which incorporates cisplatin as the active platinum agent. Two Phase I studies have been conducted with AP5280; one utilizing a once every three week dosing regimen, and the other three weekly doses monthly. It is planned to continue with a Phase II study in advanced ovarian patients sensitive to platinum.

Formulation development work is ongoing to evaluate the potential to further expand the polymer platinate program to include an alternate platinum agent and to evaluate utilization of our vitamin targeting technology. Additionally, research is being conducted to evaluate formulation parameters that will maximize the benefits of this drug delivery approach.

Commercial Strategy

It is the Company's objective to sign a licensing agreement with a strategic partner. Such a license would include our partner assuming the cost of the clinical development program. An active out-licensing program is ongoing with interest being expressed by numerous companies.

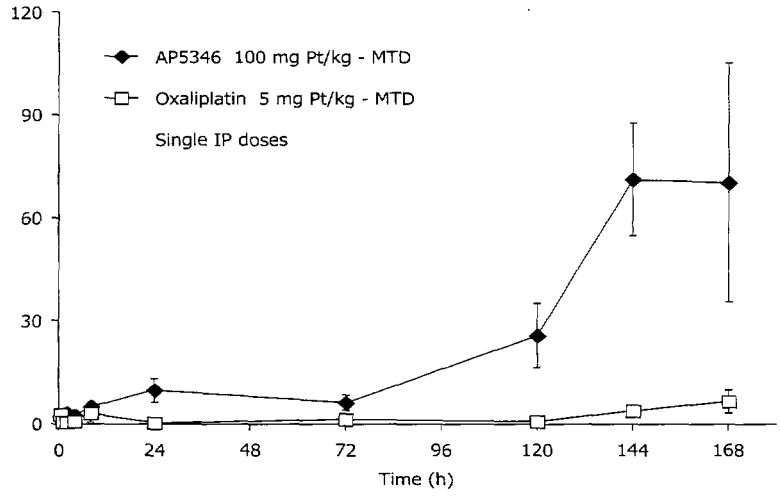
Activity of AP5346 versus Oxaliplatin: B16 melanoma



The ability of the polymer carrier to reduce the toxicity of the DACH-Platinum moiety is reflected by the much greater dose of platinum that can be administered with AP5346 relative to the small molecule analog (oxaliplatin).

This results in prolonged inhibition of tumor growth by AP5346 relative to the modest inhibition afforded by the equitoxic dose of oxaliplatin, and also permits extended growth inhibition via weekly x 3 dosing of AP5346 (Rice et al. AACR 2003; 44:318).

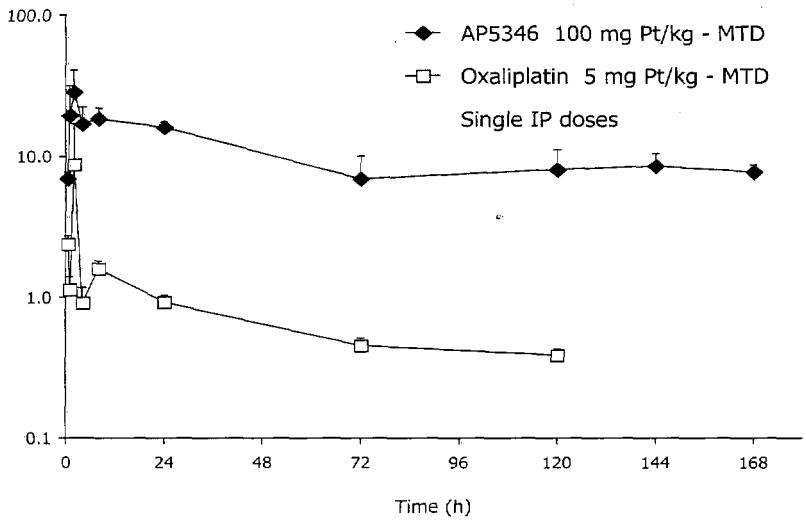
Formation of Platinum-DNA Adducts in Tumor



AP5346 at its MTD induces approximately 14-fold greater formation of Pt-DNA adducts in B16 melanoma tumor than does an equitoxic dose of oxaliplatin in this tumor model, based on the ratio of AUC values.

The tumor content of Pt-DNA adducts continues to accumulate for at least 7 days post-dose after AP5346 treatment, compared to the very low levels of oxaliplatin-induced adducts.

Concentration Profile of Total Platinum in Tumor Tissue



These results show that AP5346 markedly increases total tumor platinum levels compared to those attained with an equitoxic dose of oxaliplatin.

The $AUC_{(0\text{-}168h)}$ is 16.3-fold higher for AP5346 compared to oxaliplatin.

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Commercial Operations

The expansion of our commercial operations will occur both through the introduction of new products and the global marketing of existing products. Currently, the approved products are marketed in limited countries. During 2004, it is anticipated that the marketing of both Zindaclin® and Aphthasol® will be expanded to numerous additional markets. To achieve this objective, product approvals will be required, particularly for Aphthasol® in Europe. The European registration is ongoing, with product approvals scheduled in the later part of 2004.

The first approval of OraDisc™ A is anticipated late in 2004 which will enable a product launch in the first half of 2005. Likewise, it is anticipated that the necessary consumer testing and commercial scale-up of OraDisc™ B will enable an early 2005 launch.

Commencing in 2005, it is planned to introduce at least one new product yearly. Additionally, with the expansion of marketing of existing products worldwide it is anticipated that by late 2005, product revenues will be sufficient to fund the Company's operations.

Marketed Products

2004

- Aphthasol®
- Zindaclin®

2005

- OraDisc™ A
- OraDisc™ B

2006

- OraDisc™ G
- OraDisc™ C

Major Platform Technologies

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"Access Pharmaceuticals has a broad range of drug delivery technologies, addressing nearly all the issues that arise when formulating new or existing drugs. Access provides the pharmaceutical industry with the tools to develop and commercialize new pharmaceutical products and provide patients with more effective and user-friendly treatments."

1 Targeted Polymer Therapeutics Drug Delivery

Access is developing polymeric drug carriers to improve the therapeutic index of cancer drugs. Access has used a rational design approach to develop AP5346, polymer-linked DACH-Platinum and AP5280, polymer-linked cisplatin to deliver more platinum to the tumor while reducing systemic side effects. Both products are in clinical development.

2 Hydrogel Nanoparticle Drug Delivery

Hydrogel is an innovative biocompatible material suitable for use in a variety of drug delivery applications including proteins. The material is composed of nanometer sized particles that coalesce in the presence of water to form a strong, elastomeric biocompatible aggregate. This property gives the Hydrogel technology an advantage in that the material can be molded or shaped in the hydrated state. The ability to trap macromolecules in the spaces between particles comprising an aggregate, provides the basis for a unique drug delivery technology.

3 Mucoadhesive Drug Delivery

Mucoadhesive Liquid Technology (MLT) is a material to coat the oral cavity. The vehicle can deliver active compound and data generated to date suggests that MLT is a platform technology. MLT vehicle could represent an important advance in the management of mucositis. The mucoadhesive drug delivery technology, OraDisc™ is an erodible disc which adheres to the mucosal surface and erodes, delivering active drug. Access has developed amlexanox (OraDisc™ A) for the treatment of aphthous ulcer in this technology and benzocaine (OraDisc™ B) for oral pain.

4 Vitamin Mediated Drug Delivery

Coupling Vitamin B_{12} to a polymer or nanoparticle containing a drug, the vitamin B_{12} is recognized by the body and is transported across the gut wall into the blood stream via the mechanism by which the body absorbs vitamin B_{12}. Utilizing this technology enables drugs currently not able to be administered orally to be delivered by this route of administration.

Technology Differentiation

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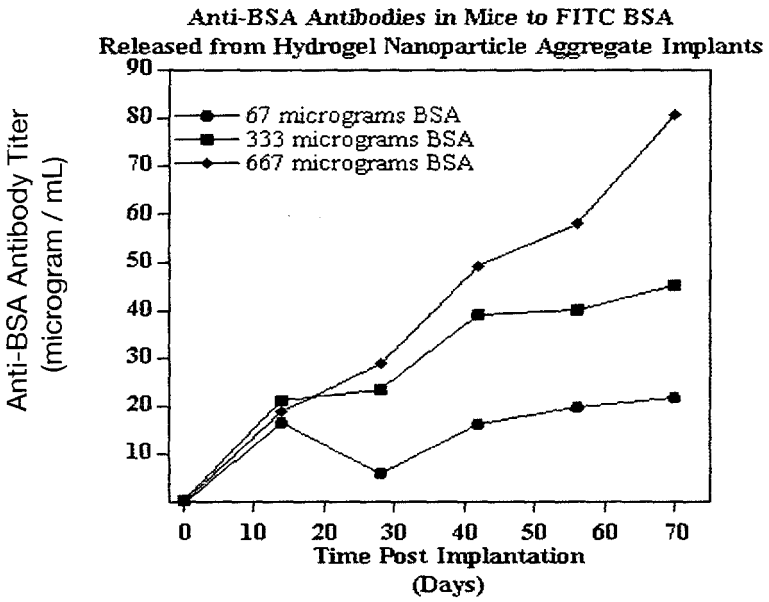
Competitive Technology	Hydrogel Nanoparticle Aggregate
Hard Rigid Implant	Soft Implant, Never Gets Hard
Contains up to 70% of an Organic Solvent	Totally Aqueous System
Surface Erosion to Release Drug	Can be Designed to Totally Erode Throughout Matrix, at Predetermined Rates
Creates Acidic Environment Around Surrounding Tissue and Causes Local Irritation	Does Not Elicit Local Tissue Irritation
Macrophages Attracted to Implant Site	No Attraction of Macrophages
Classical Burst Release	Finely Tunable Drug Release Profiles Pseudo-First Order Release Possible
Formulation of Actives Limited due to Presence of Solvent	Actives Formulated in Water, Less Chance for Denaturing or Degradation
Complex Manufacturing Processes	Simple Manufacturing Process
Suitable for Small Molecule Release	Best Suited for Macromolecular Release, Has Potential for Small Molecules



The plot on the left shows the average titer of anti-BSA antibodies in the serum of mice for 100 mg Nanoparticle Aggregate implants containing 67,333, or 677 micrograms of FITC-BSA. The antibodies increased at a near zero order rate out to 70 days. The titers show a dose-dependent antibody response to the FITC BSA.

Technology Properties

Access has developed a novel hydrogel nanoparticle aggregate for use in a variety of drug delivery and other medical applications. The initial development focus for the technology is for the delivery of proteins and peptides. This biocompatible material has extensive formulation flexibility and the versatility of the technology offers the potential for numerous applications as the material can be molded, extruded, injected and made into a film.

Protein and Peptide Delivery

The nanoparticle aggregate system has been optimized for the delivery of proteins and peptides, particularly those susceptible to degradation in solvent-based manufacturing processes. Studies of the release of model macromolecules from the space between the nanoparticles show the ability to tailor the delivery profile to that required for individual compounds. This is achieved by altering the size or chemical composition of the nanoparticles. In addition, aggregates have been shown to protect active proteins from enzymatic degradation, thus improving their utility as controlled release devices for proteins and peptides.

The materials that compose the nanoparticles have been extensively employed in the manufacture of medical devices. Studies conducted with the nanoparticle aggregates confrm that no local irritation occurs at the implant device site. In addition, the ability to load in a water environment removes the potential for protein denaturing with accompanying loss of activity.

Commercial Strategy

Access has a collaboration with a major drug delivery company to evaluate the technology for the delivery of a specific protein. It is the Company's objective to develop products in conjunction with strategic partners and identify development opportunities that the Company will advance prior to seeking a strategic partner. With the data that has already been generated on the aggregates, it is anticipated that collaborations outside drug delivery can be established utilizing the biocompatible material for tissue engineering and medical device manufacture.

Partnerships

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Access' business strategy of developing a broadly-based technology portfolio presents us with numerous opportunities to form strategic partnerships with companies for the licensing and the co-development of product candidates. The OraDisc™ technology affords us the opportunities, without the commitment of significant resources, to enter numerous near-term licensing and development agreements. The program is designed to provide near-term cash flow through product and licensing revenues.

The principal focus of our partnering strategy is to out-license our polymer platinate program and enter research collaborations for the development of products utilizing our vitamin mediated oral delivery and nanoparticle aggregate technologies. During 2003 significant data has been generated supporting these technologies which not only adds to the technology value but also expands the universe of companies interested in discussing potential collaborations. Also, the expanded data base supporting the technology enables the Company to be more selective in their choice of collaborations. The scientific feasibility, chance of success and commercial opportunity together with the economic terms of a potential relationship are the determining factors in assessing collaborative opportunities.

It is anticipated that during the upcoming 12 months a number of strategic partnerships will be established for both developed products and applications of our technology. Achieving this objective is a critical component of our business plan.

For our marketed products it is anticipated that additional partnerships, to expand our global network, will be established. The principal focus in this area is to out-license OraDisc™ A for the United States market, preferably to an OTC marketing organization.

Amlexanox
Zambon
Meda
Strakan
Esteve

Zindaclin®
Fujisawa
Strakan
Biosintetica
Unipharm
Pliva
Hyundai
Taro
Orient Europharma
Farmasel
Medlink

Oral Delivery
Celltech

OraDisc™ OTC
Wyeth Consumer Healthcare

Nanoparticle Aggregates
Drug Delivery Company

Financial Statements

Innovative Drug Delivery Solutions

This Annual Report contains certain statements that are forward-looking within the meaning of Section 27a of the Securities Act of 1933, as amended, and that involve risks and uncertainties, including but not limited to statements made relating to expected increases in revenues in 2004, our anticipated share price, our ability to generate profits, the approval of OraDisc A in the US and Europe, additional licensing, collaboration and development agreements, additional product launches and our ability to generate revenues from four products in 2004, our ability to generate over-the-counter products to generate near-term licensing and product sales revenues. These statements are subject to numerous risks, including but not limited to the uncertainties associated with research and development activities, clinical trials, our ability to raise capital, the timing of and our ability to achieve regulatory approvals, dependence on others to market our licensed products, collaborations, future cash flow, our ability to conform under our plan to regain compliance with AMEX listing standards, the timing and receipt of licensing and milestone revenues, projected future revenue growth and our ability to generate near term revenues, the future success of the Company's targeted products Apthnasol®, Zindaclin® and products in development including polymer platinate, OraDisc™ and our mucositis technology, our ability to develop products form our platform technologies, our ability to manufacture amlexanox products in commercial quantities, our sales projections and the sales projections of our licensing partners, and other risks detailed in the Company's Annual Report on Form 10-K for the year ended December 31, 2003, and other reports filed by us with the Securities and Exchange Commission.

Management's Discussion and Analysis of Financial Condition and Results of Operations

Overview

We are an emerging pharmaceutical company focused on developing both novel low development risk product candidates and technologies with longer-term major product opportunities. We are a Delaware corporation.

Together with our subsidiaries, we have proprietary patents or rights to eight drug delivery technology platforms:

- synthetic polymer targeted delivery,
- vitamin mediated targeted delivery,
- vitamin mediated oral delivery,
- bioerodible cross-linker technology,
- mucoadhesive disc technology,
- hydrogel particle aggregate technology,
- Residerm® topical delivery and
- carbohydrate targeting technology.

In addition, we are marketing in the United States - Aphthasol®, the first FDA approved product for the treatment of canker sores. We are developing new formulations and delivery forms to evaluate amlexanox in additional clinical indications, including mucoadhesive disc delivery and mucoadhesive liquid delivery.

Our amlexanox 5% paste is marketed in the US as Aphthasol®. Block Drug Company had manufactured the 5% amlexanox paste since the product was approved by the FDA in 1996 in a facility certified by the FDA for Good Manufacturing Practices. At such time we entered into a Supply Agreement whereby Block Drug Company was to produce Aphthasol® for us for a defined period of time at its Puerto Rico facility. We were subsequently advised by Block Drug Company that it was unable to comply with the terms of the Supply Agreement and that it would not be able to produce Aphthasol® for us. Due to Block Drug Company's production failure, we had sufficient product to supply wholesalers only through June 2003. We do not anticipate further sales of the product until the second quarter of 2004. We have selected Contract Pharmaceuticals Ltd. Canada as our new manufacturer of amlexanox 5% paste and it has produced initial qualifying batches of the product. Full scale production has commenced in the first quarter of 2004.

Since our inception, we have devoted our resources primarily to fund our research and development programs. We have been unprofitable since inception and to date have received limited revenues from the sale of products. We cannot assure you that we will be able to generate sufficient product revenues to attain profitability on a sustained basis or at all. We expect to incur losses for the next several years as we continue to invest in product research and development, preclinical studies, clinical trials and regulatory compliance. As of December 31, 2003, our accumulated deficit was $54,227,000, of which $8,894,000 was the result of the write-off of excess purchase price.

On February 24, 2004 we closed a private placement sale of our common stock pursuant to which we sold 1,789,371 shares of our common stock at a per share price of $5.40. We received gross proceeds of $9,663,000 from this sale and had expenses of $615,000. The investors also received 5 year warrants at an exercise price of $7.10 per share to purchase 447,344 shares of our common stock and the placement agents received warrants in the offering at an exercise price of $5.40 per share to purchase 156,481 shares of our common stock. The funds from the private placement will be used principally for general corporate purposes to support our operations and to fund clinical development of our portfolio of product candidates.

Results of Operations

Comparison of Years Ended December 31, 2003 and 2002

Our licensing revenue in 2003 was $729,000, as compared to licensing revenue of $853,000 in 2002, a decrease of $124,000. We recognize licensing revenue over the period of the performance obligation under our licensing agreements. Licensing revenue recognized in both 2003 and 2002 was from several agreements, including agreements related to various amlexanox projects and Residerm®.

Product sales of Aphthasol® totaled $532,000 in 2003, as compared to product sales of $194,000 in 2002. Our first sales were recorded in December 2002. As a result of the supply situation discussed above, there have been no product sales of Aphthasol® since June 2003.

In 2002 we had a research and development agreement which provided $89,000 in revenue. The agreement expired in 2002 and we had no such revenue in 2003.

Royalty income for 2003 was $34,000 as compared to $11,000 in 2002, an increase of $23,000. As our products are approved, marketed and accepted, royalty income is expected to increase in future periods.

Our total research spending for the year ended December 31, 2003 was $6,096,000, as compared to $7,024,000 in 2002, a decrease of $928,000. The decrease in expenses was the result of:

- lower clinical development costs ($812,000) for amlexanox development projects for OraDisc™; and
- lower development and clinical development costs for our polymer platinate project ($773,000).

These decreases were offset by:

- higher salary and salary related expenses due to additional staff ($278,000);
- higher expenses due to our Australian subsidiary ($254,000);
- higher internal lab costs due to the additional staff and projects ($102,000); and
- other net increases ($23,000).

Our cost of product sales was $277,000 for 2003 as compared to $107,000 in 2002. The commencement of our Aphthasol® sales began in the fourth quarter of 2002.

Our total general and administrative expenses were $2,514,000 for 2003 and $2,277,000 in 2002, an increase of $237,000 due to:

- higher professional fees and expenses ($151,000);
- higher shareholder-investor relations expenses ($74,000);
- higher patent and license expenses ($60,000);
- higher salary and related expense ($50,000); and
- higher rent expenses ($31,000).

These increases were offset by lower withholding taxes on foreign revenues ($129,000).

Depreciation and amortization was $621,000 in 2003 as compared to $439,000 in 2002, an increase of $182,000 primarily resulting from the acquisition of new capital equipment and a full year of amortization of acquired patents.

Our loss from operations in 2003 was $8,213,000 as compared to a loss of $8,700,000 in 2002.

Our interest and miscellaneous income was $2,559,000 for 2003 as compared to $594,000 for 2002, an increase of $1,965,000. The increase in miscellaneous income of $2,280,000 was due to a one time settlement agreement with Block Drug Company relating to Block's contractual obligation to supply Aphthasol® to us. Pursuant to the settlement, Block made a onetime cash payment to us and we were also relieved of certain future payment obligations to Block under the Asset Sale Agreement pursuant to which we purchased from Block the assets relating to amlexanox. Under the settlement agreement, Block was relieved of its obligation to supply amlexanox to us. The increase in interest and miscellaneous income was partially offset by a decrease in interest income due to lower cash balances and lower interest rates in 2003 as compared with 2002.

Interest expense was $1,281,000 for 2003 as compared to $1,278,000 for the same period in 2002, an increase of $3,000.

Net loss for 2003 was $6,935,000, or a $0.52 basic and diluted loss per common share compared with a loss of $9,384,000, or a $0.72 basic and diluted loss per common share, for 2002.

Comparison of Years Ended December 31, 2002 and 2001

Our licensing revenue in 2002 was $853,000, as compared to licensing revenue of $243,000 in 2001, an increase of $610,000. We recognize licensing revenue over the period of the performance obligation under our licensing agreements. Licensing revenue recognized in both 2002 and 2001 was from several agreements, including agreements related to various amlexanox projects and Residerm®.

Product sales of Aphthasol® totaled $194,000 in 2002, our first sales were recorded in December 2002.

We received research and development revenue of $89,000 and royalty income in 2002, whereas we did not receive either of these types of revenues in 2001. The research and development revenue was for a project that is now completed and will not continue in the future. The royalty income will continue since product sales started in 2002.

Our total research spending for the year ended December 31, 2002 was $7,024,000, as compared to $4,174,000 in 2001, an increase of $2,850,000. The increase in expenses was the result of:

- higher development and clinical development costs for our polymer platinate project ($997,000);
- higher clinical development costs ($1,148,000) for amlexanox development projects for OraDisc™;
- higher salary and salary related expenses due to additional staff ($579,000);
- higher expenses due to our Australian subsidiary ($341,000); and
- higher internal lab costs due to the additional staff and projects ($44,000).

These increases were offset by lower scientific consulting fees ($236,000) and other net decreases ($23,000).

We expect our research spending to remain higher than it has been in previous years as we intend to hire additional scientific staff, commence additional clinical trials and accelerate preclinical development activities as we continue to develop our product candidates.

Our cost of product sales was $107,000 for 2002 due to the commencement of our Aphthasol® sales in the fourth quarter of 2002.

Our total general and administrative expenses were $2,277,000 for 2002 and $1,959,000 in 2001, an increase of $318,000 due to:

- higher salary and related expense ($92,000);
- higher foreign tax expense ($92,000);
- higher patent and license expenses ($85,000);
- higher rent expenses ($78,000);
- higher professional fees and expenses ($50,000); and
- other net increases ($60,000).

These increases were offset by lower shareholder-investor relations expenses ($111,000) and lower executive search fees ($28,000).

Depreciation and amortization was $439,000 in 2002 as compared to $418,000 in 2001, an increase of $21,000.

Our loss from operations in 2002 was $8,700,000 as compared to a loss of $6,308,000 in 2001.

Our interest and miscellaneous income was $594,000 for 2002 as compared to $1,451,000 for 2001, a decrease of $857,000. The decrease in interest income was due to lower net cash balances in 2002 and lower interest rates.

Interest expense was $1,278,000 for 2002 as compared to $1,170,000 for the same period in 2001, an increase of $108,000. The increase in interest expense was due to higher interest accrued on the $13.5 million convertible notes issued in September 2000 and amortization of debt issuance costs.

Net loss for 2002 was $9,384,000, or a $0.72 basic and diluted loss per common share compared with a loss of $6,027,000, or a $0.47 basic and diluted loss per common share, for 2001.

Liquidity and Capital Resources

On February 24, 2004 we closed a private placement sale of our common stock pursuant to which we sold 1,789,371 shares of our common stock at a per share price of $5.40. We received gross proceeds of $9,663,000 from this sale and had expenses of $615,000. The investors also received 5 year warrants at an exercise price of $7.10 per share to purchase 447,344 shares of our common stock and the placement agents received warrants in the offering at an exercise price of $5.40 per share to purchase 156,481 shares of our common stock. The funds from the private placement will be used principally for general corporate

purposes to support our operations and to fund clinical development of our portfolio of product candidates. At February 27, 2004 our cash and cash equivalents were $10,354,000.

We have funded our operations primarily through private sales of common stock, convertible notes and our principal source of liquidity is cash and cash equivalents. Contract research payments, licensing fees and milestone payments from corporate alliances and mergers have also provided funding for operations. As of December 31, 2003 our cash and cash equivalents were $2,587,000 and our working capital was $1,426,000. Our working capital at December 31, 2003 represented a decrease of $6,388,000 as compared to our working capital as of December 31, 2002 of $7,594,000. This decrease was due to our overall operating expenses and the interest paid on the $13.5 million convertible notes offset by the revenues we received.

We have incurred negative cash flows from operations since inception, and have expended, and expect to continue to expend in the future, substantial funds to complete our planned product development efforts. Since inception, our expenses have significantly exceeded revenues, resulting in an accumulated deficit as of December 31, 2003 of $54,227,000. We expect that our existing capital resources will be adequate to fund our current level of operations through 2005. We cannot assure you that we will ever be able to generate product revenue or achieve or sustain profitability.

We will expend substantial funds to conduct research and development programs, preclinical studies and clinical trials of potential products, including research and development with respect to our newly acquired and developed technology. Our future capital requirements and adequacy of available funds will depend on many factors, including:

- the successful commercialization of amlexanox and Zindaclin®;
- the ability to establish and maintain collaborative arrangements with corporate partners for the research, development and commercialization of products;
- continued scientific progress in our research and development programs;
- the magnitude, scope and results of preclinical testing and clinical trials;
- the costs involved in filing, prosecuting and enforcing patent claims;
- competing technological developments;
- the cost of manufacturing and scale-up;
- the ability to establish and maintain effective commercialization arrangements and activities; and successful regulatory filings.

We have devoted substantially all of our efforts and resources to research and development conducted on our own behalf. The following table summarizes research and development spending by project category (in thousands), which spending includes, but is not limited to, payroll and personnel expense, lab supplies, preclinical expense, development cost, clinical trial expense, outside manufacturing expense and consulting expense:

Project	Three Months ended December 31, 2003	Three Months ended December 31, 2002	Twelve Months ended December 31, 2003	Twelve Months ended December 31, 2002	Inception to Date (1)
Polymer Platinante (AP5280 and AP5346)	$ 563	$ 532	$ 2,559	$ 2,941	$ 12,781
OraDisc™	114	607	1,387	2,296	6,223
Bioerodible Hydrogel Technology and Nanoparticles and Nanoparticle Networks	312	224	978	811	2,348
Vitamin Mediated Targeted Delivery	225	192	614	341	955
Mucoadhesive Liquid Technology (MLT)	(14)	39	34	220	1,429
Others (2)	348	215	524	415	4,767
Total	$ 1,548	$ 1,809	$ 6,096	$ 7,024	$ 28,503

(1) Cumulative spending from inception through December 31, 2003.

(2) The following projects are among the ones included in this line item: Carbohydrate targeting, amlexanox cream and gel and other related projects.

Due to uncertainties and certain of the risk factors described above, including those relating to our ability to successfully commercialize our drug candidates, our ability to obtain necessary additional capital to fund operations in the future, our ability to successfully manufacture our products and our product candidates in clinical quantities or for commercial purposes,

government regulation to which we are subject, the uncertainty associated with preclinical and clinical testing, intense competition that we face, market acceptance of our products and protection of our intellectual property, it is not possible to reliably predict future spending or time to completion by project or product category or the period in which material net cash inflows from significant projects are expected to commence. If we are unable to timely complete a particular project, our research and development efforts could be delayed or reduced, our business could suffer depending on the significance of the project and we might need to raise additional capital to fund operations, as discussed in the risk factors above, including without limitation those relating to the uncertainty of the success of our research and development activities and our ability to obtain necessary additional capital to fund operations in the future. As discussed in such risk factors, delays in our research and development efforts and any inability to raise additional funds could cause us to eliminate one or more of our research and development programs.

We plan to continue our policy of investing available funds in certificates of deposit, money market funds, government securities and investment-grade interest-bearing securities, none of which matures in more than two years. We do not invest in derivative financial instruments, as defined by Statement of Financial Accounting Standards No. 133 and 138.

We have issued an aggregate of $13,530,000 of convertible notes, which are due in two parts, $8,030,000 is due on September 13, 2005 and $5,500,000 is due on September 13, 2006. The notes which bear interest at a rate of 7.7% per annum with $1,041,000 of interest due annually on each September 13, may convert to Common Stock at a conversion price of $5.50 per share. Should the holders of the notes not elect to convert them to common stock, or we are not able to force the conversion of the notes by their terms, we must repay the amounts on the dates described herein. We currently do not have the funds available to repay the convertible notes. We may need to restructure the terms of the notes as we near the due date for repayment. Any such restructuring could have a significant impact on our capital structure and liquidity.

Critical Accounting Policies

The preparation of our financial statements in conformity with accounting principles generally accepted in the United State of America requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities, disclosure of contingent assets and liabilities at the date of the financial statements and the reported amount of revenues and expenses during the reported period. In applying our accounting principles, we must often make individual estimates and assumptions regarding expected outcomes or uncertainties. As you might expect, the actual results or outcomes are often different than the estimated or assumed amounts. These differences are usually minor and are included in our consolidated financial statements as soon as they are known. Our estimates, judgments and assumptions are continually evaluated based on available information and experience. Because of the use of estimates inherent in the financial reporting process, actual results could differ from those estimates.

Revenue

Revenue associated with up-front license, technology access and research and development funding payments under collaborative agreements is recognized ratably over the relevant periods specified in the agreement.

Asset Impairment

On January 1, 2002, we adopted SFAS 142, *"Goodwill and Other Intangible Assets."* Upon adoption, we performed a transitional impairment test on our recorded intangible assets that consisted primarily of acquisition related goodwill and lease intangibles. We also performed an annual impairment test in the fourth quarter of 2003. The analysis resulted in no goodwill impairment charge in 2003. We will be required to perform this test on at least an annual basis.

Our intangible assets at December 31, 2003 consist primarily of goodwill, patents acquired in acquisitions and licenses, which were recorded at fair value on the acquisition date.

Based on an assessment of our accounting policies and underlying judgments and uncertainties affecting the application of those policies, we believe that our consolidated financial statements provide a

meaningful and fair perspective of us. We do not suggest that other general factors, such as those discussed elsewhere in this report, could not adversely impact our consolidated financial position, results of operations or cash flow. The impairment test involves judgment on the part of management as to value of goodwill, licenses and intangibles.

Off-Balance Sheet Transactions

None

Contractual Obligations

The Company's significant contractual obligations as of December 31, 2003 are set forth below.

	Payment Due by Period		
	Total	Less Than 1 Year	1-3 Years
Long-Term Debt Obligations	$14,361,000	$ 338,000	$ 14,023,000
Operating Lease Obligations	390,000	176,000	214,000
Total	$14,751,000	$ 514,000	$ 14,237,000

Consolidated Balance Sheets - *December 31,*

ASSETS	2003	2002
Current assets		
Cash and cash equivalents	$ 727,000	$ 1,444,000
Short term investments, at cost	1,860,000	8,332,000
Accounts receivable	1,149,000	1,184,000
Accrued interest receivable	77,000	89,000
Inventory	108,000	461,000
Prepaid expenses and other current assets	898,000	852,000
Total current assets	4,819,000	12,362,000
Property and equipment, net	1,004,000	742,000
Debt issuance costs, net	313,000	496,000
Patents, net	2,652,000	2,991,000
Licenses, net	367,000	449,000
Goodwill, net	1,868,000	1,868,000
Other assets	788,000	579,000
Total assets	$ 11,811,000	$ 19,487,000
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)		
Current liabilities		
Accounts payable and accrued expenses	$ 1,780,000	$ 2,469,000
Accrued interest payable	311,000	311,000
Deferred revenues	1,184,000	1,199,000
Current portion of note payable and future obligations	338,000	789,000
Total current liabilities	3,613,000	4,768,000
Long-term obligations for purchased patents	211,000	346,000
Note payable, net of current portion	282,000	354,000
Convertible notes	13,530,000	13,530,000
Total liabilities	17,636,000	18,998,000
Commitments and contingencies	-	-
Stockholders' equity (deficit)		
Preferred stock - $.01 par value; authorized 2,000,000 shares; none issued or outstanding	-	-
Common stock - $.01 par value; authorized 50,000,000 shares; issued, 13,397,034 at December 31, 2003 and 13,159,119 at December 31, 2002	134,000	132,000
Additional paid-in capital	49,597,000	48,989,000
Notes receivable from stockholders	(1,045,000)	(1,045,000)
Unamortized value of restricted stock grants	(294,000)	(277,000)
Treasury stock, at cost - 819 shares	(4,000)	(4,000)
Accumulated other comprehensive income (loss)	14,000	(14,000)
Accumulated deficit	(54,227,000)	(47,292,000)
Total stockholders' equity (deficit)	(5,825,000)	489,000
Total liabilities and stockholders' equity (deficit)	$ 11,811,000	$ 19,487,000

The accompanying notes are an integral part of these statements.

Consolidated Statements of Operations and Comprehensive Loss

	Year Ended December 31,		
	2003	**2002**	**2001**
Revenues			
License revenues	**$ 729,000**	$ 853,000	$ 243,000
Product sales	**532,000**	194,000	-
Research and development	**-**	89,000	-
Royalty income	**34,000**	11,000	-
Total revenues	**1,295,000**	1,147,000	243,000
Expenses			
Research and development	**6,096,000**	7,024,000	4,174,000
Cost of product sales	**277,000**	107,000	-
General and administrative	**2,514,000**	2,277,000	1,959,000
Depreciation and amortization	**621,000**	439,000	418,000
Total expenses	**9,508,000**	9,847,000	6,551,000
Loss from operations	**(8,213,000)**	(8,700,000)	(6,308,000)
Other income (expense)			
Interest and miscellaneous income	**2,559,000**	594,000	1,451,000
Interest and debt expense	**(1,281,000)**	(1,278,000)	(1,170,000)
	1,278,000	(684,000)	281,000
Net loss	**$ (6,935,000)**	$ (9,384,000)	$ (6,027,000)
Basic and diluted loss per common share	**$ (0.52)**	$ (0.72)	$ (0.47)
Weighted average basic and diluted common shares outstanding	**13,266,733**	13,104,060	12,856,639
Net loss	**$ (6,935,000)**	$ (9,384,000)	$ (6,027,000)
Other comprehensive income (loss)	**$ 28,000**	$ (14,000)	$ -
Foreign currency translation adjustment			
Comprehensive loss	**$ (6,907,000)**	$ (9,398,000)	$ (6,027,000)

The accompanying notes are an integral part of these statements.

Consolidated Statement of Stockholders' Equity (Deficit)

	Common Stock Shares	Common Stock Amount	Additional paid-in capital	Notes receivable from stockholders	Unamortized value of restricted stock grants	Treasury stock	Accumulated other comprehensive income (loss)	Accumulated deficit
Balance, January 1, 2001	12,845,000	$ 132,000	$ 47,802,000	$ (1,045,000)	$ -	$ (4,000)	$ -	$(31,881,000)
Common stock issued for cash exercise of warrants	13,000	-	33,000	-	-	-	-	-
Common stock issued for cashless exercise of warrants and SARs	7,000	-	41,000	-	-	-	-	-
Issuance of restricted stock grants	44,000	-	181,000	-	(181,000)	-	-	-
Amortization of restricted stock grants	-	-	-	-	27,000	-	-	-
Net loss	-	-	-	-	-	-	-	(6,027,000)
Balance, December 31, 2001	12,909,000	132,000	48,057,000	(1,045,000)	(154,000)	(4,000)	-	(37,908,000)
Common stock issued for cash exercise of warrants and options	13,000	-	31,000	-	-	-	-	-
Common stock issued for cashless exercise of warrants	14,000	-	-	-	-	-	-	-
Common stock issued, purchase of assets	173,000	-	632,000	-	-	-	(14,000)	-
Warrants issued	-	-	80,000	-	-	-	-	-
Issuance of restricted stock grants	50,000	-	189,000	-	(190,000)	-	-	-
Other comprehensive loss	-	-	-	-	-	-	(14,000)	-
Amortization of restricted stock grants	-	-	-	-	67,000	-	-	-
Net loss	-	-	-	-	-	-	-	(9,384,000)
Balance, December 31, 2002	13,159,000	132,000	48,989,000	(1,045,000)	(277,000)	(4,000)	(14,000)	(47,292,000)
Common stock issued for cash exercise of warrants and options	103,000	1,000	266,000	-	-	-	-	-
Common stock issued for cashless exercise of warrants	80,000	1,000	(1,000)	-	-	-	-	-
Warrants issued	-	-	233,000	-	-	-	-	-
Issuance of restricted stock grants	55,000	-	110,000	-	(111,000)	-	-	-
Other comprehensive income	-	-	-	-	-	-	28,000	-
Amortization of restricted stock grants	-	-	-	-	94,000	-	-	-
Net loss	-	-	-	-	-	-	-	(6,935,000)
Balance, December 31, 2003	**13,397,000**	**$134,000**	**$ 49,597,000**	**$(1,045,000)**	**$294,000**	**$(4,000)**	**$14,000**	**$ (54,227,000)**

The accompanying notes are an integral part of this statement.

Consolidated Statements of Cash Flows

	Year Ended December 31,		
	2003	**2002**	**2001**
Cash flows from operating activities:			
Net loss	**(6,935,000)**	(9,384,000)	(6,027,000)
Adjustments to reconcile net loss to net cash used in operating activities:			
Warrants issued in payment of consulting expenses	**57,000**	37,000	41,000
Amortization of restricted stock grants	**94,000**	64,000	27,000
Depreciation and amortization	**621,000**	439,000	418,000
Amortization of debt costs	**183,000**	183,000	182,000
Other long-term obligations	**-**	43,000	-
Change in operating assets and liabilities:			
Accounts receivable	**35,000**	(1,101,000)	168,000
Accrued interest receivable	**12,000**	21,000	86,000
Inventory	**353,000**	(461,000)	-
Prepaid expenses and current assets	**130,000**	(241,000)	(478,000)
Other assets	**(209,000)**	130,000	(1,000)
Accounts payable and accrued expenses	**(689,000)**	983,000	328,000
Accrued interest payable	**-**	1,000	27,000
Deferred revenue	**(15,000)**	691,000	(43,000)
Net cash used in operating activities	**(6,363,000)**	(8,595,000)	(5,272,000)
Cash flows from investing activities:			
Capital expenditures	**(462,000)**	(403,000)	(419,000)
Redemptions (purchases) of short-term investments and certificates of deposit, net	**6,472,000**	4,368,000	4,094,000
Purchase of businesses, net of cash acquired	**-**	(1,313,000)	-
Net cash provided by investing activities	**6,010,000**	2,652,000	3,675,000
Cash flows from investing activities:			
Proceeds from notes payable	**126,000**	-	600,000
Payments of notes payable	**(784,000)**	(107,000)	(25,000)
Proceeds from stock issuance, net	**266,000**	32,000	33,000
Net cash provided by (used in) financing activities	**(392,000)**	(75,000)	608,000
Net increase (decrease) in cash and cash equivalents	**(745,000)**	(6,018,000)	(989,000)
Effect of exchange rate changes on cash	**28,000**	36,000	-
Cash and cash equivalents at beginning of period	**1,444,000**	7,426,000	8,415,000
Cash and cash equivalents at end of period	**$ 727,000**	$ 1,444,000	$ 7,426,000
Cash paid for interest	***1,281,000***	*$ 1,083,000*	*$ 959,000*
Cash paid for income taxes	**-**	-	-
Supplemental disclosure of noncash transactions			
Acquisitions of Australia patents			
Assets acquired	**-**	*676,000*	-
Stock and warrants issued	**-**	*(676,000)*	-

The accompanying notes are an integral part of this statement.

NOTE 1 – NATURE OF OPERATIONS AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Nature of Operations

Access Pharmaceuticals, Inc. is a diversified emerging pharmaceutical company engaged in the development of novel therapeutics based primarily on the adaptation of existing therapeutic agents using its proprietary drug delivery platforms. We operate in a single industry segment. Our efforts have been principally devoted to research and development, resulting in significant losses since inception on February 24, 1988. Prior to 2002, we presented our financial statements as a development stage enterprise. We no longer consider ourselves to be in the development stage.

A summary of the significant accounting policies applied in the preparation of the accompanying consolidated financial statements follows.

Principles of Consolidation

The consolidated financial statements include the financial statements of Access Pharmaceuticals, Inc. and our wholly-owned subsidiaries. All significant intercompany balances and transactions have been eliminated in consolidation.

Cash and Cash Equivalents

We consider all highly liquid instruments with an original maturity of three months or less to be cash equivalents for purposes of the statements of cash flows. We invest our excess cash in government and corporate securities. Cash and cash equivalents consist primarily of cash in banks, money market funds and short-term corporate securities. All other investments are reported as short-term investments.

Short-term Investments and Certificates of Deposit

All short term investments are classified as held to maturity. The cost of debt securities is adjusted for amortization of premiums and accretion of discounts to maturity. Such amortization is included in interest income. The cost of securities sold is based on the specific identification method.

Property and Equipment

Property and equipment are recorded at cost. Depreciation is provided using the straight-line method over estimated useful lives ranging from three to seven years.

Patents and Applications

We expense internal patent and application costs as incurred because, even though we believe the patents and underlying processes have continuing value, the amount of future benefits to be derived there from are uncertain. Purchased patents are capitalized and amortized over the life of the patent.

Licenses

We recognize the purchase cost of licenses and amortize them over their estimated useful lives.

Revenue Recognition

Licensing revenues are recognized over the period of our performance obligation. Licensing agreements generally require payments of fees on executing the agreement with milestone payments based on regulatory approvals and cumulative sales. Some agreements allow for the return of a portion of the initial execution fee if regulatory approvals are not received. Many of our agreements are for ten years with automatic extensions. Sponsored research and development revenues are recognized as research and development activities are performed under the terms of research contracts. Advance payments received are recorded as unearned revenue until the related research activities are performed. Royalty income is recognized as earned at the time the licensed product is sold. Option revenues

are recognized when the earnings process is completed pursuant to the terms of the respective contract.

Revenue from product sales is recognized when the customer's order is shipped from our third party logistics company's warehouse.

Research and Development Expenses

Pursuant to SFAS No. 2, *"Accounting for Research and Development Costs,"* our research and development costs are expensed as incurred. Research and development expenses include, but are not limited to, payroll and personnel expense, lab supplies, preclinical, development cost, clinical trial expense, outside manufacturing and consulting.

Income Taxes

Income taxes are accounted for under the asset and liability method. Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases and operating loss and tax credit carryforwards. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date. A valuation allowance is provided for deferred tax assets to the extent their realization is in doubt

Loss Per Share

We have presented basic loss per share, computed on the basis of the weighted average number of common shares outstanding during the year, and diluted loss per share, computed on the basis of the weighted average number of common shares and all dilutive potential common shares outstanding during the year. Potential common shares result from stock options, convertible notes and warrants. However, for all years presented, stock options, convertible notes and warrants are anti-dilutive.

Acquisition Related Intangible Assets and Changes in Accounting Principles

Effective January 1, 2002, we adopted SFAS 142, *"Goodwill and Other Intangible Assets."* Under SFAS 142, goodwill is no longer amortized but is subject to an impairment test at least annually or more frequently if impairment indicators arise. Separately identified and recognized intangible assets resulting from business combinations completed before July 1, 2001 that did not meet the new criteria for separate recognition of intangible assets were subsumed in goodwill upon adoption. The intangible assets of the company that did not meet the separate recognition criteria were licenses and acquired patents. We continue to amortize intangible assets that meet the new criteria over their useful lives. In accordance with SFAS 142, we performed a transitional impairment test of goodwill as of January 1, 2002, and an annual test in the fourth quarter of 2003 and 2002, which did not result in an impairment of goodwill.

Intangible assets consist of the following (in thousands):

	December 31, 2003		December 31, 2002	
	Gross carrying value	Accumulated amortization	Gross carrying value	Accumulated amortization
Amortizable intangible assets				
Patents	$ 3,179	$ 527	$ 3,179	$ 188
Licenses	830	463	830	381
Total	$ 4,009	$ 990	$ 4,009	$ 569
Intangible assets not subject to amortization				
Goodwill	$2,464	$ 596	$ 2,464	$ 596

Amortization expense related to intangible assets totaled $421,000, $301,000 and $359,000 for the twelve months ended December 31, 2003, 2002 and 2001, respectively. The aggregate estimated amortization expense for intangible assets remaining as of December 31, 2003 is as follows (in thousands):

2004	$ 421
2006	421
2007	421
2008	396
2009	371
Thereafter	989
Total	$ 3,019

Net loss and loss per share for the twelve months ended December 31, 2003 and 2002, adjusted to exclude goodwill amortization expense, is as follows (in thousands):

	Twelve months ended December 31,		
	2003	2002	2001
Net loss			
Reported net loss allocable to common stockholders	$(6,935)	$ (9,384)	$ (6,027)
Goodwill amortization	-	-	246
Adjusted net loss allocable to common stockholders	$(6,935)	$ (9,384)	$ (5,781)
Basic and diluted loss per share			
Reported basic and diluted loss per share	$ (.52)	$ (.72)	$ (.47)
Goodwill amortization	-	-	.02
Adjusted basic and diluted loss per share	$ (.52)	$ (.72)	$ (.45)

Stock-Based Compensation

We account for our stock option plan in accordance with the provisions of Accounting Principles Board ("APB") Opinion No. 25, Accounting for Stock Issued to Employees, and related interpretations. Compensation expense is recorded only if the current market price of the underlying stock exceeds the exercise price on the date of grant. We have adopted the disclosure provisions of Statement of Financial Accounting Standards (SFAS) No. 123, Accounting for Stock-Based Compensation, which recognizes the fair value of all stock-based awards on the date of grant.

At December 31, 2003 we had two stock-based employee compensation plans, which are described more fully in Note 11. No stock-based employee compensation cost, other than compensation associated with options assumed in acquisitions, is reflected in net loss, as all options granted under those plans had an exercise price equal to the market value of the underlying common stock on the date of grant. The following table illustrates the effect on net loss and net loss per share if we had applied the fair value recognition of SFAS 123, *Accounting for Stock-Based Compensation*, to stock-based employee compensation.

	December 31,		
	2003	2002	2001
Net loss			
As reported	$ (6,935,000)	$(9,384,000)	$(6,027,000
Pro forma stock option expense	(1,232,000)	(1,662,000)	(1,565,000
Pro forma	(8,167,000)	(11,046,000)	(7,592,000
Basic and diluted loss per share			
As reported	$ (.52)	$ (.72)	$ (.47
Pro forma stock option expense	(.09)	(.12)	(.12
Pro forma	$ (.61)	$ (.84)	$ (.59

Stock compensation expense for options granted to nonemployees has been determined in accordance with SFAS 123 and EITF 96-18, *"Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services,"* as the fair value of the consideration received or the fair value of the equity instruments issued, whichever is more reliably measured.

Use of Estimates

In preparing consolidated financial statements in conformity with accounting principles generally accepted in the United States of America, management is required to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the financial statements, and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

We tested goodwill for impairment based on estimates of fair value. It is at least reasonably possible that the estimates used by us will be

materially different from actual amounts. These differences could result in the impairment of all or a portion of our goodwill, which could have a materially adverse effect on our results of operations.

Fair Value of Financial Instruments

The carrying value of cash, cash equivalents, short-term investments and certificates of deposit approximates fair value due to the short maturity of these items. It is not practical to estimate the fair value of the Company's long-term debt because quoted market prices do not exist and there were no available securities as a basis to value our debt.

NOTE 2 – SHORT-TERM INVESTMENTS

Short-term investments consist of certificates of deposit maturing from March 2003 through April 2004.

NOTE 3 - ACQUISITIONS

Our wholly-owned subsidiary, Access Pharmaceuticals Australia Pty. Limited acquired the targeted therapeutic technology business of Biotech Australia Pty. Ltd under an Asset Sale Agreement dated February 26, 2002. Under the terms of the Asset Sale Agreement, Access Pharmaceuticals Australia Pty. Limited acquired the patents to three targeted therapeutics technologies and retained the scientific group that has developed this technology. The total consideration payable by us will be paid in a combination of cash and stock over a three-year period and is dependent on the achievement of certain technology milestones. We paid $500,000 at closing and an additional total of up to $525,000 will be paid over a three-year period. Additionally up to $350,000 may be payable if events occur that result in certain new agreements. We also issued as consideration 172,584 shares of our common stock (valued at $633,000) and warrants to purchase 25,000 shares of our common stock at an exercise price of $5.00 per share (valued at $43,000 using the Black-Scholes option pricing model).

The three patented targeted therapeutic technologies acquired in this transaction are:

- folate conjugates of polymer therapeutics to enhance tumor delivery by targeting folate receptors which are upregulated in certain tumor types;
- the use of vitamin B12 to target the transcobalamin II receptor which is upregulated in numerous diseases including cancer, rheumatoid arthritis and certain neurological and autoimmune disorders; and
- oral delivery of a wide variety of molecules, which cannot otherwise be orally administered, using the active transport mechanism which transports vitamin B12 into the systemic circulation.

The cost of the acquisition has been assigned principally to patents and will be amortized over the remaining useful life of the patents which averages ten years.

On July 22, 2002, we acquired from GlaxoSmithKline the patents, trademarks and technology covering the use of amlexanox for the treatment of mucosal and skin disorders. The two major components of the acquisition are the US marketing rights to amlexanox 5% paste which is currently marketed for the treatment of canker sores under the trademark Aphthasol®, and the remaining worldwide marketing rights for this indication which were the subject of a prior licensing agreement between the companies. Under the terms of the agreement, we made an initial upfront payment of $750,000 and an additional payment of $250,000 on January 22, 2003.

NOTE 4 - RELATED PARTY TRANSACTIONS

Under a former consulting agreement between Thoma Corporation ("Thoma") and us, Thoma received payments for consulting services and reimbursement of direct expenses. Herbert H. McDade, Jr., our Chairman of the Board of Directors, is an owner of Thoma Corp. Thoma received payments for consulting services and was also reimbursed for expenses as follows:

Year	Consulting fees	Expense reimbursement
2002	$ 18,000	$ -
2001	54,000	-

Stephen B. Howell, M.D., a Director, receives payments for consulting services and reimbursement of direct expenses and has also received warrants for his consulting services. Dr. Howell's payments for consulting services, expense reimbursements and warrants are as follows:

Year	Consulting fees	Expense reimbursement	Warrants	Exercise price	Fair value
2003	$ 60,000	$ 6,000	30,000	$ 3.00	$30,000
2002	55,000	3,000	10,000	4.91	37,000
2001	101,000	16,000	15,000	3.00	41,000

See Note 10 for a discussion of our Restricted Stock Purchase Program.

NOTE 5 - PROPERTY AND EQUIPMENT

	December 31, 2003	December 31, 2002
Laboratory equipment	$ 1,972,000	$ 1,524,000
Laboratory and building improvements	166,000	157,000
Furniture and equipment	196,000	191,000
	2,334,000	1,872,000
Less accumulated depreciation and amortization	1,330,000	1,130,000
Net property and equipment	$ 1,004,000	$ 742,000

Depreciation and amortization on property and equipment was $200,000, $138,000, and $57,000 for the years ended December 31, 2003, 2002 and 2001, respectively.

NOTE 6 – 401(k) PLAN

We have a tax-qualified employee savings and retirement plan (the "401(k) Plan") covering all our employees. Pursuant to the 401(k) Plan, employees may elect to reduce their current compensation by up to the statutorily prescribed annual limit ($12,000 in 2003; $11,000 in 2002; and $10,500 in 2001) and to have the amount of such reduction contributed to the 401(k) Plan. We have a 401(k) matching program whereby we contribute for each dollar a participant contributes a like amount, with a maximum contribution of 2% of a participant's earnings. The 401(k) Plan is intended to qualify under Section 401 of the Internal Revenue Code so that contributions by employees or by us to the 401(k) Plan, and income earned on 401(k) Plan contributions, are not taxable to employees until withdrawn from the 401(k) Plan, and so that contributions by us, if any, will be deductible by us when made. At the direction of each participant, we invest the assets of the 401(k) Plan in any of 23 investment options. Company contributions under the 401(k) Plan were approximately $45,000 in 2003; $37,000 in 2002; and $32,000 in 2001.

NOTE 7 – NOTE PAYABLE AND OTHER OBLIGATIONS

On September 20, 2001, we completed a $600,000 installment loan with a bank. The loan was used to purchase capital equipment and for leasehold improvements to expand our laboratory and office space. The loan is due in 60 equal installments, including interest at 6.5%. The loan is secured by a $354,000 certificate of deposit classified as an other asset at December 31, 2003.

On February 26, 2002, our wholly-owned subsidiary, Access Pharmaceuticals Australia Pty. Limited acquired the targeted therapeutic technology business of Biotech Australia Pty. Ltd under an Asset Sale Agreement. We will pay $175,000 each February 26, starting in 2003, for a total of up to $525,000, over a three-year period.

Future maturities of the note payable and other obligations are as follows:

2004	$338,000
2005	330,000
2006	110,000
Thereafter	53,000
	$ 831,000

NOTE 8 – CONVERTIBLE NOTES

On September 20, 2000, we completed a $13.5 million convertible note offering. The offering was placed with three investors. Our convertible notes are due in two parts, $8,030,000 due on September 13, 2005 and $5,500,000 due on September 13, 2007. The notes bear interest at 7.7% per annum with $1,041,000 of interest due annually on September 13th. The notes have a fixed conversion price of $5.50 per share of common stock and may be converted by the note holder or us under certain circumstances as defined in the note. If the notes are not converted we will have to repay the notes on the due dates. Total expenses of issuance were $915,000 and are amortized over the life of the notes.

NOTE 9 - COMMITMENTS

At December 31, 2003, we have commitments under noncancelable operating leases for office and research and development facilities and equipment as follows:

2004	176,000
2005	171,000
2006	43,000
Total future minimum lease payments	$ 390,000

Rent expense for the years ended December 31, 2003, 2002 and 2001 was $165,000, $138,000 and $114,000, respectively.

NOTE 10 - STOCKHOLDERS' EQUITY

Restricted Stock Purchase Program

On October 12, 2000, the Board of Directors authorized a Restricted Stock Purchase Program. Under the Program, the Company's executive officers and corporate secretary were given the opportunity to purchase shares of common stock in an individually designated amount per participant determined by the Compensation Committee of the Board of Directors. A total of 190,000 shares were purchased under the Program by four eligible participants at $5.50 per share, the fair market value of the common stock on October 12, 2000, for an aggregate consideration of $1,045,000. The purchase price was paid through the participant's delivery of a 50%-recourse promissory note payable to the Company for three executive officer participants and a full-recourse promissory note payable to the Company for the corporate secretary. Each note bears interest at 5.87% compounded semi-annually and has a maximum term of ten years. The notes are secured by a pledge of the purchased shares to the Company. The Company recorded the notes receivable from participants in this Program of $1,045,000 as a reduction of equity in the Consolidated Balance Sheet. Interest on the notes is neither being collected nor accrued. The stock granted under the Program other than to the corporate secretary vests ratably over a four year period. The stock granted to the corporate secretary vested on the date of grant.

Warrants

There were warrants to purchase a total of 542,062 shares of common stock outstanding at December 31, 2003. All warrants vested on issuance except the warrants in note a. Except for 62,000 warrants (see a), all of the warrants were exercisable at December 31, 2003. The warrants had various prices and terms as follows:

Summary of Warrants	Warrants outstanding	Exercise price	Expiration date
2003 financial advisor (a)	72,000	$3.92	10/30/08
2003 scientific consultant (b)	30,000	3.00	1/1/06
2002 warrants offered in acquisition (c)	25,000	5.00	2/26/05
2002 scientific consultant (d)	10,000	4.96	2/01/09
2001 scientific consultant (e)	15,000	3.00	1/1/08
2000 offering (f)	242,812	2.00	3/01/05
2000 scientific consultant (g)	30,000	2.00	1/01/07
2000 scientific consultant (h)	7,500	3.00	1/01/04
1999 offering (i)	9,750	2.00	7/20/04
1999 financial advisor (j)	100,000	2.93	3/26/04
Total	542,062		

a) During 2003, a financial advisor received warrants to purchase 72,000 shares of common stock at any time from October 30, 2003 until October 30, 2008, for financial consulting services rendered in 2003 and 2004. The warrants vest at a rate of 5,000 shares per month for the first six months and 7,000 shares per month for the second six months. The fair value of the

warrants was $2.82 per share on the date of the grant using the Black-Scholes pricing model with the following assumptions: expected dividend yield 0.0%, risk-free interest rate 2.9%, expected volatility 92% and a term of 5 years.

b) During 2003, a scientific advisor received warrants to purchase 30,000 shares of common stock at an exercise price of $3.00 per share at any time from January 1, 2003 until January 1, 2006, for scientific consulting services rendered in 2003. The fair value of the warrants was $.99 per share on the date of the grant using the Black-Scholes pricing model with the following assumptions: expected dividend yield 0.0%, risk-free interest rate 3.26%, expected volatility 98% and a term of 3 years.

c) During 2002, a company received warrants to purchase 25,000 shares of common stock at an exercise price of $5.00 per share at any time from February 26, 2002 until February 26, 2005. The warrants were issued in connection with the acquisition of patents in Australia. The fair value of the warrants was $1.72 per share on the date of the grant using the Black-Scholes pricing model with the following assumptions: expected dividend yield 0.0%, risk-free interest rate 3.67%, expected volatility 81% and a term of 3 years.

d) During 2002, a scientific advisor received warrants to purchase 10,000 shares of common stock at an exercise price of $4.91 per share at any time from February 1, 2002 until February 1, 2009, for scientific consulting services rendered in 2002. The fair value of the warrants was $3.70 per share on the date of the grant using the Black-Scholes pricing model with the following assumptions: expected dividend yield 0.0%, risk-free interest rate 3.90%, expected volatility 81% and a term of 7 years.

e) During 2001, a scientific advisor received warrants to purchase 15,000 shares of common stock at an exercise price of $3.00 per share at any time from January 1, 2001 until January 1, 2008, for scientific consulting services rendered in 2001. The fair value of the warrants was $2.74 per share on the date of the grant using the Black-Scholes pricing model with the following assumptions: expected dividend yield 0.0%, risk-free interest rate 5.03%, expected volatility 118% and a term of 7 years.

f) In connection with offerings of common stock in 2000, warrants to purchase a total of 509,097 shares of common stock were issued. All of the warrants are exercisable immediately and expire five years from date of issuance.

g) During 2000, a scientific advisor received warrants to purchase 30,000 shares of common stock at an exercise price of $2.00 per share at any time from January 1, 2000 until January 1, 2007, for scientific consulting services rendered in 2000. The fair value of the warrants was $1.68 per share on the date of the grant using the Black-Scholes pricing model with the following assumptions: expected dividend yield 0.0%, risk-free interest rate 5.625%, expected volatility 118% and a term of 5 years.

h) During 2000, a scientific advisor received warrants to purchase 7,500 shares of common stock at any time from January 1, 1999 until January 1, 2004, for scientific consulting services rendered in 2000. The fair value of the warrants was $1.87 per share on the date of the grant using the Black-Scholes pricing model with the following assumptions: expected dividend yield 0.0%, risk-free interest rate 5.38%, expected volatility 122% and a term of 4 years.

i) In connection with offerings of common stock in 1999, warrants to purchase a total of 165,721 shares of common stock were issued. All of the warrants are exercisable

immediately and expire five years from date of issuance.

j) During 1999, a financial advisor received warrants to purchase 100,000 shares of common stock at any time from March 26, 1999 until March 26, 2004, for financial consulting services rendered in 1999. The fair value of the warrants was $2.48 per share on the date of the grant using the Black-Scholes pricing model with the following assumptions: expected dividend yield 0.0%, risk-free interest rate 5.42%, expected volatility 122% and a term of 5 years.

2001 Restricted Stock Plan

We have a restricted stock plan, the 2001 Restricted Stock Plan, under which 200,000 shares of our authorized but unissued common stock were reserved for issuance to certain employees, directors, consultants and advisors. The restricted stock granted under the plan generally vests over five years, 25% two years after the grant date with additional 25% vesting every anniversary date. All stock is vested after five years. At December 31, 2003 there were 149,376 shares granted and 50,624 shares available for grant under the 2001 Restricted Stock Plan.

NOTE 11 - STOCK OPTION PLANS

We have a stock option plan, as amended, (the "1995 Stock Awards Plan"), under which 2,500,000 shares of our authorized but unissued common stock were reserved for issuance to optionees including officers, employees, and other individuals performing services for us. The 1995 Stock Awards Plan replaced the previously approved stock option plan (the "1987 Stock Awards Plan"). On February 11, 2000 we adopted the 2000 Special Stock Option Plan and Agreement (the "Plan"). The Plan provides for the award of options to purchase 500,000 shares of the authorized but unissued shares of common stock of the Company. Options granted under all the plans generally vest ratably over a four to five year period and are generally exercisable over a ten-year period from the date of grant. Stock options are generally granted with an exercise price equal to the market value at the date of grant.

At December 31, 2003, there were 368,000 additional shares available for grant under the 1995 Stock Awards Plan.

The fair value of options was estimated at the date of grant using the Black-Scholes option pricing model with the following weighted average assumptions used for grants in fiscal 2003, 2002 and 2001, respectively: dividend yield of 0% for all periods; volatility of 117%, 98% and 90%; risk-free interest rates of 2.26%, 2.03% and 3.70% and expected lives of four years for all periods. The weighted average fair values of options granted were $1.56, $2.46 and $2.52 per share during 2003, 2002 and 2001, respectively.

Summarized information for the 1995 Stock Awards Plan is as follows:

	Shares	Weighted-average exercise price
Outstanding options at January 1, 2001	1,126,584	$3.68
Granted fair value of $2.52 per share	154,000	3.65
Outstanding options at December 31, 2001	1,280,584	3.68
Granted, fair value of $2.46 per share	493,000	3.53
Exercised	(2,428)	2.08
Forfeited	(60,000)	3.17
Outstanding options at December 31, 2002	1,711,156	3.59
Granted fair value of $1.56 per share	374,500	2.20
Exercised	(28,000)	2.55
Forfeited	(4,000)	2.70
Outstanding options at December 31, 2003	2,053,656	3.45
Exercisable at December 31, 2001	733,851	3.20
Exercisable at December 31, 2002	997,570	3.35
Exercisable at December 31, 2003	1,389,185	3.49

Further information regarding options outstanding under the 1995 Stock Awards Plan at December 31, 2003 is summarized below:

Range of exercise price	Number of shares outstanding	Weighted Average Remaining life in years	Weighted Average Exercise price	Number of shares exercisable	Weighted-average exercise price
$1.49-2.18	492,972	7.5	$2.00	309,180	$2.00
$2.30-2.81	379,100	8.7	2.43	229,779	2.51
$2.94-3.99	751,584	7.4	3.44	500,226	3.30
$4.05-7.8125	430,000	7.1	5.80	350,000	5.74
	2,053,656			1,389,185	

Under the 2000 Special Stock Option Plan, 500,000 options were issued in 2000 and are outstanding at December 31, 2003. 468,749 of the options in the 2000 Special Stock Option Plan were exercisable at December 31, 2003, 343,749 of the options were exercisable at December 31, 2002 and 218,749 of the options were exercisable at December 31, 2001. All of the options expire on March 1, 2010 and have an exercise price of $2.50 per share.

All issued options under the 1987 Stock Awards Plan are vested, exercisable and have a remaining life of one year. No further grants can be made. Summarized information for the 1987 Stock Awards Plan is as follows:

	Shares	Weighted-average exercise price
Outstanding awards at January 1, 2001	28,752	$ 37.38
Forfeited	(2,750)	23.52
Outstanding awards at December 31, 2001,	26,002	46.18
Forfeited	(8,824)	90.45
Outstanding awards at December 31, 2002	17,178	23.31
Forfeited	(5,750)	35.00
Outstanding awards of December 31, 2003	11,428	17.42

NOTE 12 - INCOME TAXES

Income tax expense differs from the statutory amounts as follows:

	December 31, 2003	2002	2001
Income taxes at U.S. statutory rate	$ (2,358,000)	$ (3,191,000)	$ (2,049,000)
Change in valuation allowance	(111,000)	1,153,000	1,897,000
Expenses not deductible	40,000	15,000	8,000
Expiration of net operating loss and general business credit carryforwards, net of revisions	2,429,000	2,023,000	144,000
Total tax expense	$ -	$ -	$ -

Deferred taxes are provided for the temporary differences between the financial reporting bases and the tax bases of our assets and liabilities. The temporary differences that give rise to deferred tax assets were as follows:

	December 31, 2003	2002	2001
Deferred tax assets (liabilities)			
Net operating loss carryforwards	$ 20,193,000	$ 20,487,000	$ 19,259,000
General business credit carryforwards	1,960,000	1,356,000	1,396,000
Property, equipment and goodwill	113,000	119,000	154,000
Gross deferred tax	22,266,000	21,962,000	20,809,000
Valuation allowance	(22,266,000)	(21,962,000)	(20,809,000)
Net deferred taxes	$ -	$ -	$ -

At December 31, 2003, we had approximately $59,390,000 of net operating loss carryforwards and approximately $1,960,000 of general business

credit carryforwards. These carryforwards expire as follows:

	Net operating loss carryforwards	General business credit carryforwards
2004	$ 5,713,000	$ 26,000
2005	2,897,000	38,000
2006	198,000	26,000
2007	994,000	138,000
2008	3,330,000	185,000
Thereafter	46,258,000	1,547,000
	$ 59,390,000	$ 1,960,000

As a result of a merger on January 25, 1996, a change in control occurred for federal income tax purposes which limits the utilization of pre-merger net operating loss carryforwards of approximately $3,100,000 to approximately $530,000 per year.

NOTE 13 – SETTLEMENT WITH BLOCK DRUG COMPANY

On July 22, 2002 we entered into a Supply Agreement whereby Block Drug Company (Block) was required to produce Aphthasol® for us for a defined period of time at its Puerto Rico facility. Subsequently we were advised by Block that it was unable to produce Aphthasol® for us pursuant to the Supply Agreement. In May 2003, we reached a settlement with Block relating to this matter whereby Block made a one-time cash payment to us, we recorded $2,280,000 in Miscellaneous Income and Block was relieved of its obligations under the Supply Agreement and the Asset Sale Agreement, pursuant to which we had purchased certain assets relating to amlexanox and Aphthasol® from Block, and we were relieved from certain future obligations under the Asset Sale Agreement.

NOTE 14 - CONTINGENCIES

William Hall ("Hall") filed suit against Access, and certain officers of Access, in Dallas County, Texas, District Court, on or about February 7, 2003. Although the claims in Hall's complaint are not clearly delineated, he appears to bring claims for fraud, conspiracy, and theft against all defendants, and a claim for breach of contract against Access. Each of the allegations relates to an allegedly unfulfilled contractual obligation to deliver to Hall 45,000 warrants to purchase our stock. Hall alleges in his complaint and in a subsequent letter that the warrants, had they been delivered, could have been worth up to $540,000. He seeks as damages this amount, his attorney's fees, and an unstated amount of punitive damages.

We answered Hall's complaint on March 3, 2003, and brought counterclaims against him relating to certain alleged misrepresentations, his failure to perform certain obligations to Access, and his interference with the our right to enjoy certain contractual benefits. Discovery, substantive fact investigation, and legal analysis have not been completed. Access intends to be vigorous in both its defense of Hall's claims and its pursuit of our counterclaims.

Mipharm S.p.A. ("Mipharm") filed an arbitration against Access in the International Court of Arbitration of the International Chamber of Commerce (the "ICC") on or about October 23, 2003. Mipharm claims that we breached certain license agreements that existed between Mipharm and Access by failing to (1) make commercially reasonable efforts to obtain European Union regulatory approval for certain pharmaceutical products and (2) inform Mipharm of all significant news and actions relating to the approval process. Mipharm seeks damages of approximately $350,000, and an order compelling us to perform pursuant to the license agreements.

We have answered Mipharm's arbitration demand, and simultaneously asserted counterclaims against Mipharm. In the counterclaims, Access alleges, *inter alia*, that Mipharm has itself breached the license agreements and is pursuing claims that it had previously agreed to release in exchange for valuable consideration. We seek approximately $2.2 million in damages.

On January 16, 2004, Mipharm commenced a related lawsuit in Texas Federal Court, in which it alleges that one of Access's counterclaims should have been brought before a different arbitral body. We have since withdrawn the disputed counterclaim. Mipharm nonetheless continues to pursue the Texas action. Our motion to dismiss is currently pending.

Discovery, substantive fact investigation, and legal analysis have only recently begun in both the ICC arbitration and the Texas action. Access intends to vigorously defend against Mipharm's claims and to pursue its own counterclaims.

Del Pharmaceuticals, Inc. ("Del") filed a complaint against Access on or about March 12, 2004, in the Court of Chancery in New Castle County, Delaware. Each of the allegations in the complaint relates to allegedly unfulfilled or breached contractual obligations that Del claims arose from two confidentiality agreements entered into between Del and Access and from a supposed license and supply agreement that Access did not execute. The complaint seeks relief in the form of specific performance of the supposed license and supply agreement, an unspecified amount of money damages, and an order enjoining Access from misappropriating or transferring Del's supposed confidential information or trade secrets to third parties.

Discovery, substantive fact investigation, and detailed legal analysis have not yet begun. We believe that the allegations in the complaint are without merit and we intend to defend vigorously against all claims asserted. We are also considering bringing counterclaims against Del.

NOTE 15 – QUARTERLY FINANCIAL DATA (UNAUDITED)

Our results of operations by quarter for the years ended December 31, 2003 and 2002 were as follows (in thousands, except per share amounts):

	2003 Quarter Ended			
	Mar. 31	Jun. 30	Sep. 30	Dec. 31
Revenue	$ 393	$ 683	$ 11	$ 208
Operating loss	(2,194)	(1,694)	(1,943)	(2,382)
Net Income (loss)	$ (2,411)	$ 316	$ (2,206)	$ (2,634)
Basic and diluted loss per common share	$ (0.18)	$ 0.02	$ (0.17)	$ (0.19)

	2002 Quarter Ended			
	Mar. 31	Jun. 30	Sep. 30	Dec. 31
Revenue	$ 116	$ 263	$ 91	$ 677
Operating loss	(1,763)	(2,118)	(2,675)	(2,144)
Net loss	$ (1,866)	$ (2,308)	$ (2,858)	$ (2,352)
Basic and diluted loss per common share	$ (0.14)	$ (0.18)	$ (0.22)	$ (0.18)

NOTE 16 – SUBSEQUENT FINANCING

On February 24, 2004 we closed a private placement sale of our common stock pursuant to which we sold 1,789,371 shares of our common stock at a per share price of $5.40. We received gross proceeds of $9,663,000 from this sales and had expenses of $615,000. The investors also received 5 year warrants to purchase 447,344 shares of our common stock at an exercise price of $7.10 per share and the placement agents received warrants in the offering to purchase 156,481 shares of our common stock at an exercise price of $5.40 per share.

Report of Independent Certified Public Accountants

Board of Directors and Stockholders

Access Pharmaceuticals, Inc.

We have audited the accompanying consolidated balance sheets of Access Pharmaceuticals, Inc. and Subsidiaries as of December 31, 2003 and 2002, and the related consolidated statements of operations and comprehensive loss, stockholders' equity (deficit), and cash flows for each of the three years in the period ended December 31, 2003. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with auditing standards generally accepted in the United States of America. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of Access Pharmaceuticals, Inc. and Subsidiaries as of December 31, 2003 and 2002, and the consolidated results of their operations and their consolidated cash flows for each of the three years in the period ended December 31, 2003, in conformity with accounting principles generally accepted in the United States of America.

As discussed in Note 1 to the consolidated financial statements, the Company adopted Statement of Financial Accounting Standards No. 142, " Goodwill and Other Intangible Assets" on January 1, 2002.

GRANT THORNTON LLP

Dallas, Texas
March 13, 2004

Selected Financial Data [1]

(in thousands, except for net loss per share)

The following data has been derived from our audited consolidated financial statements and notes thereto appearing elsewhere herein and prior audited consolidated financial statements of Access and notes thereto. The data should be read in conjunction with the Financial Statements and Notes thereto and "Management's Discussion and Analysis of Financial Condition and Results of Operations" appearing elsewhere in this Annual Report.

	For the Year Ended December 31,				
	2003	**2002**	**2001**	**2000**	**1999**
Consolidated Statement of Operations and Comprehensive Loss Data:					
Total revenues	**$ 1,29**	$ 1,147	$ 243	$ 107	$ 15
Operating loss	**(8,21**	(8,700)	(6,308)	(6,058)	(3,364)
Interest and miscellaneous income	**2,559**	594	1,451	972	53
Interest expense	**1,281**	1,278	1,170	342	12
Net loss	**(6,935)**	(9,384)	(6,027)	(5,428)	(3,308)
Common Stock Data:					
Net loss per basic and diluted common share	**$ (0.52)**	$ (0.72)	$ (0.47)	$ (0.49)	$ (0.72)
Weighted average basic and diluted common shares outstanding	**13,267**	13,104	12,857	11,042	4,611

	December 31,				
	2003	**2002**	**2001**	**2000**	**1999**
Consolidated Balance Sheet Data:					
Cash, cash equivalents and short term investments	**$ 2,587**	$ 9,776	$ 20,126	$ 25,809	$ 869
Restricted cash	**649**	468	600	-	-
Total assets	**11,811**	19,487	25,487	30,526	4,600
Deferred revenue	**1,184**	1,199	508	551	155
Convertible notes	**13,530**	13,530	13,530	13,530	-
Total liabilities	**17,636**	18,998	16,409	15,522	986
Total stockholders' equity (deficit)	**(5,825)**	489	9,078	15,004	3,614

Corporate Information

Directors

Robert E. McDade, Jr.
Chairman of the Board
Former Chairman and President
of Fujisawa Pharmaceuticals

Kerry P. Gray
President and Chief Executive
Officer

Stuart M. Duty
Partner of Oracle Partners LP

J. Michael Flinn
Investment Consultant

Stephen B. Howell, M.D.
Professor of Medicine at the
University of California
San Diego
Director of the Cancer
Pharmacology
Program at the UCSD
Cancer Center

Max Link, Ph.D.
Former CEO of Corange Ltd and
Sandoz Pharma Ltd

John J. Meakem, Jr.
Former Chairman, President &
CEO of Advanced Polymer
Systems

Officers

Kerry P. Gray
President and Chief Executive
Officer

David P. Nowotnik, Ph.D.
Sr. Vice President Research and
Development

Stephen B. Thompson
Vice President and Chief
Financial Officer

Corporate Headquarters

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Corporate Counsel
Bingham McCutchen LLP
Boston, Massachusetts

Patent Counsel
Bingham McCutchen LLP
Palo Alto, California

Independent Auditors
Grant Thornton LLP
Dallas, Texas

Transfer Agent
American Stock Transfer &
Trust Company
Shareholder Services
6201 15th Avenue, 3rd Floor
Brooklyn, New York 11219
718-921-8200
800-937-5449

Australian Office

Access Pharmaceuticals
Australia Pty. Limited
Greg Russell-Jones
Vice President of Targeted
Therapeutics
Unit 5, 15-17 Gibbes Street
Chatswood NSW, 2068
Australia

Investor Relations

SEC Form 10-K
A copy of our annual report
to the Securities and Exchange
Commission on Form 10-K
is available without charge
upon written request to:

Access Pharmaceuticals, Inc.
2600 Stemmons Freeway
Suite 176
Dallas, Texas 75207

Price Range of Common
Stock

2003	High	Low
1st quarter	$ 2.74	$ 1.75
2nd quarter	$ 3.50	$ 1.81
3rd quarter	$ 4.40	$ 2.91
4th quarter	$ 5.50	$ 3.75

2002	High	Low
1st quarter	$ 5.74	$ 3.40
2nd quarter	$ 3.80	$ 1.40
3rd quarter	$ 2.85	$ 1.50
4th quarter	$ 2.18	$ 1.05

Our Common Stock trades on
the American Stock Exchange
under the trading symbol AKC.

No cash dividends have been
paid on our Common Stock and
we do not anticipate paying any
cash dividends on our Common
Stock in the foreseeable future.
As of April 9, 2004 there were
approximately 4,600 holders of
record of our Common Stock
and the closing price on that
date was $7.95.

Access
Pharmaceuticals, Inc.

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