

2008

LIFECYCLE PHARMA A/S

A N N U A L R E P O R T



IMPROVING TREATMENTS
IMPROVING LIVES



About LifeCycle Pharma A/S (LCP)

Based in Hørsholm, Denmark, with an office in New York, LCP is an emerging specialty pharmaceutical company. Clinical development is the core of LCP's effort to develop a product portfolio which includes products for immunosuppression, specifically organ transplantation, and products to combat certain cardiovascular diseases. As a fully integrated company, LCP adapts new technologies on a fast commercial timetable. LCP's unique, patented delivery technology, MeltDose[®], can improve absorption and bioavailability – at low-scale up costs – not only for a broad spectrum of drugs already on the market but also for new chemical entities. LCP has a cholesterol-lowering product, Fenoglide[™], currently on the US market and a diversified near- and medium-term pipeline with six clinical development programs with four product candidates and a number of product candidates in pre-clinical development. LCP is listed on the Nasdaq OMX Nordic Exchange Copenhagen under the trading symbol (OMX: LCP).

For further information, please visit www.lcpharma.com

Business Summary

LifeCycle Pharma (LCP) currently has two key areas of therapeutic focus:

Immunosuppressive Treatment for Organ Transplantation:

LCP-Tacro™ is the Company's lead product candidate for immunosuppression in kidney and liver transplantation. Currently in Phase 3 clinical trials.

Cholesterol Lowering Treatments (dyslipidemia and hypertension):

LCP's first commercialized product, LCP-FenoChol, has received FDA approval for sale in the US under the brand name Fenoglide™ for the treatment of dyslipidemia as an adjunct to dietary changes in adult patients. Launched in February 2008, Fenoglide™ is marketed by Sciele Pharma, Inc., a partner. LCP intends to rely on partnering for marketing and sales of products for cardiovascular indications.

Currently, LCP has one of its products on the market; six clinical development programs with four product candidates; and a number of product candidates in pre-clinical development.

MeltDose® – A New Revolution In Drug Delivery

Our proprietary MeltDose® technology platform enables the creation of new, potentially best-in-class versions of drugs currently on the market.

MeltDose® has been validated in clinical studies. Its success to date has led LCP to form several partnerships with leading international pharmaceutical companies.

MeltDose® provides efficacious new versions of a wide spectrum of existing compounds more quickly, more economically, and with a higher success rate than traditional drug-making methods.

We believe MeltDose® has broad application across a wide range of compounds and therapeutic areas with established commercial potential.

Product Pipeline

Product	Indication	Preclinical	Phase 1	Phase 2	Phase 3	Market
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Immunosuppression Projects

LCP-Tacro™	Kidney Transplant					
LCP-Tacro™	Liver Transplant					
LCP-Tacro™	Autoimmune Hepatitis					
LCP-3301	Immunosuppression					

Cholesterol Lowering Projects

Fenoglide™	High Triglycerides					
LCP-AtorFen	Dyslipidemia					
LCP-Feno	High Triglycerides					

Preclinical Projects

Internal projects	Undisclosed					
External partner projects	Undisclosed					

Company History

2002 Established as a spin-off from H. Lundbeck A/S and based on MeltDose® technology.

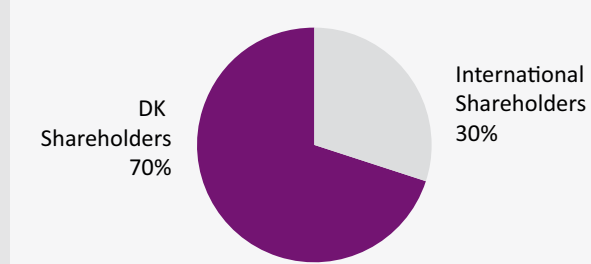
2004 Initiated clinical studies of tacrolimus and fenofibrate.

2006 Commercialized agreement for LCP-Feno with Sandoz (US) and Mylan (EU). EU patent for the MeltDose® technology. New Drug Application (NDA) for Fenoglide™. Listed on Nasdaq OMX Nordic Exchange Copenhagen raising more than DKK 500 million.

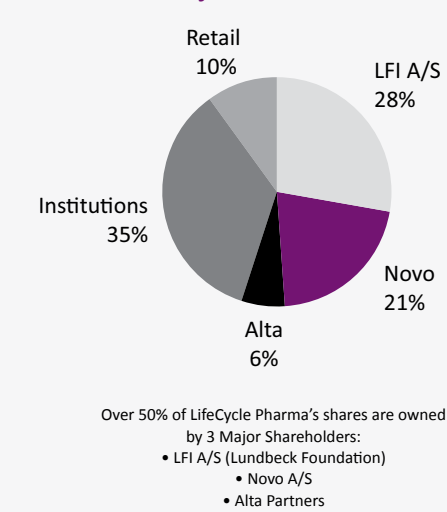
2007 Established affiliate in New York. Agreement with Sciele Pharma, Inc. to market Fenoglide™ in North America and Mexico. US patent for MeltDose® technology. FDA approved Fenoglide™.

Shareholders

Geographical split



Major shareholders



Shareholder Information

Official Listing:
Nasdaq OMX Nordic Exchange Copenhagen

Trading Admission:
13 November, 2006

Trading Symbol: OMX:LCP

LCP ID Code (ISIN): DK0060048148

Nominal Share Capital:
DKK 56,287,507

2008 Highlights

- Jan. 02** LifeCycle Pharma initiates Phase 2 clinical trial of LCP-Tacro™ for the treatment of autoimmune hepatitis
- Feb. 21** LifeCycle Pharma has its first product Fenoglide™ in the US launched through its partner Sciele (a Shionogi Company)
- Mar. 03** LifeCycle Pharma announces positive top-line results of Phase 2 clinical trial of LCP-Tacro™ for the prevention of organ rejection after kidney transplantation
- Apr. 17** Life Cycle Pharma announces successful conclusion of a rights issue with gross proceeds of DKK 407.8 million
- May 07** LifeCycle Pharma announces positive data from LCP-AtorFen Phase 2 clinical program
- May 28** LifeCycle Pharma announces successful completion of pilot studies of LCP-Feno
- Jul. 09** LifeCycle Pharma announces positive top-line results from Phase 2 clinical study of LCP-Tacro™ once daily in stable liver transplant patients
- Aug. 21** LifeCycle Pharma sells Fenoglide™ royalty stream to Cowen Healthcare Royalty Partners for up to USD 105 million, including an upfront payment of USD 29 million.
- Oct. 17** LifeCycle Pharma appoints Dr. Jim New as President and Chief Executive Officer
- Dec. 29** LifeCycle Pharma progresses LCP-Tacro™ into clinical Phase 3

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To Our Shareholders

Dear Shareholder,

In 2008, we took solid, proactive steps to position LifeCycle Pharma for long-term success and sustainable growth in a business environment characterized by turbulence and changing structures.

Over the past year, LifeCycle Pharma achieved important milestones that strengthened our ability to capitalize on attractive business opportunities:

- Despite the tough financial environment, we completed a rights issue with gross proceeds of DKK 407.8 million, securing a strong cash position.
- We sold our future Fenoglide™ royalty stream in North America to Cowen Healthcare Royalty Partners, L.P. for up to USD 105 million (DKK approx. 551 million), including an upfront payment of USD 29 million (DKK approx. 152 million). This transaction followed our achievement earlier in 2008 as one of very few Danish life science companies that have taken an initial product directly to the US primary healthcare market.
- In the field of immunosuppression, we announced positive results from two Phase 2 clinical studies of LCP-Tacro™ tablets in stable kidney and liver transplant patients, respectively.
- Further, we initiated a Phase 3 clinical study with LCP-Tacro™ tablets in stable kidney transplant patients. In this study, patients will either continue on their existing immunosuppressive therapy or convert to treatment with LCP-Tacro™ tablets. The study will enroll approximately 300 patients each of whom will be treated for 12 months.
- In the field of cholesterol-lowering therapies, we achieved positive Phase 2 results on our fixed dose combination product LCP-AtorFen (combining atorvastatin and a low dose of fenofibrate).

Each of these 2008 achievements helped to solidify our position as a specialty pharmaceutical company that constantly strives to live up to our simple, inspirational statement: Improving Treatments - Improving Lives.

Improving Treatments

LifeCycle Pharma is dedicated to broadening the horizons of specialty medicine. Clinical development is the core of our effort to develop a differentiated product portfolio with a focus on two markets: immunosuppression and cholesterol-lowering products.

A truly revolutionary tool for this purpose is the MeltDose® technology, our patented technology for enhancing drug delivery. We invite you to take an insider's look (page 20) at the MeltDose® platform, which enables the creation of new, patent protected best-in-class versions of a broad spectrum of drugs currently on the market on a fast commercial timetable. Moreover, MeltDose® provides unique solutions to new drugs developed in cases where low absorption and poor bioavailability present barriers to patient convenience and compliance.

To shape the market for LifeCycle Pharma's immunosuppression products, we will – subject to market conditions, and due care of our shareholders' interests – develop our own marketing expertise in partnership with transplant specialists and surgeons to maximize the commercial potential of our immunosuppressive product portfolio.

Also, and as we remain committed to investing in our product pipeline, we will continue to out-licence selected cholesterol-lowering products to strategic partners.

Improving Lives

With elegant logic, Improving Treatments leads to Improving Lives. The second half of LifeCycle Pharma's statement speaks clearly to the compassionate side of our science-based business. To put it simply, we feel responsibility toward the users of medicines.

Improving Lives also extends to the lives of our own devoted employees. To achieve the ambitious objectives, our Company must be a magnet for the best minds and skill sets in the life science industry offering challenging opportunities in an international work environment with high work ethics and quality. In 2008, our employee ranks increased from 84 to 106, of which 92 were based in Hørsholm and 14 at our office in New York.

Our Future Together

We are very proud of, and grateful for, the support of our shareholders and commitment by our employees during 2008.

LifeCycle Pharma is an emerging specialty pharma company that is contemplating further investments in research and development. In this respect we focus on bringing our lead product candidate, LCP-Tacro™ tablets, closer to the market place, on further differentiating LCP-AtorFen from its competitors as well as ensuring a well-balanced product portfolio, including a satisfactory early-stage pipeline.

Simultaneously, the responsibility rests on us to be flexible and position ourselves in a changing world – both in terms of governmental initiatives regarding healthcare systems as well as in relation to the business dynamics of the pharmaceutical industry.

We will continuously evaluate the composition of our product portfolio in the light of the competitive environment and we will be brave enough to take the needed measures to serve our shareholders' best long-term interests. This declared open-mindedness and willingness to change should also apply in relation to pursuing opportunities offered to us by our innovative MeltDose® technology – be that from our own laboratories or from external current and potential partners.

For 2009, we foresee more exciting news from our Company. We are honored to put your continuing investment in LifeCycle Pharma to good use – and we look forward to keeping you well-informed.

Yours sincerely,

Dr. Claus Braestrup
Chairman of the Board of Directors

Dr. Jim New
President and Chief Executive Officer

Milestones 2009

LCP-Tacro™ Kidney:

Results from Phase 2 in de novo kidney patients in H1
Initiation of Phase 3 in de novo kidney patients in H2

LCP-Tacro™ Liver:

Results from Phase 2 in de novo liver patients in H1
Results from Phase 2 extension study in stable liver patients in H2

LCP-Tacro™ (Autoimmune Hepatitis):

Results from ongoing Phase 2 study in H2

LCP-3301:

Results from Phase 1 studies

LCP-AtorFen:

Results from Phase 2 extension studies in H1.
Preparation for Phase 3 studies and differentiation of product

LCP-Feno:

Results from pivotal bioequivalence studies in H2

Outlook 2009

LifeCycle Pharma is projecting an operating loss of DKK 450 – 480 million compared to the realized operating loss of DKK 174.1 million in 2008. The net loss is expected to be in the range of 430 – 460 million compared to the net loss of DKK 149.8 million in 2008. As of 31 December 2008, the Company's cash position equaled DKK 600.1 million and the Company's 31 December 2009 cash position is expected to be in the range of DKK 150 - 200 million.

The above estimates are subject to possible changes primarily due to the timing and variation of clinical activities, related costs, royalty and other partner income, and fluctuating exchange rates.

Important Events

Following the Balance Sheet Date

On 27 January, 2009, LifeCycle Pharma announced the receipt of a notification from H. Lundbeck A/S informing of a decrease in its shareholdings in LifeCycle Pharma from 15,313,816 shares, corresponding to 27.21%, to 0 shares. At the same time, LifeCycle Pharma announced the receipt of a notification informing that LFI A/S (100 % owned by the Lundbeck Foundation) now owns 15,878,066 shares, corresponding to 28.21%.

Immunosuppressive Treatment

Immunosuppressive treatment is required for prevention of rejection after organ -transplantation, and may also be used to treat specific autoimmune diseases. In this section, the history and key issues related to immunosuppression are presented, the most important features distinguishing LifeCycle Pharma's pipeline products are outlined, and the scope of the immunosuppressant market is defined.

How the Drugs Work

Immunosuppressive drugs work by interfering with a variety of pathways that are required for the proper functioning of highly specialized cells. These cells are responsible for the body's normal defense against infectious microbial pathogens, or for allergic reactions after contact with foreign proteins (as in the case of bee stings and food allergies). These highly specialized cells are divided into two main groups — so-called T-lymphocytes (T-cells) and B-lymphocytes (B-cells). The same T-cells and B-cells that help maintain good health by preventing and fighting infectious diseases are also responsible for recognition of a transplanted organ (allograft) as "foreign" and mounting an immune attack against it. This is also known as "acute rejection." By selectively interfering with the normal activity of T- and B-cells, immunosuppressive drugs block the immune response and prevent rejection of the allograft.

Because the recipient's immune system will always recognize the donor organ as foreign, transplant patients must continue to take immunosuppressive medications for the rest of their lives. Immunosuppression requires careful management to achieve just the right balance to protect the allograft from immune attack while maintaining sufficient function for the patient to fend off infection.

Autoimmune diseases are the result of a defect in the patient's immune system whereby the patient's own tissues are recognized as "foreign" and the immune system attempts to "reject itself." This results in signs and symptoms that can be disabling or life-threatening and are the cause of significant morbidity. Autoimmune diseases include rheumatoid arthritis, inflammatory bowel disease, systemic lupus erythematosus (SLE), psoriasis and many others.

The Evolution of Immunosuppression

The first successful kidney transplant in 1954 was between identical twins; thus the recipient did not need immunosuppression. Azathioprine, the first true immunosuppressive developed for transplantation, was introduced in 1962.

The modern era of immunosuppression began in the early 1960s with the introduction of azathioprine, the first drug developed specifically to prevent rejection after kidney transplantation. For the next twenty years, the combination of azathioprine and corticosteroids (prednisone, prednisolone) was used routinely after kidney transplantation. Although results improved with this combination, the incidence of acute rejection during the first year post-transplantation remained high — about 80%. Only about 50% of the transplanted kidneys survived beyond one year and this regimen was not sufficiently potent to allow transplantation of extrarenal organs (liver, heart, lung, pancreas or small intestine). Progress with these organs had to await the introduction of more potent and efficacious immunosuppressive drugs.

The field was revolutionized in 1982 with the introduction of cyclosporine (cyclosporin-A, Sandimmune®, Novartis Pharmaceuticals Corp.). Cyclosporine is a naturally occurring product of a soil fungus that was found to have profound but selective effects on the immune system that are mediated by a unique molecular pathway. By inhibition of a key enzyme called calcineurin, cyclosporine interferes with the ability of T-cells to proliferate and mount a rejection response against the allograft. Thus the calcineurin-inhibitor era was born. The combination of cyclosporine, azathioprine and corticosteroids quickly became the new gold standard for kidney transplantation around the world, and for the first time allowed transplantation of extrarenal organs to succeed.



Research in the 1980s led to the development of another unique natural product, tacrolimus. Tacrolimus shares with cyclosporine the same basic mechanism of action — inhibition of calcineurin — but is about 100 times more potent than cyclosporine and displays a different clinical profile. Tacrolimus (Prograf®) was introduced into widespread use in 1994 by Astellas Pharma Inc. ("Astellas"). Treatment with a calcineurin inhibitor, either cyclosporine or tacrolimus, has become universal after organ transplantation. The combined use of tacrolimus with new immunosuppressive drugs has reduced the incidence of acute rejection after kidney transplantation to 10 – 15%, with one-year kidney allograft survival above 95%. Similar excellent results are now achieved after liver and heart transplantation.

Our Potential for 'Best-in-Class'

Transplant patients need to maintain a minimum level of tacrolimus in the blood to prevent organ rejection after transplantation. On the other hand, overly high levels increase the risk of serious side effects such as kidney damage or hypertension. Therefore tacrolimus levels need to be managed carefully. Ideally, they must remain stable over the administration period, but this is complicated by the low bioavailability of tacrolimus, the drug's variable absorption and its well-documented potential for interaction with food and other drugs.

LifeCycle Pharma has developed an oral formulation of tacrolimus — LCP-Tacro™ — with improved absorption and bioavailability due to use of the proprietary MeltDose® technology. As an oral formulation that can be taken by the patient once daily, LCP-Tacro™ would be expected to promote adherence in the clinical setting and could present an improved safety profile for the patient.



Branding a Clinical Program

Branding a clinical trial is a well known tool to increase attention at the participating centers, thereby speeding up enrollment and supporting patient retention in the trial (Ref. Applied Clinical Trials 2009, Jan.)

And...since time is money and everyday counts in getting our products to the market, we decided to brand the clinical Phase 3 program for LCP-Tacro™. We selected the MELT logo, where MELT stands for Multicenter Evaluation of LCP-Tacro™ Tablets but obviously also links to our technology on which we base our products. The MELT logo was launched upon initiation of the LCP-Tacro™ study of conversion from Prograf® capsules to LCP-Tacro™ tablets in stable kidney transplant patients. It will be used in correspondence and news letters sent to the participating centers. The circles symbolize the three phases of clinical development, how these are interlinked as well as the globalization and expansion of our clinical program.



LCP-Tacro™ Global Phase 3 Study Sites.

LCP-Tacro™ has potential to achieve a “best-in-class” profile with:

- Once-a-day administration
- Improved bioavailability and a lower daily dose
- Reduced variability
- Improved safety profile

Astellas recently announced the withdrawal of their US NDA for Advagraf®, also known as a once-daily extended release version of Prograf® or MR-4 (Astellas Press Release 2 February, 2009). This comes as no big surprise as Advagraf® has been facing an uphill struggle in gaining regulatory approval in the US across several indications, given its pharmacokinetic challenges. LifeCycle Pharma recently reported results from a Phase 1 head-to-head clinical trial comparing LCP-Tacro™ to Advagraf®. The results confirm that with LCP-Tacro™ a product is developed with improved pharmacokinetic characteristics compared with Advagraf® and that LCP-Tacro™ with a high likelihood may be expected to steer clear of the challenges facing Advagraf® in the US. The Phase 1 head-to-head multiple-dose clinical trial comparing LCP-Tacro™ to Advagraf® enrolled 19 healthy volunteers. Clinical data confirmed that LCP-Tacro™, when compared with Advagraf®, demonstrated:

- Approximately 50% higher bioavailability
- Lower Cmax/Cmin (peak-to-trough) ratio
- Potential for administration at lower daily doses

These data are consistent with the results, announced by LifeCycle Pharma in 2008, of two completed Phase 2 studies in stable kidney and liver transplant recipients who were maintained on twice-a-day Prograf® and then switched to an appropriately reduced dose of LCP-Tacro™ once a day. These studies confirm that LCP-Tacro™ displays a clear once-a-day profile, improved bioavailability allowing about 30% reduction in the daily dosage requirement, and reduced peak blood concentration of tacrolimus with extended release owing to the application of the proprietary MeltDose® technology. Additional Phase 2b trials in de novo kidney and liver transplant recipients are ongoing with top-line results expected during the first half of 2009.

Market Overview

In the area of immunosuppression, the aim is to improve the delivery of standard immunosuppressive drugs to optimize their clinical profile, i.e. to balance the need for constant immunosuppression in order to prevent allograft rejection versus the potential safety issues related to life-long administration of the therapy. A further aim is to develop novel therapies to address important unmet medical needs.



LCP Goes Global

By initiation of the clinical Phase 3 program for LCP-Tacro™, LifeCycle Pharma has extended its clinical activities beyond the North American region where most activities have taken place so far. The first LCP-Tacro™ study will run on more than 50 transplant centers in North America, UK, France, Germany, Spain and Poland. In the future, we plan to extend this to even more countries and we will actively be looking for new ways to complete our clinical programs as fast and cost-effectively as possible.

The international spirit at LCP as well as the need for our data to support applications on LCP-Tacro™ on several markets will drive this process, and we will actively be expanding our network of clinical centers and key opinion leaders in new countries to support the continued development and future marketing of LCP-Tacro™.

LCP has elected to focus on organ transplantation and autoimmune disorders.

Since transplantation in humans became a reality only fifty years ago, the combination of new, effective immunosuppressive drugs, advances in immunology, surgical techniques, donor selection and postoperative care has resulted in improved outcomes for solid organ transplant patients. Transplantation is now an established treatment for organ failure of the kidney, pancreas, liver, heart or lung.

In 2007, approximately 50,000 organ transplants were conducted worldwide and the transplantation immunosuppression market in the US, Japan, the United Kingdom, France, Germany, Italy and Spain was valued at USD 3.3 billion in 2005 (IMS, all rights reserved). By 2015, it is estimated that this market will increase to USD 4.3 billion, corresponding to an average annual growth rate of 3% (Datamonitor).

Immunosuppression Product Pipeline

LCP-Tacro™ (organ transplantation: kidney and liver) is a once-daily dosage formulation of tacrolimus being developed for immunosuppression treatment in kidney and liver transplant recipients. LCP-Tacro™ is believed to have less variable blood concentration levels than either Prograf®, a twice-daily dosage tacrolimus product currently marketed worldwide by Astellas, or Advagraf®, a once-daily dosage version of tacrolimus currently marketed by Astellas in some European countries. Currently, tacrolimus is believed only to be available in suboptimal formulations with highly variable bioavailability. Tacrolimus has a narrow therapeutic window, and, therefore, the variability of Prograf® and Advagraf® may be a key drawback for its efficacy and side effects profile.

Development Status: Phase 2 PK clinical studies in stable kidney and liver transplant patients were successfully completed in 2008. Phase 2 PK clinical studies in de novo kidney and liver transplant patients are presently ongoing and are expected to be completed in first half (H1) of 2009. Both studies will have a one year extension phase. The clinical Phase 3 program in stable kidney transplant patients was initiated in December 2008, as previously announced. This program consists of a conversion (switch) study in which patients are being randomized to either stay on treatment with Prograf® (Astellas) or to switch to LCP-Tacro. This first Phase 3 study will include patients at more than 50 centers in North America and 5 European countries. We expect to complete the Phase 3 study in stable kidney patients in second half (H2) of 2010, as previously announced. A subsequent study in de novo kidney transplant patients is planned for a late 2009 start. Phase 3 clinical activities for liver transplant patients are awaiting discussions with the FDA, planned for second half of 2009.

Commercial potential: In 2008, worldwide sales of tacrolimus were approximately 1.9 billion, an increase of 17% over 2007 sale (IMS, all rights reserved).

Marketing rights: Worldwide – LCP

Getting Ready for Clinical Phase 3

Taking a company into clinical Phase 3 – and doing it successfully – is a lot of work! Thus, the clinical organization of LCP has undergone a rapid transformation from a start-up business with “everyone doing everything” to an emerging Specialty Pharma Company with a more structured organization and defined roles and responsibilities. Pharmacovigilance and GCP roles have been defined and will be firmly established in the coming months. The Clinical Operational Group now spans several products and indications in the US as well as in Europe with responsibility for international clinical trials being clearly allocated to one function and region. Also, this program takes us into a new age of electronic features with the use of the Interactive Voice Response System (IVRS) and Electronic Data Capture (EDC). IVRS will be used for randomization of patients and to keep track of our clinical trial supplies and EDC is a system for electronic (rather than paper based) recording and processing of all trial data to ensure that this is done as fast and cost-effectively as possible. As part of the initiation of clinical Phase 3, LifeCycle Pharma invited all participating centers in the LCP-Tacro™ study to take part in an Investigator’s Meeting in New York City. The meeting was an overwhelming success with participation from almost all participating centers, our vendors and the LifeCycle Pharma study team. We shared a couple of very intense days with training on protocol issues, drug distribution, electronic data handling, serious adverse event reporting and many other topics needed for all of us to be prepared for the future.

LCP-Tacro™ (other indications)

LCP-Tacro™ is designed to be an immunosuppressant but may also be efficacious in selected autoimmune diseases such as autoimmune hepatitis, lupus, nephritis, myasthenia gravis, ulcerative colitis, Crohn’s disease, multiple sclerosis and scleroderma. Currently, patients with such diseases have limited treatment options. The potential efficacy of tacrolimus has been shown in some of these indications, including inflammatory bowel disease, but its usage has been hampered by the inconvenience, variability and unwanted side effects associated with the current formulation. LCP-Tacro™ could potentially ameliorate these problems and offer a safer and effective alternative.

Development Status: Phase 2 clinical studies for the treatment of autoimmune hepatitis initiated in January 2008.

Due to slow recruitment difficulties, we have decided to continue the study with the number of patients enrolled. Patients already included in the trial will complete treatment as originally planned with top-line results expected in H2 2009.

Commercial potential: Autoimmune hepatitis represents a niche market with an estimated 50,000 patients in the US alone; however, other treatment options like azathioprine and corticosteroids are widely used.

Marketing rights: Worldwide - LCP

LCP-3301 (organ transplantation/ autoimmune diseases)

LCP-3301 is developed to be a unique once-daily dosage form of another immunosuppressive agent for the prevention of rejection after organ transplantation.

Development Status: Initiated Phase 1 activities in 2008, formulation activities ongoing.

Commercial potential: Not disclosed.

Marketing rights: Worldwide – LCP

The Rationale for LCP-Tacro™

Transplant patients are generally prescribed tacrolimus so that they maintain a minimal level of the drug in the blood to prevent organ rejection after transplantation. However, high levels can increase the risk of serious side effects such as kidney damage or hypertension. Therefore, tacrolimus levels need to be managed carefully. This is complicated by tacrolimus’ low bioavailability, its variable absorption and frequent interactions with food and other drugs.

LCP has developed a proprietary once daily dosage oral formulation of tacrolimus - LCP-Tacro™ - with improved absorption and bioavailability employing our MeltDose® technology. As an oral formulation that can be taken by the patient once daily, LCP-Tacro™ is expected to be easier and more cost-effective to use in the clinical setting during long-term maintenance of immunosuppression after organ transplantation compared to the typical twice daily dosage treatment of Prograf®.

Transplantation in the 21st Century

Organ transplantation has rapidly progressed from a daring experimental therapy with uncertain outcomes to become a widely available standard treatment option for patients with life-threatening end-stage organ failure. The introduction of new immunosuppressive drugs represents a tremendous success story and has resulted in dramatic improvement in patient and allograft survival after transplantation. Transplant recipients can now expect many years of life with the

Getting It Right!

Getting it right from the start is extremely important. Especially when dealing with as complicated an indication as transplantation! In order to get the best possible advice, LifeCycle Pharma collaborates with experts in nephrology and transplantation. Together, these form our Transplant Scientific Advisory Board (SAB). The SAB meets 2-4 times a year, usually in the context of a scientific meeting or congress, to discuss the results of our clinical trials and to advise on new clinical activities. The SAB members also serve as speakers at LCP ACADEMY: “Topics in Transplantation”, our internal education program, headed by Sr. Director, Medical Affairs, Larry Chodoff. The experts in our Transplant SAB come from both US and Europe and all are highly recognized within their field. They are: Rita Alloway, John R. Lake, Josep Grinyo, Sundaran Hariharan, Mark Pescovitz, Flavio Vincenti and Klemens Budde.

new organ and the community has now turned its attention to improving the long-term tolerability of immunosuppressive regimens to optimize long-term outcomes. Current trends confirm that both organ donors and organ recipients display a complex pattern of comorbidities that challenge our ability to maintain the good outcomes we now take for granted, and highlight the need for refinements in immunosuppression to address outstanding unmet medical needs as well as patient convenience.

Karin Hamberg, EVP, R&D, joined LifeCycle Pharma in June 2008. “Working with drug development often involves a lot of disappointments,” she says. “Chances that a new drug will ever overcome the technical challenges of drug development and at the same time demonstrate an adequate efficacy and safety profile, are extremely low. However, our work with LCP-Tacro™ and the other immunosuppressive products in our pipeline is completely different. Here, we are working with immunosuppressants that have already demonstrated their value to transplant patients. Even so, by use of our proprietary MeltDose® technology, we are able to improve them significantly. The work of our pharmaceutical, clinical and regulatory team and not least the clinical results obtained with LCP-Tacro™ in stable kidney and liver transplant patients in 2008 deserve attention and recognition. We are extremely pleased with these data as they confirm what we have known all along: LCP-Tacro™ is a unique product with improved characteristics for the benefit of patients and health care providers. That is why we all look forward to bringing LCP-Tacro™ to the market.”





Three Keys

to After-Care Success

The story of Christine Galan’s organ transplant experience is nothing short of astonishing. To highlight the reality of post-transplantation everyday life and pinpoint her after-care success story, Christine Galan says that three factors have helped her stay healthy and strong. This is her story...

The heart-liver procedure – undertaken in October 1998 at Cedars-Sinai Medical Center in Los Angeles, California, when Jamaican-born Christine was thirty-six years old – was only the eleventh heart-liver transplant ever done in the United States, and the first one performed on the West Coast.

In personal terms, the procedure marked the end of an excruciating nineteen-year decline in Christine’s health – and the beginning of a new life vibrant with energy and hope.

“I marvel every day at the fact that my second chance at life was the gift of a complete stranger,” said Christine in an interview in the sun-lit living room of her spacious new apartment on the outskirts of New York City, on October 24, 2008, the tenth anniversary of the transplant. “My gratitude to that donor and his family knows no bounds.”

In 1976, fourteen-year-old Christine, her older sister Deborah and their parents Sam and Jean moved to San Diego, California. In her senior year at The Bishop’s School, in La Jolla, CA, Christine, then 17, suddenly grew weak and listless: “All I wanted to do was sleep.”

She was diagnosed with autoimmune hemolytic anemia, a rare disorder in which the spleen produces antibodies that de-

stroy red blood cells. After massive doses of the strong steroid prednisone failed to correct the problem, surgeons removed her spleen and her stone-filled gall bladder. Over subsequent years, she was also diagnosed with congestive heart failure, lupus and chronic liver failure.

Shortly after her thirty-sixth birthday in June 1998, Christine found herself too weak to function outside a hospital. She was admitted to Cedars-Sinai for what she hoped would be a one-week stay before a suitable heart-liver transplant donor would emerge. But as one week became eleven weeks and her kidneys failed, Christine prepared herself for the looming inevitability: “On the evening of Friday, October 23, my heart surgeon, Dr. Carlos Blanche, came into my room, leaned over the bed, and kissed me gently on the forehead. He stroked my cheek and said, ‘You hang in there.’ I started to weep. Both of us knew I was dying. I looked and felt ninety years old.”

The next night – Dr. Blanche announced that a suitable heart-liver donor candidate had become available at a hospital across town: a six-foot-two-inch, 235-pound, highly athletic African-American male. The donor’s family had signed off on his previously declared intention; Christine’s transplant could begin within an hour. A MedEvac helicopter would deliver the donor heart to Dr. Blanche and his team. Later, the second

organ would arrive– and the liver surgery team would take over.

The twelve-hour double transplant was instantly successful. A few days later, Christine was sitting up in bed, happily chatting with visitors.

“I just knew that from then on, with two huge, new, healthy organs in my body, I would feel better than I ever had before,” said Christine, with a loud, hearty laugh. “And that has been true, to this very day, ten years later. Once I left that hospital, I never looked back.”

Christine Galan has three observations to make, which she feels can help other transplant recipients combine after-care and a successful way of life:

- An enthusiastic, “can-do” outlook, accepting the reality and moving forward
- A regular program of exercise: “After I was diagnosed with congestive heart failure, more than one cardiologist told me that I’d never again do anything more rigorous than walking slowly. But I joined a health-and-fitness center, started walking on a treadmill, then took up bench-stepping and progressed to twice-daily, forty-five-minute workouts on the Stairmaster. I have also participated in an NYC marathon
- Careful compliance with a specialized drug regimen: When interviewed in late October 2008, Christine was taking a twice-daily capsule of tacrolimus. Marketed worldwide as Prograf® by Astellas, this drug prevents rejection after organ transplantation

At the same time, unbeknownst to Christine, LifeCycle Pharma was working behind the scenes to make special improvements to this standard immunosuppressive medicine.

Dr. Karin Hamberg, LCP’s Executive Vice President of Research & Development and Chief Medical Officer, responsible for Clinical, Regulatory and Medical Affairs, explains: “In completed Phase 2 clinical studies in stable kidney and liver transplant patients, we confirmed a potential best-in-class profile of our once-daily tablet formulation LCP-Tacro™ when compared to the twice-daily Prograf® capsule. These exciting data indicate that our formulation decreases peak-to-trough variability and improves bioavailability by 30-40 percent. In other words, by taking the drug only once daily, a patient could get the same drug exposure at 60-70 percent of the Prograf® dose – and with concentrations of the drug in the blood stream remaining much more stable over time than is presently the case. Although the importance of these findings is to be further investigated in large-scale clinical trials, the peaks of an immunosuppressive agent in the blood stream are usually believed to be associated with potential safety issues, whereas the troughs may represent an increased risk of organ rejection.”

Adapting an immunosuppressive drug regimen to become so much more physiological and convenient “would greatly help a patient like Christine maintain her state of post-transplant vitality,” notes Dr. Hamberg.

Cholesterol-lowering Treatments

A cholesterol-lowering treatment is a therapeutic approach to controlling abnormal or excessive fats (lipids) in order to reduce the risk of coronary heart disease (CHD). Initially, this treatment encompasses managing lifestyle and dietary changes, but a medicinal regimen will often be required to attain lipid goals within established clinical guidelines.

What Is Cholesterol?

Cholesterol – a fat-like substance (lipid) found in all cells in the body – is a precursor of bile acids and steroid hormones. Cholesterol travels in the blood in particles containing both lipid and proteins (lipoproteins). Three major classes of lipoproteins are found in blood:

1. Low density lipoprotein cholesterol (LDL-C), or “bad” -cholesterol
2. High density lipoprotein cholesterol (HDL-C), or “good” cholesterol
3. Very low density lipoprotein cholesterol (VLDL-C)

Elevated levels of these lipoproteins is called hyperlipoproteinemia (hyperlipidemia). Elevated cholesterol in blood is called hypercholesterolemia. It is a prerequisite and risk factor for the development of coronary artery disease, heart attack and stroke.

Triglycerides — the most common type of fat in the body — either come from food or are produced by the body. An elevated level of triglycerides in the blood is called hypertriglyceridemia and is often found in people who have hypercholesterolemia.

Dyslipidemia is an abnormal level of lipids, cholesterol, triglycerides, or both (mixed dyslipidemia) in blood. This term includes hyperlipoproteinemia.

LifeCycle Pharma’s Area of Focus

LifeCycle Pharma is developing LCP-AtorFen (a fixed dose atorvastatin/fenofibrate combination) as a cholesterol-lowering treatment for patients with mixed dyslipidemia and inadequate control of their cholesterol and triglycerides —

even after lifestyle and dietary changes with concurrent statin treatment.

Our cholesterol-lowering therapy aims not only to decrease “bad” cholesterol and triglycerides but also to increase “good” cholesterol, i.e. to attain individual lipid goals as defined by the National Cholesterol Education Program Adult Treatment Panel III (NCEP ATP III).

The Range of Treatment Options

Currently, five classes of cholesterol-lowering drugs may be used alone or in specific combinations: statins, fibrates, niacins, cholesterol absorption inhibitors and resins (also called bile acid sequestrants). In addition to these, the Omega-3 fatty acids may be used for lowering of high levels of triglycerides.

Statins (known as HMG CoA reductase inhibitors) work in the liver to prevent the formation of cholesterol. They are most effective at lowering LDL-C but also have modest effects on lowering triglycerides and raising HDL-C. Most of the side effects of statins are mild and generally go away as the body adjusts to treatment. In rare instances, muscle problems and liver abnormalities may occur.

Fibrates (known as PPAR- α agonists) also work in the liver and are best at lowering triglycerides and, in some cases, raising HDL-C. They are not very effective at lowering LDL-C. This is why fibrates are generally used in people who, having reached LDL-C goals, still have high triglycerides or low HDL. Fibrates may be used alone or in combination with the statins.

Niacins work in the liver to affect the production of blood

fats. They are effective at lowering triglycerides and LDL-C and raising HDL-C. Niacin side effects may include flushing, itching and stomach upset. Liver functions should be closely monitored, as niacin can cause toxicity. Also, niacin should be used cautiously in diabetic patients as it can raise blood sugar levels.

Cholesterol absorption inhibitors – a relatively new class of medications – work by absorbing cholesterol from the intestine. They are most effective at lowering LDL-C but have modest effects on lowering triglycerides and raising HDL-C. The first medication in this class, ezetimibe (Zetia[®], Merck/Schering-Plough Pharmaceuticals), was approved in 2002 for the treatment of high cholesterol and certain inherited lipid abnormalities.

Resins are mainly LDL-lowering drugs that work in the intestine by promoting increased disposal of cholesterol. The body uses cholesterol to make bile, an acid used in the digestive process. These medicines bind to bile, so it cannot be used during digestion. The liver responds by making more bile; the more it makes, the more cholesterol it uses. This leaves less cholesterol to circulate in the bloodstream.

Dyslipidemia

Cardiovascular disease includes a variety of disorders, such as dyslipidemia, hypertension (high blood pressure), heart attack, atrial fibrillation, congestive heart failure, angina and coronary artery disease and is the leading cause of death in the US, Japan, UK, France, Germany, Italy and Spain. LifeCycle Pharma’s product candidates are for the treatment of mixed dyslipidemia and hypertriglyceridemia.

Dyslipidemia was estimated to affect approximately 309 mil-

lion individuals in the US, Japan, UK, France, Germany, Italy and Spain in 2007 (source: Datamonitor). According to a 2005 report, an estimated 78% of patients diagnosed with dyslipidemia are treated with pharmaceuticals (source: Datamonitor). In 2006, the anti-dyslipidemic market accounted for approximately USD 21 billion in annual US retail sales, which represented a 21% annual growth over 2005. In 2007, it was estimated that the anti-dyslipidemic market totaled approximately USD 23 billion in annual retail sales — a 10% increase over the prior year (source: Datamonitor).

Statins have been and continue to be the mainstay of initial drug therapy. This drug class was estimated to have sales in the US of approximately USD 19 billion in 2007 (source: Datamonitor). However, NEPTUNE II and other recent studies indicate that significant patient populations do not achieve NCEP ATP III goals. This is especially true in patients with diabetes mellitus and other CHD risk equivalents. That means that these patients require more intense cholesterol-lowering treatment to attain established goals. Therefore, many cardiologists now recommend combination drug therapy with statin/fibrate or statin/niacin treatment. Currently, approximately 13% of patients on statins are also being treated with a fibrate. The fixed-dose combination class is expected to grow and to capture 30% of the dyslipidemia market by 2016 (source: Decision Resources 2008).

Mixed Dyslipidemia

Mixed dyslipidemia is characterized by elevated LDL, decreased HDL and elevated levels of triglycerides. Due to the mixed nature of this condition, combination therapies are often considered the most beneficial treatment. Mixed dyslipidemia comprised approximately 29% of the total dyslipidemia market in 2005 (source: Datamonitor).



Hypercholesterolemia

Historically, dyslipidemia treatment has focused on hypercholesterolemia (patients with elevated cholesterol), targeting LDL levels in the blood. In the US in 2004, approximately 80.4 million people age 20 and older had LDL levels of 130 mg/dL and above (source: AHA Heart Disease and Stroke Statistics, 2008 Update). In the treatment of hypercholesterolemia, a key diagnostic factor is the proportion of LDL to HDL. The aim of the treatment is to reduce LDL and increase HDL in the blood, which cleanses the body of excessive fat by delivering cholesterol to the liver, where it is broken down and eliminated from the body.

Statins are typically recommended as first line therapy to reduce elevated LDL. There are many different statins, but the market leader is the atorvastatin drug Lipitor® (Pfizer, Inc., "Pfizer"). For 2008, Pfizer reported Lipitor® sales of USD 12.4 billion (Pfizer, Press Release 26 January 2009). Statins alone have limited impact on HDL and triglycerides, which are increasingly a treatment focus, with numerous clinical studies having shown the added benefits of combinations of fenofibrates and statins when compared with monotherapy, e.g., in patients with Type II diabetes and metabolic syndrome (source: IMS Health; all rights reserved).

LCP-AtorFen is superior to atorvastatin monotherapy

- Superior control of HDL-C, triglycerides and VLDL
- Potential for superior anti-inflammatory profile, i.e. fibrinogen



LCP-AtorFen in short

- Superior, well-controlled and broad lipid control
- Superior and broad anti-inflammatory profile with significant effect on major risk factors
- Lowest fenofibrate dose ever marketed
- Favorable safety profile
- Convenient once-a-day tablet

Hypertriglyceridemia

In North America alone, sales of atorvastatin and fenofibrate were approximately USD 10.7 billion in 2008 (source: IMS Health; all rights reserved). The hypertriglyceridemia (HTG) market comprises approximately 22% of the total dyslipidemia population (source: Datamonitor). In 2005, there were estimated to be over 22 million patients diagnosed with HTG in the US, Japan, UK, France, Germany, Italy and Spain (source: Datamonitor). According to an IMS report, in 2005 50% of HTG patients suffered from "very high" triglyceride levels, approximately 30% suffered from "high" triglyceride levels, and the remainder suffered from "borderline-high" triglyceride levels. The ATP III Guidelines recommend greater emphasis on elevated triglycerides as a marker for increased risk of coronary heart disease. If widely followed, this would significantly increase the potential patient population requiring treatment.

Fibrates and niacin, either in monotherapy or in concomitant treatment with statins, are currently the most frequently used triglyceride-lowering drugs (source: Datamonitor). Fibrates are used to lower triglycerides and increase the content of HDL in the blood and are also associated with a moderate decrease in LDL. In 2008 the fibrate segment of

LCP-AtorFen is superior to fenofibrate monotherapy

- Superior control of non-HDL-C, LCL-C and triglycerides
- Potential for superior anti-inflammatory profile, i.e. CRP

the anti-dyslipidemic market accounted for more than USD 1.7 billion dollars sales in North America (IMS, all rights reserved).

Because fenofibrate is more difficult to formulate into a tablet, it remains predominantly a branded market. Tricor®, marketed by Abbott Laboratories ("Abbott"), is the most widely prescribed fenofibrate product. Abbott's leading position in the fenofibrate market has been maintained to this date, even though two new products — Antara® from Oscient Pharmaceuticals and Triglide® from Sciele Pharma, Inc. — entered the US market in 2005. Sales of fenofibrate products, and in particular Tricor®, have increased significantly in the last few years, with 2008 worldwide sales exceeding USD 2.2 billion (IMS, all rights reserved). In the US, Abbott reported sales of Tricor®/TriLipix® of USD 1.3 billion in 2008 (Abbott Press Release 21 January, 2009). In December 2008, a new product, TriLipix® (Abbott), an extended release product based on fenofibric acid, was approved by the FDA for use as a monotherapy and as an add-on therapy to statins. Based on the labeling text of the not yet launched TriLipix®, i.e. not based on direct comparisons, LCP-AtorFen may still be expected to possess superiority efficacy to this product when used as monotherapy.

Our Approach to Unmet Needs

LCP-AtorFen is a fixed dose combination of atorvastatin (10, 20 or 40 mg) and a low dose fenofibrate (100 mg). It combines one of the most efficacious statins with a PPAR-α agonist to provide a treatment for all three components of mixed dyslipidemia (increased LDL-C and TG, and decreased HDL-C).

Combination therapy with statins and fibrates, particularly fenofibrate, results in lipid and lipoprotein changes beyond those associated with monotherapy with either drug. The effects of combination therapy include additive LDL-C lowering, substantial lowering of TG and increase of HDL-C. The net result is a robust reduction in non-HDL-C. Combination statin/fenofibrate therapy is common in clinical practice as a means of reducing atherogenic lipids, given the high prevalence of mixed dyslipidemia in populations increasingly burdened by overweight and obesity, insulin resistance, and marked heart disease risk. The proposed fixed-dose combination of atorvastatin and fenofibrate is intended to address the growing



In a recent 12-week, double-blind, parallel-group, Phase 2 study in subjects with dyslipidemia, LCP AtorFen 40/100 mg was shown to have improved efficacy and a similar safety profile compared to either atorvastatin 40 mg or fenofibrate 145 mg monotherapy. The combination of atorvastatin 40 mg and fenofibrate 100 mg compared to either monotherapy resulted in significantly greater reductions in LDL-C and TG and increases in HDL-C. LCP AtorFen 40/100 mg also produced greater reductions in non-high-density lipoprotein cholesterol (non-HDL-C) and apolipoprotein B (apo B) than either monotherapy. Specifically, LCP-AtorFen 40/100 mg showed an additive effect in terms of lowering TG; treatment with LCP-AtorFen 40/100 mg reduced TG by 49.1% compared to an approximate 28-29% reduction observed with the atorvastatin 40 mg and fenofibrate 145 mg monotherapies. Furthermore, LCP AtorFen 40/100 mg improved cardiac risk markers such as lipoprotein (a) (Lp[a]), myeloperoxidase, and fibrinogen compared to atorvastatin 40 mg monotherapy, and reduced lipoprotein-associated phospholipase A2 (Lp PLA2, 8.8%) in contrast to fenofibrate 145 mg monotherapy (+8.1%). The LCP AtorFen 40/100 mg fixed combination was not associated with any incidences of rhabdomyolysis, significant shifts in creatine kinase (CK), or changes in creatinine clearance and the adverse event profile was similar (with a non-significant trend of being superior) to those associated with the atorvastatin 40 mg or fenofibrate 145 mg monotherapies. A 12-month, open-label, extension phase of this study is currently ongoing (American Heart Association, New Orleans, Nov. 2008)

need for this combination of agents, with the convenience of single-tablet administration.

LCP-AtorFen is being developed for use in patients with primary hypercholesterolemia (Frederickson Type IIa) or mixed dyslipidemia (Frederickson Type IIb). The first type consists of patients who have already been treated with a statin or fenofibrate alone and require additional non-HDL-C (total cholesterol minus HDL-C) lowering to goal. The second type consists of patients who have already been treated with combination statin and fenofibrate therapy and desire the convenience of single-tablet therapy.

LCP-AtorFen contains a lower dose of fenofibrate than typically used in monotherapy because MeltDose® technology has been designed to enhance the release and absorption of fenofibrate by incorporating soluble forms of the drug in a tablet matrix. This lower dose of fenofibrate could potentially be associated with a superior safety profile, both alone and in combination with statin.

Cholesterol-lowering Product Pipeline

Fenoglide™ (containing 120 mg or 40 mg active substance) is our FDA-approved fenofibrate product for the treatment of dyslipidemia, and is the lowest dose of fenofibrate available for patients. Given the strong correlation between uptake and dosage within the fenofibrate market, this low dose formulation is believed to be a strong driver to increase market penetration.

Status: Fenoglide™ is currently marketed in the US by our partner Sciele Pharma, Inc. (a Shionogi company.)

Commercial potential: In 2008, worldwide sales of all fenofibrate drugs were approximately USD 2.2 billion (IMS, all rights reserved).

Marketing rights: North America and Mexico – Sciele Pharma, Inc. Rest of the world – LCP

LCP-AtorFen is our proprietary product candidate for the treatment of dyslipidemia, combining atorvastatin (the active ingredient of Lipitor®, marketed by Pfizer and often referred to as the best-selling drug in the world) and the lowest dose of fenofibrate ever to be marketed. It is believed that LCP-AtorFen will prove to be a safe and efficacious treatment

for dyslipidemia, addressing three primary cardiovascular risk factors: low levels of HDL, high levels of LDL and elevated levels of triglycerides.

Status: Phase 2 clinical trial data presented at the Annual Meeting of the American Heart Association (AHA), New Orleans, 11 November, 2008. Preparation of clinical Phase 3 is ongoing, as well as further studies aiming at differentiating LCP-AtorFen from its competitors. Results from a Phase 2 extension study are expected in H1 2009.

Commercial potential: In the US alone, combined sales of atorvastatin and fenofibrate were approximately USD 10.7 billion in 2008 (IMS, all rights reserved)

Marketing rights: Worldwide - LCP

LCP-Feno (containing 145 mg or 48 mg active substance) is our development stage fenofibrate product candidate for the treatment of dyslipidemia. LCP-Feno has been designed to be marketed as an AB-rated (substitutable) generic version of Tricor®, which is currently marketed in the US by Abbott and in Europe by Solvay S.A. under the trade name Lipanthyl®.

Status: LifeCycle Pharma is currently producing clinical supplies for a pivotal bioequivalence study and the results from this study is expected in H2 2009.

Commercial potential: For 2008, Abbott reported Tricor®/TriLipix® sales of USD 1.3 billion in the US market alone, an increase 10% over 2007 sales (Abbott Press Release 21 January 2009).

Marketing rights: EU – Mylan. Rest of the world - LCP

“LCP-AtorFen remains one of our most interesting products. By combining our LCP expertise in developing a low-dose fenofibrate with the use of a statin, and adding in our proprietary MeltDose® technology, we will create an attractive product that will play a pivotal role, in providing superior lipid control combined with a favourable safety profile – and with the benefits of a single tablet. We look forward to taking this product into further development with the assistance of a partner who is thoroughly committed, as we are, to providing a next-generation treatment for patients with mixed dyslipidemia.” says Dr. Karin Jexner Hamberg, Executive Vice President of Research & Development and Chief Medical Officer.



MeltDose® – A Proven Technology to Enhance Drug Performance

LifeCycle Pharma's proprietary MeltDose® technology platform enables the creation of new, patent protected, potentially best-in-class versions of drugs that are poorly absorbed.

MeltDose® technology is a one step industrial process designed to enhance absorption and oral bioavailability of poorly water soluble drugs. Improving drug absorption can increase a drug's efficacy, enable lower dosing, reduce food effect and, in some cases, possibly even reduce side effects. Originally developed by H. Lundbeck A/S, LifeCycle Pharma's scientists have continuously improved it, validated its working principle in a number of different drugs in animal and

human clinical trials and ramped up the MeltDose® process to commercial scale production.

The Challenge

Drug solubility is a critically important factor for the drug's efficacy. Only a dissolved and absorbed drug can have a beneficial effect on the patient – and an oral drug must be dissolved in the stomach and intestinal tract before it can be absorbed into the bloodstream. In other words, the efficacy of a drug depends on how well the body absorbs and circulates it to the treatment site.

In addition, low water solubility often results in large variations in the drug's bioavailability and creates a "food effect" defined as different degree of absorption when the drug is taken with or without food.

Independent studies have shown that approximately 30% of existing drugs have suboptimal uptake and absorption because of poor solubility in water.

Moreover, new drugs in development (New Chemical Entities or NCEs), especially over the past decade, seem to have a solubility which is dramatically lower than previous NCEs. In fact, it has been estimated that 40-70% of all NCEs identified in drug discovery programmes are insufficiently soluble to allow for adequate and reproducible absorption from the gut. In other words, poorly soluble drugs are prime candidates

Fluid bed unit at Glatt GmbH, Germany.



for abandonment, fuelling the pharmaceutical industry's current spiral of reduced success rates, increased costs for R&D programmes and decreasing return on investment (ROI).

It has therefore become essential to provide drug formulators with a tool to improve oral bioavailability and MeltDose® technology is such a tool.

MeltDose® technology is believed to have broad application across a wide range of compounds and therapeutic areas with established commercial potential and that many of these drugs may be suitable candidates for reformulation using our technology.

MeltDose® technology is believed to also be of high value for New Chemical Entities in development where poor water solubility and the resulting low absorption present a significant barrier to achieving an optimal commercial formulation.

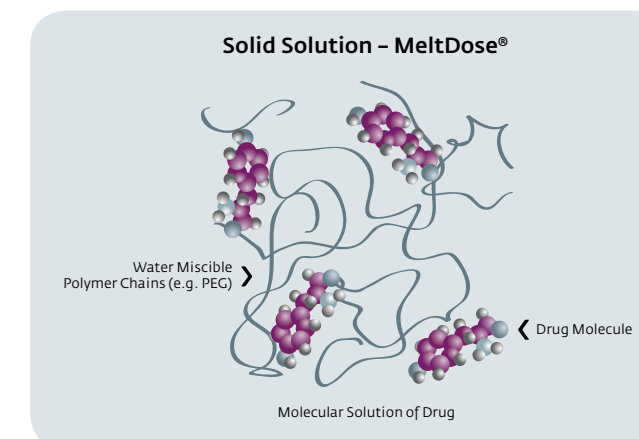
MeltDose® – Breakthrough Technology with Tangible Benefits at Low Cost

The majority of conventional drug delivery technologies aimed at increasing the bioavailability of compounds with low water-solubility rely on reduction of the particle size of the drug substance. Such processes can be costly to control and implement and difficult to manage. MeltDose® technology does not rely upon a complex milling process to achieve particle size reduction, but involves creation of a solid dispersion, or a solid solution, of the drug substance through a simple physical process. This makes it easy to implement using conventional manufacturing equipment and more flex-

ible to work with than other technologies used to improve drug solubility.

MeltDose® - How It Works

MeltDose® technology is based on a patented "Controlled Agglomeration" process that works by incorporating the drug substance with low water-solubility into a "meltable" vehicle. It is then sprayed on an inert particulate carrier using conventional fluid bed equipment. The melt is solidified when deposited on the particle carrier which serves to capture the drug in the solid dispersion state either as a solid solution or in a nano-crystalline state. The particle size of the granulate which is the outcome of the fluidized bed process is controlled by optimizing the product temperature and feed rate of the melt. The granulate can be directly compressed into tablets without additional processing steps besides blending



with a lubricant. Once in tablet form, the dissolution profile and the particle size of drugs manufactured using MeltDose® technology remain stable allowing for a long shelf-life of the MeltDose® based drug product.

MeltDose® - A Flexible Technology

MeltDose® technology allows for customization of the release profile, to create various profiles including immediate and controlled release products that are also suitable for enteric coating.

- Drug can be immediately released while in the stomach;
- Release can be delayed until the drug has reached the small intestine; or
- Release from the intestinal tract can be controlled, extending over a longer period of time.

MeltDose® – Differs from Conventional Platforms

MeltDose® technology is a flexible and validated technology that, compared to most drug delivery platforms that increase oral bioavailability of poorly soluble drugs, offers an unprecedented combination of the following characteristics:

✓ Clinically Proven

- The ability of MeltDose® technology to improve bioavailability and/or reduce the food effect has been confirmed in numerous clinical studies with a range of poorly soluble compounds
- MeltDose® technology is the basis for partnerships between LCP and several leading international pharmaceutical companies

✓ Commercially Viable

- The first MeltDose® based product, Fenoglide™, is approved by the FDA and marketed in the US
- Several MeltDose® based products are in late stage development and have already been manufactured in commercial scale
- The MeltDose® manufacturing process has been inspected by the FDA and is fully validated in commercial scale
- The approval process is facilitated by the fact that MeltDose® uses exclusively GRAS (Generally Recognized As Safe) excipients

✓ Patent Protected

- MeltDose® basic patents have been issued in both the US and Europe and do not expire until 2022
- MeltDose® is an efficient tool to extend the commercial life cycle of important medicines beyond the expiration of their original patents

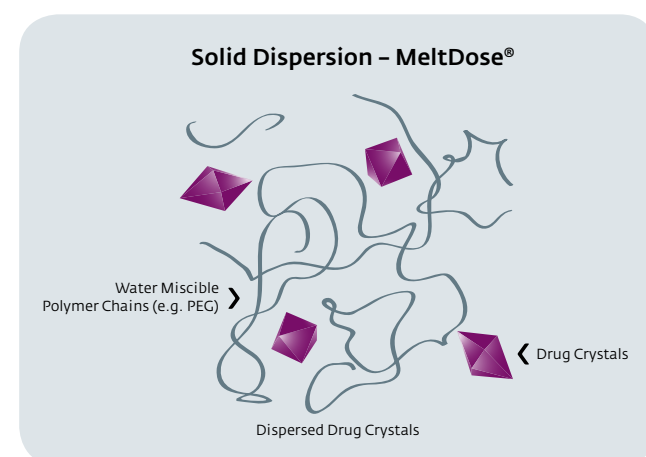
✓ Scalable and transferrable

- MeltDose® employs conventional manufacturing equipment, does not require significant additional investment and is easily scalable to commercial batch sizes
- MeltDose® manufacturing process has been established at leading CMOs (Contract Manufacturing Organizations) in both Europe and the US.

✓ Cost Effective, Fast and Flexible

- The first MeltDose® based product, Fenoglide™, was developed from pre-clinical trials to FDA approval for sale in the US within five years as compared with a traditional drug development time of around 8-11 years
- The cost of goods of the MeltDose® based tablets is comparable to that of conventional plain tablets
- MeltDose® can be used to create customized release profiles including immediate or controlled release and is suitable for enteric coating
- MeltDose® is a solvent-free, one-step process that also can be carried out in an inert atmosphere. The resulting granulate is suitable for direct compression to tablets
- MeltDose® technology has broad application across a wide range of low water soluble compounds and therapeutic areas and gives increased flexibility in the choice of excipients, processing, and vehicle

We therefore believe that by applying our proprietary MeltDose® technology to new chemical entities or to create new versions of existing drugs, we are able to develop products with differentiated characteristics significantly faster, cheaper, and with a higher success rate as compared with traditional drug development.



Financial Review

Revenues

During 2008, LifeCycle Pharma recognized DKK 170.1 million in revenue compared to DKK 64.7 million in 2007. The revenue mainly consists of USD 29 million (equivalent to DKK 152 million at the exchange rate prevailing at the date of transaction) in up-front payment, which LifeCycle Pharma received from Cowen Healthcare Royalty Partners, L.P. in connection with sales of the future royalty stream from Fenoglide™ in North America. Additional revenue consists of payments under LifeCycle Pharma's collaboration agreements.

Research and Development Costs

Research and development costs increased by DKK 87.3 million, or by 48%, from DKK 183.6 million in 2007 to DKK 270.9 million in 2008. The higher research and development costs reflect increased activity in LifeCycle Pharma's product pipeline, primarily costs related to the clinical trials, including Phase 2 clinical studies for LCP-Tacro™ (kidney and liver) and LCP-AtorFen as well as initiation of Phase 3 for LCP-Tacro™ in stable kidney patients.

Over the course of 2008, the number of employees in research and development has increased from 68 in 2007 to 86 in 2008, an increase of 26%.

On an overall basis, research and development costs account for 78.7% of total cost of operations. The comparable figure for 2007 was 77.3%.

Administrative Expenses

Administrative expenses increased from DKK 54.0 million in 2007 to DKK 73.3 million in 2008. This increase is attributable to the continued strengthening of administrative functions in the beginning of the year following the company's IPO in November 2006, and the rights issue completed in April 2008, the build-up of administrative functions in the US subsidiary established in 2007, along with an overall increase in activity.

Over the course of 2008, the number of employees in administration has increased from 16 in 2007 to 20 in 2008, an increase of 25%.

Share-based Compensation Costs

During 2008, a total of DKK 16.9 million was recognized as share-based compensation. The comparable number for 2007 was DKK 18.0 million.

Operating Loss

During 2008, LifeCycle Pharma recognized DKK 174.1 million in operating loss compared to DKK 172.9 million in 2007.

Financial Income

Net financial items increased by DKK 11.6 million, from DKK 12.7 million in 2007 to DKK 24.3 million in 2008. The increase in financial income is a reflection of the interest on the net proceeds from LifeCycle Pharma's rights issue in April 2008.

Due to increase in the DKK/USD exchange rate LifeCycle Pharma has recognized an exchange gain of DKK 3.9 million in 2008 compared to a loss of DKK 2.2 million in 2007

Net Loss

During 2008, LifeCycle Pharma recognized DKK 149.8 million in net loss compared to DKK 160.2 million in 2007.

The 2008 guidance was an operating loss of DKK 220-250 million and a net loss of DKK 210-240 million. Operating loss was realized at DKK 174.1 million, and net loss at DKK 149.8 million. The improved results is due to timing of Phase 3 clinical cost related to LCP-Tacro™, now scheduled for 2009, along with implementation of a cost containment program to reduce LifeCycle Pharma's costs.

Cash Flow

As per 31 December, 2008, the balance sheet reflects cash and cash equivalents of DKK 600.1 million compared to DKK 331.7 million as per December 31, 2007. The net increase reflects the proceeds from the rights issue in April 2008 and the operating activities in 2008, including the up-front payment from the sale of the future royalty stream from Fenoglide™ to Cowen Healthcare Royalty Partners, L.P.

Of the year-end cash position, DKK 121.4 million is held in a USD deposit, to off-set DKK/USD currency fluctuations, as a significant part of LifeCycle Pharma's research and development costs are invoiced in USD. A 10% change in the DKK/USD exchange rate would lead to a DKK 12.1 million change in net results from unrealized exchange gain or loss.

Balance Sheet

As per 31 December, 2008, total assets were DKK 646.3 million compared to DKK 381.9 million at the end of 2007.

Shareholders' equity equalled DKK 572.3 million as of 31 December, 2008, compared to DKK 325.7 million at the end of 2007.

Subsequent Events

On 27 January, 2009, LifeCycle Pharma announced the receipt of a notification from H. Lundbeck A/S informing of a decrease in its shareholdings in LifeCycle Pharma from 15,313,816 shares, corresponding to 27.21%, to 0 shares.

At the same time, LifeCycle Pharma announced the receipt of a notification informing that LFI A/S (100 % owned by the Lundbeck Foundation) now owns 15,878,066 shares, corresponding to 28.21%.

Outlook for 2009

LifeCycle Pharma is projecting an operating loss in 2009 of DKK 450-480 million compared to the realized operating loss of DKK 174.1 million in 2008. The net loss is expected to be in the range of 430-460 million compared to the net loss of DKK 149.8 million in 2008.

As of 31 December 2008, LifeCycle Pharma's cash position equalled DKK 600.1 million and the Company's 31 December 2009 cash position is expected to be in the range of DKK 150 - 200 million.

The above estimates are subject to possible changes primarily due to the timing and variation of clinical activities, related costs, royalty and other partner income and fluctuating exchange rates.

Figures & Ratios

Financial highlights and financial ratios comply with the requirements under IFRS and the Danish financial reporting requirements. All figures and financial ratios are in conformity with the current accounting policies.

Financial ratios have been calculated in accordance with the recommendations of the Association of Danish Financial Analysts.



Financial Highlights (DKK)

	2008 DKK'000	2007 DKK'000	2006 DKK'000	2005 DKK'000	2004 DKK'000
Income Statement					
Revenue	170 122	64 705	9 740	2 754	4 648
Research and development costs	(270 875)	(183 608)	(129 403)	(80 919)	(36 542)
Administrative expenses	(73 311)	(54 033)	(29 395)	(16 170)	(12 543)
Operating loss	(174 064)	(172 936)	(149 058)	(94 335)	(44 437)
Net financial income / (expenses)	24 285	12 697	1 345	(834)	(281)
Net loss for the year	(149 779)	(160 239)	(147 713)	(95 169)	(44 718)
Balance Sheet					
Cash and cash equivalents	600 130	331 740	464 658	87 224	9
Total assets	646 293	381 912	507 057	136 357	24 538
Share capital	56 288	31 771	30 370	4 429	2 634
Total equity	572 323	325 689	458 083	92 430	(1 647)
Investment in property, plant and equipment	6 571	5 900	7 222	13 572	15 169
Cash Flow Statement					
Cash flow from operating activities	(102 560)	(129 291)	(125 813)	(86 771)	(43 530)
Cash flow from investing activities	(6 628)	7 298	(7 222)	(13 572)	(15 169)
Cash flow from financing activities	373 637	3 769	510 469	187 558	48 087
Cash and cash equivalents at period end	600 130	331 740	464 658	87 224	9
Financial Ratios					
Basic and diluted EPS	(3.06)	(5.19)	(7.65)	(6.81)	(4.58)
Weighted average number of shares	49 006 500	30 875 434	19 313 737	13 965 252	9 768 052
Average number of employees (FTEs)	102	64	44	35	21
Assets/equity	1.13	1.17	1.11	1.48	N/A

Financial Highlights (EUR)

	2008 EUR'000	2007 EUR'000	2006 EUR'000	2005 EUR'000	2004 EUR'000
Income Statement					
Revenue	22 817	8 685	1 306	370	625
Research and development costs	(36 330)	(24 644)	(17 348)	(10 859)	(4 912)
Administrative expenses	(9 833)	(7 252)	(3 941)	(2 170)	(1 686)
Operating loss	(23 346)	(23 211)	(19 983)	(12 659)	(5 973)
Net financial income / (expenses)	3 257	1 704	180	(112)	(38)
Net loss for the year	(20 088)	(21 507)	(19 803)	(12 771)	(6 011)
Balance Sheet					
Cash and cash equivalents	80 548	44 489	62 320	11 691	1
Total assets	86 744	51 218	68 007	18 277	3 299
Share capital	7 555	4 261	4 073	594	354
Total equity	76 816	43 678	61 438	12 389	(221)
Investment in property, plant and equipment	882	791	969	1 819	2 039
Cash Flow Statement					
Cash flow from operating activities	(13 755)	(17 353)	(16 867)	(11 644)	(5 851)
Cash flow from investing activities	(889)	980	(968)	(1 821)	(2 039)
Cash flow from financing activities	50 112	506	68 436	25 169	6 463
Cash and cash equivalents at period end	80 490	44 526	62 294	11 705	1
Financial Ratios					
Basic and diluted EPS	(0.41)	(0.70)	(1.03)	(0.91)	(0.62)
Weighted average number of shares	49 006 500	30 875 434	19 313 737	13 965 252	9 768 052
Average number of employees (FTEs)	102	64	44	35	21
Assets/equity	1.13	1.17	1.11	1.48	N/A

Figures are translated into EUR as supplementary information. The translation of income statement and cash flow statement items is based on average exchange rate that year, and the translation of balance sheet items is based on the exchange rate at the end of that year.

Average DKK/EUR exchange rate	7.455974	7.450551	7.459100	7.451927	7.439837
Ending DKK/EUR exchange rate	7.450600	7.456600	7.456000	7.460500	7.438100

Source: www.nationalbanken.dk

Risk Management

As an emerging specialty pharmaceutical company, LifeCycle Pharma is exposed to certain risks. Some of these may significantly affect our ability to execute our strategy. We categorize these as critical risks – and we have a program in place to ensure that we proactively identify, manage and mitigate them.

Contrary to the majority of biotechnology and pharma companies, LifeCycle Pharma is less susceptible to development risks. LifeCycle Pharma is currently working solely with drug substances already approved and being marketed by originator companies. This substantially decreases typical development risks such as lack of efficacy or unacceptable toxicological findings that normally account for more than 90% of the attrition rates in the pharmaceutical industry.

As a tool to identify and manage the critical risks, we have implemented a control environment with internal systems designed to reduce identified risks to an acceptable level. We assess the identified risks on an ongoing basis and report them to the Executive Management and the Board of Directors.

We are exposed to critical risks within such areas as research and development, commercialization, financial management and legal affairs. In the following are offered examples of these risks and how they are addressed.

Research and Development Risks

Performing research and development work within the pharmaceutical industry is subject to significant risk. It is well known that new potential pharmaceutical products have to undergo a lengthy process from early research through clinical studies and development activities before they can be approved and authorized for sale on the market. Some product candidates are never approved; other projects are abandoned, for various reasons, during the research and development process.

To help us mitigate the risks, we have established several scientific advisory boards with recognized experts and thought

leaders from the pharmaceutical industry and academia in the United States and Europe. Together with our employees, these experts monitor not only our selection of product candidates, but also our progress on specific product candidates in research and development.

Clinical studies are lengthy, time-consuming and expensive – and they have uncertain outcomes. Nevertheless, it is a regulatory requirement to conduct them in order to provide the necessary documentation for our product candidates to obtain a marketing authorization. Over the development period, we work closely with the health authorities in order to ensure our development programs the best possible chance of success.

We seek to minimize the development risk by having a variety of products in development at the same time. Moreover, we have implemented detailed project management tools to ensure early detection and reporting of risk-related issues as well as contingency plans for their resolution.

Commercial Risks

Diverse commercial risk factors includes risks related to market acceptance, effective commercialization and competition related to Fenoglide™ and our product candidates; and the ability to retain and attract employees and partners. We continuously monitor and evaluate the market development and competitive landscape for our products and product candidates with an effort to proactively manage applicable risks.

Our business strategy provides us with the freedom to seek partners for certain product candidates and develop our own sales and marketing organization for others. In August 2008,

we concluded an agreement with Cowen Healthcare Royalty Partners whereby we sold the future royalty stream related to the sale of Fenoglide™ in North America and thereby mitigated the commercial risk significantly.

Within the immunosuppressant market, we intend to commercialize LCP-Tacro™ for kidney and liver transplantation on the US market, subject to successful conclusion of our clinical studies. We acknowledge that we do not have sufficient capabilities to commercialize products ourselves within the cardiovascular area. We therefore will continue to seek partners within areas where we assess such partners can achieve stronger financial results.

Financial Risks

Our expenses and investments are primarily in Danish Kroner (DKK) and US Dollars (USD). However, our revenues are in currencies other than DKK, primarily USD and, to a smaller extent, in Euro (EUR). Therefore, our net expenses and any future investment or other income may be vulnerable to fluctuations in exchange rates. We have partly mitigated such fluctuation by placing some of our cash position in demand deposits in USD. We currently do not enter into foreign exchange contracts to cover our exposure to exchange rate fluctuations. If we fail to manage foreign exchange risk adequately, our results of operations and expectations, and the value of LifeCycle Pharma may be adversely affected.

We do not have any interest-bearing debt except for finance lease arrangements as outlined in note 13 to the financial statements. Our interest risk is therefore primarily related to our cash position and cash equivalents. It is essential to our activities to ensure we maintain our capital while at the

same time maximizing the income derived from our excess cash without significantly increasing the risk. Currently our cash position is held in demand deposits with a major Danish bank.

Legal Risks

Biotechnology and pharmaceutical companies are often involved in legal proceedings concerning a variety of issues, including product liability claims, claims related to quality and safety, and infringement of intellectual property rights. Currently, we are not involved in any legal proceedings.

The appropriateness of LifeCycle Pharma's insurance policies is assessed regularly. At least once a year, the Board of Directors reviews the insurance policies in detail. Currently, LifeCycle Pharma carries product liability insurance for our product candidates in clinical development.

At LifeCycle Pharma, quality and safety matters are of utmost importance. A detailed quality assurance system is in place for in-house company activities as well as for our external partners and suppliers.

Although we believe that the activities relating to Fenoglide™ and our product candidates do not infringe any third-party intellectual property rights, we can never rule out that we may become involved in costly and time-consuming intellectual property litigation. Our product and product candidates are subject to ongoing freedom-of-operation analyses in relation to third parties' intellectual property rights, and our competitors' activities are constantly under surveillance.





Corporate Governance

LifeCycle Pharma recognizes the value of an active and positive approach to issues of corporate governance, including those embodied in the Corporate Governance Recommendations promulgated by Nasdaq OMX Nordic Exchange Copenhagen in 2005 (revised in February 2008) concerning remuneration guidelines to the Board of Directors and Executive Management. LifeCycle Pharma generally agrees with the Recommendations and complies with a majority of them.

LifeCycle Pharma has established a duly qualified Board of Directors in terms of professional background and experience within its business area. The composition of the Board of Directors reflects a diversity of relevant qualifications, nationalities, personalities and age in order for the Board to be able, now and in the future, to perform its managerial and strategic duties. In addition, our Articles of Association stipulate that the members of the Board of Directors are up for re-election each year at the annual general meeting. A Board member must retire from the Board of Directors at the annual general meeting immediately following his or her 70th birthday. In addition, the activities of the Board are governed by internal rules of procedure.

The Board of Directors has established a Compensation Committee whose sole purpose is to evaluate and make recommendations to the Board of Directors regarding the remuneration paid to the members of Executive Management and the Board of Directors. Also, the Board of Directors has established an Audit Committee whose sole purpose is to review LifeCycle Pharma's financial controls and to work with independent auditors in connection with their audit of the financial statements and to make reports and recommendations to the Board of Directors on these matters. Both committees serve to assist the entire Board of Directors in its decision-making processes, and we believe that the committees provide a valuable support for the work of the entire Board of Directors. Finally, LifeCycle Pharma has established internal rules governing the allocation of powers between the Board of Directors and Executive Management.

However, LifeCycle Pharma does not comply with all of the Recommendations:

- The Board of Directors has not elected a deputy chairman and has not established a program to evaluate on an annual basis the skills and professional qualifications of each Board member. Likewise, no formal self-appraisal program of the Board and its work has been established. We believe that currently there is no need to formalize these matters given the relative size of LifeCycle Pharma, and the background of each Board member.
- Some of the members of the Board of Directors hold directorships in excess of the number of directorships prescribed in the Recommendations. We regard the Recommendations' limit for the number of directorships as guidance only and wish to leave the matter to the professional judgment of each Board member.
- Five members of the Board of Directors have been issued warrants conferring a right to subscribe shares in LifeCycle Pharma. We believe that the ability to offer warrants as well as other forms of shares as incentive compensation is necessary to attract key people from within the industry (whether as Board members, managers or employees).
- LifeCycle Pharma reports remuneration for the Board of Directors and Executive Management on a group basis rather than on an individual basis. We do not believe that individual reporting is relevant for the appraisal of the Company and its performance.
- Due to the composition of the Board of Directors, the Audit Committee has less than three members. However, the committee is not authorized to make independent decisions.

LifeCycle Pharma intends to continue to actively pursue a strategy of good corporate governance consistent with the main contents of the Recommendations.

Guidelines for Incentive Pay

At the general meeting on 14 March, 2008, LifeCycle Pharma adopted general guidelines for incentive pay to the members of the Board of Directors and the Executive Management, as stipulated in section 69 b of the Danish Companies Act.

Members of the Board of Directors receive a fixed annual fee. The Chairman of the Board of Directors and the Chairman of the Audit Committee receive a supplement to the fixed annual fee. In addition to the fixed annual fee, the members of the Board of Directors are annually granted a fixed number of warrants.

The estimated present value of warrants granted in a given financial year may be up to 100 % of the fixed annual fee to the individual member of the Board of Directors. The estimated present value is calculated in accordance with the International Financial Reporting Standards (IFRS). The general terms and conditions applying to the grant, vesting, exercise, etc. of the warrants must be within the general terms and conditions applying if warrants are to be granted to members of the Executive Management (cf. below), and which also apply to other employees in LifeCycle Pharma who have been granted warrants.

Upon election, each member of the Board of Directors may decide to exchange the annual fee for an additional number of warrants. Likewise, the fixed number of warrants may be exchanged for an additional annual fee.

The aggregated annual fees, the supplemental and additional annual fees, and warrants granted are disclosed on page 51 and are subject to approval at the annual general meeting.

The Compensation Committee performs an annual review of the remuneration package paid to members of the Executive Management.

The remuneration paid to members of the Executive Management consists of a fixed and a variable part. The fixed pay consists of cash salary, pension contribution and other benefits.

As an element of the variable pay, members of the Executive Management may receive an annual bonus, subject to achievement of certain benchmarks. The bonus proportion varies among the members of the Executive Management, but is subject to target on 45 % of the fixed annual cash salary. The actual bonus paid to the members of the Executive Management is disclosed on page 51 at an aggregated level. The bonus benchmarks comprise primarily of the progress in LifeCycle Pharma's development of its product candidates, but they may be changed by the Board of Directors.

Another element of the variable pay is made up of new warrants and is intended to ensure that the Executive Management's incentive correlates with creation of shareholder value. The estimated aggregated present value of new warrants granted in a given financial year to the members of the Executive Management may be up to 100 % of the aggregated fixed annual cash salary to the member of the Executive Management. The estimated present value is calculated in accordance with International Financial Reporting Standards (IFRS). The grant of new warrants may or may not be subject to achievement of defined benchmarks. The exercise price of the new warrants cannot be less than the market price of LifeCycle Pharma's shares at the date of grant. The new warrants may have a maximum term of up to seven years and the exercise of the new warrants may be subject to a vesting period of up to four years. New warrants may be granted on such terms that the gain is taxed as share income while the costs of the grant are not tax deductible for LifeCycle Pharma. The number of new warrants granted to each member of the Executive Management is disclosed on page 59.

Change of Control

The Danish Financial Statements Act has implemented the EU Takeovers Directive, which contains certain rules relating to listed companies on disclosure of information that may be of interest to the market and potential takeover bidders.

LifeCycle Pharma discloses that it has an agreement concerning the right to use certain manufacturing facilities. The agreement might be either amended or terminated upon a change of control of LifeCycle Pharma. Termination of the contract would not materially affect LifeCycle Pharma financially.

Shareholder Information

In April 2008, LifeCycle Pharma successfully completed a rights issue adding new shares to the share capital and increasing the equity and cash position with net 374.5 DKK million. The new shares were offered with pre-emption rights to the existing shareholders at a subscription price of DKK 17 per share.

LifeCycle Pharma strives to maintain an open and continuous dialogue with existing and potential shareholders, stakeholders and the general public. LCP aims for a high degree of openness and effective communication, respecting the principle of equal treatment of all market players.

About our Shares

LifeCycle Pharma's shares were admitted to trading and listed on the Nasdaq OMX Nordic Exchange Copenhagen on 13 November 2006 after an IPO of 12.65 million new shares. The symbol is "LCP" and the securities identification code (ISIN) is DK0060048148. LCP is included in the MidCap+ segment of the Danish companies on the Nasdaq OMX Nordic Exchange Copenhagen.

Share Capital

As of 31 December 2008, LCP had a registered share capital of DKK 56,287,507 with a nominal value of DKK 1 per share. LCP has only one share class and all shares have equal voting rights.

The Board of Directors is in the period up until April 2013 authorized, at one or more times, to increase LCP's share capital with up to nominal DKK 5,500,000. Further, the Board of Directors is authorized, until the annual general meeting in 2009, to arrange for LCP to acquire its own shares up to a nominal value of 10% of the nominal share capital. The purchase price of such shares may not differ by more than 10% from the price quoted on the Nasdaq OMX Nordic Exchange Copenhagen at the time of purchase.

Ownership Structure

As of 31 December 2008, a total of 3,582 of LCP's shareholders were registered in the shareholder register. LCP invites all shareholders to register in LCP's shareholder register.

The following shareholders have reported ownership of 5% or more of LifeCycle Pharma's shares:

- LFI A/S (100% owned by the Lundbeck Foundation)
- Novo A/S (100% owned by the Novo Nordisk Foundation)
- Alta Partners (Alta BioPharma Partners III, L.P., Alta -BioPharma III GmbH & Co. Beteiligungs KG and Alta -Embarcadero BioPharma Partners III, LLC)

About our Major Shareholders

• About LFI A/S

LFI A/S, the Lundbeck Foundation's investment and holding company, was established in 1999 with the main objective of ensuring a clearer separation of the Lundbeck Foundation's grant-making activities and the business activities. The grant making activities take place in the Foundation, while business activities primarily take place in LFI A/S.

• About Novo A/S

Novo A/S, the holding company in the Novo Group, was established prior to the demerger of Novo Nordisk in 2000. Novo A/S is a private limited liability company fully owned by the Novo Nordisk Foundation. Besides being the majority shareholder in Novo Nordisk A/S and Novozymes A/S, Novo A/S provides seed, venture and growth capital to development stage companies within life science and biotechnology as well as manages a broad portfolio of financial assets. For further information, visit www.novo.dk.

• About Alta Partners

Alta Partners is a leading venture capital firm in life sciences, funding over 130 companies in the industry since 1996. A diverse and integrated team brings together a powerful depth of knowledge and experience, delivering tangible results for their companies and investors.



Analyst Coverage

The following financial analysts frequently issue reports and updates on the LCP share:

Carnegie Bank

Carsten Lønborg Madsen
www.carnegie.dk

Morgan Stanley

Karl D. Bradshaw
www.morganstanley.com

Danske Equities

Thomas Bowers
www.danskeequities.com

SEB Enskilda

Peter Sehested
www.sebenskilda.se



Stock Exchange Releases 2008

Jan. 02	1/2008: LifeCycle Pharma Initiates Phase 2 Clinical Trial of LCP-Tacro™ for the Treatment of Autoimmune Hepatitis	Apr. 30	21/2008: Total Number of Voting Rights and Size of Share -Capital in LifeCycle Pharma A/S as of April 30, 2008
Jan. 18	2/2008: LifeCycle Pharma Announces Transplantation Programs on Track	May 07	22/2008: LifeCycle Pharma Announces Positive Data from LCP-AtorFen Phase 2 Clinical Program
Jan. 31	3/2008: LifeCycle Pharma's Financial Calendar 2008	May 14	23/2008: Interim Report for the 3 Months Ended March 31, 2008
Feb. 21	4/2008: LifeCycle Pharma Launches Its First Product in the U.S. through its partner	May 28	24/2008: LifeCycle Pharma Announces Successful Completion of Pilot Studies on LCP-Feno and is Currently Preparing for Pivotal Studies LifeCycle Pharma Discontinues Service Agreements with Partners
Feb. 28	5/2008: LifeCycle Pharma Releases Preliminary Annual Report for 2007	Jun. 04	25/2008: Dr. Flemming Ornskov Steps Down as CEO of LifeCycle Pharma in July, 2008
Mar. 03	6/2008: LifeCycle Pharma Announces Positive Top line Results of Phase 2 Clinical Trial of LCP-Tacro™ for the Prevention of Organ Rejection after Kidney Transplantation	Jul. 08	26/2008: LifeCycle Pharma Announces Positive Top line Results from Phase 2 Clinical Study of LCP-Tacro™ Once Daily in Stable Liver Transplant Patients
Mar. 04	7/2008: LifeCycle Pharma Summons Extraordinary General Meeting	Aug. 14	27/2008: LifeCycle Pharma's Updated Financial Calendar 2008
Mar. 14	8/2008: LifeCycle Pharma Announces Minutes of Extraordinary General Meeting	Aug. 21	28/2008: LifeCycle Pharma Sells Fenoglide™ Royalty Stream to Cowen Healthcare Royalty Partners for up to USD 105 Million Including an Upfront Payment of USD 29 Million
Mar. 14	9/2008: LifeCycle Pharma Announces Changes in Share Capital and Votes: LifeCycle Pharma Increases Share Capital by 334,469 Shares as a Consequence of the Exercise of Employee Warrants	Aug. 21	29/2008: LifeCycle Pharma Announces Interim Report for the 6 Months Ended June 30, 2008
Mar. 16	10/2008: LifeCycle Pharma: Updated Financial Calendar 2008	Sep. 11	30/2008: LifeCycle Pharma Increases Share Capital by 194,562 Shares as a Consequence of the Exercise of Employee Warrants
Mar. 17	11/2008 LifeCycle Pharma Announced Publication of Rights issue	Sep. 11	31/2008: LifeCycle Pharma - Report Pursuant to the Danish Securities Trading Act, Section 28(a)
Mar. 31	12/2008: Report Pursuant to the Danish Securities Trading Act, Section 28(a)	Sep. 18	32/2008: Dr. Michael Beckert Steps Down as EVP and CMO of LifeCycle Pharma Effective December 31, 2008
Apr. 01	13/2008: LifeCycle Pharma - Report Pursuant to the Danish Securities Trading Act, Section 28(a)	Sep. 30	33/2008: Total Number of Voting Rights and Size of Share-Capital in LifeCycle Pharma A/S as of September 30, 2008
Apr. 08	14/2008: LifeCycle Pharma - Major Shareholder Exercises Significant Number of Preemptive Rights in Connection with the Announced Offering	Oct. 17	34/2008: LifeCycle Pharma Appoints Dr. Jim New, an Internationally Experienced Pharmaceutical Executive, as the President and Chief Executive Officer.
Apr. 10	15/2008: LifeCycle Pharma - Report Pursuant to the Danish Securities Trading Act, Section 28(a)	Oct. 17	35/2008: LifeCycle Pharma Grants 500,000 Warrants to the President and CEO Dr. Jim New
Apr. 14	16/2008: LifeCycle Pharma Summons Annual General Meeting	Nov. 27	36/2008: LifeCycle Pharma Announces Interim Report for the 9 Months Ended September 30, 2008
Apr. 17	17/2008 LifeCycle Pharma Announces Completion of Right issue	Dec. 22	37/2008: LifeCycle Pharma Announces Financial Calendar for 2009
Apr. 17	18/2008: Major Shareholder Announcements	Dec. 29	38/2008: LifeCycle Pharma Moves LCP-Tacro™ into Clinical Phase 3
Apr. 17	19/2008: LifeCycle Pharma - Report Pursuant to the Danish Securities Trading Act, Section 28(a)		
Apr. 24	20/2008: LifeCycle Pharma Passing of Annual General Meeting - Subsequent Constitution of the Board of Directors, Appointment of Executive (Registered) Officers and Grant of Warrants to Executive Management and Employees		



Dr. Claus Braestrup Kurt Anker Nielsen Dr. Thomas Dyrberg Dr. Gérard Soula Dr. Jean Deleage Paul Edick Anders Götzsche



Dr. Jim New Dr. Karin Jexner Hamberg Peter G. Nielsen

Board of Directors

Listed on these pages are the board memberships of the Board of Directors and the Executive Management of LifeCycle Pharma A/S. Detailed biographical information on the individual board members and executives is available in the About Us section of our website.

<p>Dr. Claus Braestrup – Chairman Dr. Claus Braestrup, MSc, M.D., has been a Board member since March 2006 and Chairman of our Board of Directors since September 2006. Dr. Braestrup was President and CEO of H. Lundbeck A/S until March 2008.</p> <p>Directorships Bavarian Nordic A/S Danish National Advanced Technology Foundation Profound Invest A/S Santaris Pharma A/S University of Copenhagen</p>	<p>Dr. Jean Deleage Dr. Jean Deleage, MSc, Ph.D. has been a Board member since June 2005. He is a founder and managing director of Alta Partners, a venture capital firm founded in 1996 and investing in information technologies and life science companies.</p> <p>Directorships AGY Therapeutics Inc Genedata AG IDM Pharma, Inc. Innate Pharma SA Kosan Biosciences Incorporated Nereus Pharmaceuticals, Inc. PamGene B.V. (Chairman) Plexxikon, Inc. Rigel Pharmaceuticals, Inc. 7TM Pharma A/S Torrey Pines Therapeutics, Inc. U3 Pharma AG</p>	<p>Dr. Gérard Soula Dr. Gérard Soula, Ph.D., M.B.A., has been a Board member since November 2005. Dr. Soula founded in December 2005, and is presently the President and CEO of Proteins & Peptides Management.</p> <p>Kurt Anker Nielsen Kurt Anker Nielsen, MSc has been a Board member since September 2006.</p> <p>Directorships Collstrup Mindelegat (Chairman) Novo Nordisk A/S Novo Nordisk Foundation Novozymes A/S (Vice Chairman) Reliance A/S (Chairman) StatoilHydro ASA Vestas Wind Systems A/S ZymoGenetics, Inc.</p>
<p>Dr. Thomas Dyrberg Dr. Thomas Dyrberg, M.D., D.MSc, has been a Board member since September 2003. Dr. Dyrberg has served as a Partner at Novo Ventures, Novo A/S, a Danish firm that provides capital for life science companies, since December 2000.</p> <p>Directorships Allocure, Inc hemofocus ApS (Chairman) Lux Biosciences, Inc Ophthotech Corp.</p>	<p>Paul Edick Paul Edick has been a Board member since April 2008. Poul Edick is President and CEO of Ganic Pharmaceutical Inc.</p> <p>Directorships Board member in Amerita Healthcare Inc. Informed Medical Communications Inc.</p>	<p>Anders Götzsche Has been a Board member since April 2008. Anders Götzsche is EVP and CFO at H.Lundbeck A/S since September 2007.</p> <p>Directorships Board member in OL Holding A/S</p>

Executive Management

Registered Management

Jim New, MSc, Ph.D, MBA

President and Chief Executive Officer

Jim New has served as Chief Executive Officer since October 2008.

Prior Positions:	Consultant to Emerging Companies in the Specialty Pharma and Biotech Sectors	2007 to 2008
	Chief Executive Officer and Co founder, Abrika Pharmaceuticals	2002 to 2007
	Head of Mergers and Acquisitions and Development, Novartis	2000 to 2002

Karin Jexner Hamberg, M.D.

Executive Vice President of Research and Development & CMO

Dr. Karin Hamberg has served as Executive Vice President of Research and Development since June 2008.

Prior Positions:	Vice President, Development, LEO Pharma A/S (pharmaceutical, preclinical, clinical)	2004 to 2008
	Director, Corporate Project Management, LEO Pharma A/S	2001 to 2004
	Staff function, VP Biological Research & Core Team Project Manager, LEO Pharma A/S	1999 to 2001

Peter G. Nielsen

Executive Vice President of Pharmaceutical Development and CMC

Peter G Nielsen has served as responsible for the CMC area including drug delivery research, pharmaceutical development and manufacturing activities since early 2007.

Prior Positions:	Corporate Vice President, Formulation & Clinical Supplies, Novo Nordisk A/S	2005 to 2007
	Vice President, CMC Development, Novo Nordisk A/S	2002 to 2005
	Vice President, Pharmaceutical Development, Novo Nordisk A/S	1997 to 2002

Other Leading Members of Management

Dr. Andreas Konar, VP of Alliance & Project Management
Dr. Anil Patel, VP of Pharmaceutical and Analytical Development
Ira Weisberg, VP of Business Development
Lars Bjørn Christensen, VP of Manufacturing
Dr. Per Holm, VP of Drug Delivery Research
Johnny Stilou, VP Finance
Peter Schøtt Knudsen, General Counsel and Secretary to the Board

Company Information and List of Subsidiaries

Company Information

LifeCycle Pharma A/S
Kogle Allé 4
DK-2970 Hørsholm
Denmark
www.lcpharma.com
CVR-no. 26 52 77 67

Subsidiary

LifeCycle Pharma, Inc. (100 % ownership)
100 Park Avenue - 13th Floor
New York, NY 10017
USA



Executive Management's and Board of Directors' Statement on the Annual Report

The Executive Management and the Board of Directors have considered and adopted the Annual Report of LifeCycle Pharma A/S for the financial year 2008.

The Annual Report is prepared in accordance with the International Financial Reporting Standards as adopted by the EU and additional Danish disclosure requirements for the annual reports of listed companies.


We consider the applied accounting policies to be appropriate and, in our opinion, the Annual Report gives a true

and fair view of the assets and liabilities, financial position, results of the operation and cash flow of the Group and the Parent Company. Furthermore, in our opinion the management review includes a fair review of the development and performance of the business and the financial position of the Group, together with a description of the material risks and uncertainties the Group faces.


The Annual Report will be submitted to the annual general meeting for approval.

Hørsholm, 3 March, 2009


Executive Management


Jim New
(President and CEO)


Peter G Nielsen
(Executive Vice President)


Karin Jexner Hamberg
(Executive Vice President)

Board of Directors


Claus Braestrup
(Chairman)


Kurt Anker Nielsen


Thomas Dyrberg


Jean Deleage


Gérard Soula


Paul Edick


Anders Götzsche

Independent Auditor's Report

To the Shareholders of LifeCycle Pharma A/S

We have audited the Annual Report of LifeCycle Pharma A/S for the financial year 1 January to 31 December 2008, pages 4-62, which comprises Management's Review, statement by the Executive Management and Board of Directors on the Annual Report, income statement, balance sheet, cash flow statement, statement of changes in equity and notes to the financial statements for the Group as well as for the Parent Company. The Annual Report is prepared in accordance with International Financial Reporting Standards as adopted by the EU and additional Danish disclosure requirements for annual reports of listed companies.

Management's Responsibility for the Annual Report

Management is responsible for the preparation and fair presentation of the Annual Report in accordance with International Financial Reporting Standards as adopted by the EU and additional Danish disclosure requirements for Annual Report of listed companies. This responsibility includes: designing, implementing and maintaining internal controls relevant to the preparation and fair presentation of an Annual Report that is free from material misstatement, whether due to fraud or error; selecting and applying appropriate accounting policies; and making accounting estimates that are reasonable in the circumstances.

Auditor's Responsibility

Our responsibility is to express an opinion on the Annual Report based on our audit. We conducted our audit in accordance with Danish auditing standards. Those standards require that we comply with ethical requirements and plan and perform the audit to obtain reasonable assurance that the annual report is free from material misstatement.

An audit involves performing procedures to obtain audit evidence about the amounts and disclosures in the Annual Report. The procedures selected depend on the auditor's judgment, including the assessment of the risks of material

misstatement of the Annual Report, whether due to fraud or error. In making those risk assessments, the auditor considers internal control relevant to the Entity's preparation and fair presentation of the Annual Report in order to design audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the entity's internal control. An audit also includes evaluating the appropriateness of accounting policies used and the reasonableness of accounting estimates made by Management, as well as evaluating the overall presentation of the Annual Report.

We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our audit opinion.

Our audit has not resulted in any qualification.

Opinion

In our opinion, the Annual Report gives a true and fair view of the financial position at 31 December 2008 of the Group and the Parent Company and of the results of the Group's and the Parent Company's operations and cash flows for the financial year 1 January to 31 December 2008 in accordance with International Financial Reporting Standards as adopted by the EU and additional Danish disclosure requirements for annual reports of listed companies.

Copenhagen, March 3, 2009

PricewaterhouseCoopers
Statsautoriseret Revisionsaktieselskab


Lars Holtug
State Authorized Public Accountant


Claus Køhler Carlsson
State Authorized Public Accountant

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Income Statements

for the period 1 January – 31 December

(DKK'000)	Note	Consolidated		Parent	
		2008	2007	2008	2007
Revenue		170 122	64 705	170 122	64 705
Research and development costs	3, 4	(270 875)	(183 608)	(272 770)	(182 327)
Administrative expenses	3, 4	(73 311)	(54 033)	(72 125)	(53 200)
Operating loss		(174 064)	(172 936)	(174 773)	(170 822)
Financial income	5	45 474	18 553	45 906	19 118
Financial expenses	6	(21 189)	(5 856)	(21 188)	(5 856)
Loss before tax		(149 779)	(160 239)	(150 055)	(157 560)
Tax for the year	7	-	-	-	-
Net loss for the year		(149 779)	(160 239)	(150 055)	(157 560)
Basic and diluted EPS (DKK)		(3.06)	(5.19)	(3.06)	(5.10)
Weighted average number of shares		49 006 500	30 875 434	49 006 500	30 875 434

The Board of Directors proposes the net loss for the year to be carried forward to next year

Balance Sheets

– Assets at 31 December

(DKK'000)	Note	Consolidated		Parent	
		2008	2007	2008	2007
Licenses and rights	8	679	729	679	729
Intangible assets		679	729	679	729
Property, plant and equipment	8	20 628	21 837	20 470	21 636
Leasehold improvements	8	5 224	6 220	5 042	5 982
Tangible fixed assets		25 852	28 057	25 512	27 618
Equity interest in subsidiary	9	-	-	2 592	2 592
Financial fixed assets		-	-	2 592	2 592
Non-current assets		26 531	28 786	28 783	30 939
Receivable from subsidiary		-	-	-	3 709
Trade receivables		1 670	3 842	1 670	3 842
Other receivables		10 928	14 379	10 625	14 294
Prepayments		7 034	3 165	6 739	2 852
Receivables		19 632	21 386	19 034	24 697
Cash and cash equivalents		600 130	331 740	597 591	325 268
Current assets		619 762	353 126	616 625	349 965
Assets		646 293	381 912	645 408	380 904

Balance Sheets

– Equity and Liabilities at 31 December

(DKK'000)	Note	Consolidated		Parent	
		2008	2007	2008	2007
Share capital	10	56 288	31 771	56 288	31 771
Share premium		1 078 740	724 645	1 078 740	724 645
Translation reserves		1 743	821	-	-
Retained earnings/loss		(564 448)	(431 548)	(562 045)	(428 870)
Equity		572 323	325 689	572 983	327 546
Provisions	2	10 492	-	10 492	-
Finance lease	13	16 082	20 416	16 082	20 416
Non-current liabilities		26 574	20 416	26 574	20 416
Finance lease	13	4 450	5 092	4 450	5 092
Trade payables		22 910	15 066	22 572	14 469
Deferred revenue		-	1 716	-	1 716
Debt to subsidiary		-	-	2 216	-
Other payables		20 036	13 933	16 613	11 665
Current liabilities		47 396	35 807	45 851	32 942
Liabilities		73 970	56 223	72 425	53 358
Equity and liabilities		646 293	381 912	645 408	380 904
Financial risks	11				
Warrants	12				
Other Commitments	14				
Related parties	15				
Fees to auditors	17				

Cash Flow Statements

for the period 1 January – 31 December

(DKK'000)	Note	Consolidated		Parent	
		2008	2007	2008	2007
Operating loss		(174 064)	(172 936)	(174 773)	(170 822)
Share-based payment	4	16 879	18 017	16 879	16 299
Depreciation and amortization	3	8 834	7 004	8 663	6 981
Net loss on sale of fixed assets	3	-	60	-	60
Changes in working capital	16	23 371	4 994	20 047	2 405
Cash flow from operating activities before interest		(124 980)	(142 861)	(129 184)	(145 077)
Interest received		43 503	17 914	45 906	18 382
Interest paid		(21 083)	(4 344)	(21 188)	(4 344)
Corporate tax paid	7	-	-	-	-
Cash flow from operating activities		(102 560)	(129 291)	(104 466)	(131 039)
Purchase of property, plant and equipment		(6 571)	(5 900)	(6 507)	(5 437)
Net loss on sale of property, plant and equipment		-	(60)	-	(60)
Cash transfer to restricted security deposit		(57)	(1 338)	-	-
Investment in subsidiary		-	-	-	(2 592)
Payable to / receivable from subsidiary		-	-	5 925	(2 848)
Cash flow from investing activities		(6 628)	(7 298)	(582)	(10 937)
Proceeds from bank borrowings and finance lease		-	1 118	-	1 118
Installments on bank borrowings and finance lease		(4 975)	(6 356)	(4 975)	(6 356)
Proceeds from issuance of shares, net		378 612	9 007	378 612	9 007
Cash flow from financing activities		373 637	3 769	373 637	3 769
Increase/(decrease) in cash and cash equivalents		264 449	(132 820)	268 589	(138 207)
Cash and cash equivalents at beginning of period		330 402	464 658	325 268	464 658
Exchange gains/(losses) on cash and cash equivalent		3 884	(1 436)	3 734	(1 183)
Cash and cash equivalents at end of period		598 735	330 402	597 591	325 268
Cash and cash equivalents at end of period comprise:					
Restricted bank deposit		1 395	1 338	-	-
Deposit on demand and cash		598 735	330 402	597 591	325 268
		600 130	331 740	597 591	325 268

Statements of Changes in Equity

– Consolidated

	Number of Shares	Share Capital DKK'000	Share Premium DKK'000	Translation Reserves DKK'000	Retained Earnings DKK'000	Total DKK'000
Equity as of 1 January 2007	30 369 816	30 370	717 039	-	(289 326)	458 083
Comprehensive income:						
Net loss for the year					(160 239)	(160 239)
Currency translation differences				821		821
Total comprehensive income						(159 418)
Warrant exercises	1 400 889	1 401	7 663			9 064
Share-based payment					18 017	18 017
Costs related to capital increases			(57)			(57)
Equity as of December 31, 2007	31 770 705	31 771	724 645	821	(431 548)	325 689
Comprehensive income:						
Net loss for the year					(149 779)	(149 779)
Currency translation differences				922		922
Total comprehensive income						(148 857)
Issuance of shares	23 987 771	23 988	383 804			407 792
Warrant exercises	529 031	529	3 560			4 089
Share-based payment					16 879	16 879
Costs related to capital increases			(33 269)			(33 269)
Equity as of December 31, 2008	56 287 507	56 288	1 078 740	1 743	(564 448)	572 323

Statements of Changes in Equity

– Parent Company

	Number of Shares	Share Capital DKK'000	Share Premium DKK'000	Translation Reserves DKK'000	Retained Earnings DKK'000	Total DKK'000
Equity as of 1 January 2007	30 369 816	30 370	717 039	-	(289 326)	458 083
Comprehensive income:						
Net loss for the year					(157 560)	(157 560)
Total comprehensive income						(157 560)
Warrant exercises	1 400 889	1 401	7 663			9 064
Share-based payment					18 017	18 017
Costs related to capital increases			(57)			(57)
Equity as of December 31, 2007	31 770 705	31 771	724 645	-	(428 869)	327 547
Comprehensive income:						
Net loss for the year					(150 055)	(150 055)
Total comprehensive income						(150 055)
Issuance of shares	23 987 771	23 988	383 804			407 792
Warrant exercises	529 031	529	3 560			4 089
Share-based payment					16 879	16 879
Costs related to capital increases			(33 269)			(33 269)
Equity as of December 31, 2008	56 287 507	56 288	1 078 740	-	(562 045)	572 983

Notes

NOTE 1. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Basis of Presentation

The financial statements have been prepared in accordance with the International Financial Reporting Standards (IFRS) as issued by the International Accounting Standards Board and adopted by the EU, and additional Danish disclosure requirements for annual reports of listed companies. The financial statements have been prepared under the historical cost convention, as modified by the revaluation of financial assets and financial liabilities (including derivative instruments) at fair value through profit or loss.

The financial statements are presented in Danish Kroner (DKK), which is the functional and presentation currency of the Parent Company.

New Accounting Policies

In 2008, LifeCycle Pharma has adopted the following new or revised standards and interpretations endorsed by EU effective for the accounting period beginning on 1 January 2008.

- IFRIC 11, 'IFRS 2" Group and treasury share transactions', provides guidance on whether share-based transactions involving treasury shares or involving group entities (for example, options over a parent's shares) should be accounted for as equity-settled or cash-settled share-based payment transactions in the stand-alone accounts of the parent and group companies. This interpretation has been implemented in the group's financial statements.

Except for the adoption of the new and amended standards issued by the IASB, the accounting policies are consistent with the accounting policies used in prior year's financial statements.

Standards Not Adopted by the Group

The following standards and interpretations relevant to LifeCycle Pharma have been issued and endorsed by EU as per 31 December 2008 and are mandatory for the Group's accounting periods beginning on or after 1 January 2009. These have not yet been adopted by LifeCycle Pharma:

- IFRS 8 'Operating segments' The standard is not expected to have a material impact on the Group's financial statements.
- IAS 1 (Revised), 'Presentation of financial statements' (ef-

fective from 1 January 2009). The revised standard will prohibit the presentation of items of income and expenses (that is, 'non-owner changes in equity') in the statement of changes in equity, requiring 'non-owner changes in equity' to be presented separately from owner changes in equity (comprehensive income statement).

- IAS 23 (Amendment) 'Borrowing costs' (effective from 1 January 2009). The option of immediately expensing borrowing costs of a qualifying asset will be removed. Given the present capital structure of the Group the impact is expected to be limited.

- IFRS 2 (Amendment), 'Share-based payment' (effective from 1 January 2009). The amended standard deals with vesting conditions and cancellations. All cancellations, whether by the entity or by other parties, should receive the same accounting treatment. It is not expected to have a material impact on the Group's financial statements.

Standards Not Endorsed by EU

- IAS 27 (Revised), 'Consolidated and separate financial statements', (effective from 1 July 2009). The revised standard requires the effects of all transactions with non-controlling interests to be recorded in equity if there is no change in control and these transactions will no longer result in goodwill or gains and losses. It is not expected to have a material impact on the Group's financial statements.

- IAS 36 (Amendment), 'Impairment of assets' (effective from 1 January 2009). Where fair value less costs to sell is calculated on the basis of discounted cash flows, disclosures equivalent to those for value-in-use calculation should be made.

- IAS 38 (Amendment), 'Intangible assets' (effective from 1 January 2009). A prepayment may only be recognized in the event that payment has been made in advance of obtaining right of access to goods or receipt of services. It is not expected to have a material impact on the Group's financial statements.

- There are a number of minor amendments to IFRS 7, 'Financial instruments: Disclosures', IAS 1 (Amendment), 'Presentation of financial statements', IAS 8, 'Accounting policies,

changes in accounting estimates and errors', IAS 10, 'Events after the reporting period', IAS 18, 'Revenue', IAS 34, 'Interim financial reporting' and IAS 39 (Amendment), 'Financial instruments: Recognition and measurement'. These amendments are not expected to have an impact on the Group's financial statements.

LifeCycle Pharma will adopt all new standards in accordance with the transitional provisions of each standard.

Consolidated Financial Statements

The consolidated financial statements include LifeCycle Pharma A/S (the Parent Company) and subsidiaries in which the Parent Company directly or indirectly exercises a controlling interest through shareholding or otherwise. Accordingly, the consolidated financial statements include LifeCycle Pharma A/S and LifeCycle Pharma, Inc. (collectively referred to as the LifeCycle Pharma group).

The group's consolidated financial statements have been prepared on the basis of the financial statements of the Parent Company and the subsidiary – prepared under the group's accounting policies – by combining similar accounting items on a line-by-line basis. On consolidation, intercompany income and expenses, intercompany receivables and payables, and unrealized gains and losses on transactions between the consolidated companies are eliminated.

The recorded value of the equity interests in the consolidated subsidiary is eliminated with the proportionate share of the subsidiary's equity. The subsidiary is consolidated from the date when control is transferred to the group.

The income statement for the foreign subsidiary is translated into the group's reporting currency at the year's weighted average exchange rate and the balance sheet is translated at the exchange rate in effect at the balance sheet date. Exchange rate differences arising from the translation of the foreign subsidiary's shareholders' equity at the beginning of the year, and exchange rate differences arising as a result of the foreign subsidiary's income statement being translated at average exchange rates, are recorded in translation reserves in shareholders' equity.

Foreign Currency

Transactions in foreign currencies are translated at the exchange rates in effect at the date of the transaction.

Exchange rate gains and losses arising between the transaction date and the settlement date are recognized in the income statement as financial items.

Unsettled monetary assets and liabilities in foreign currencies are translated at the exchange rates in effect at the balance sheet date. Exchange rate gains and losses arising between the transaction date and the balance sheet date are recognized in the income statement as financial items.

Income Statement

Revenues

Revenues comprise milestone payments, royalties and cost reimbursement from research and development and commercialization agreements. Revenue is recognized when it is probable that future economic benefits will flow to the Company and these benefits can be measured reliably. Further, revenue recognition requires that all significant risks and rewards of ownership of the goods or services included in the transaction have been transferred to the buyer, and that LifeCycle Pharma retains neither continuing managerial involvement to the degree usually associated with ownership nor effective control over the goods or services sold.

Revenues are stated less of VAT, charges and discounts.

Research and Development Costs

Research and development costs comprise license costs, manufacturing costs, pre-clinical and clinical trial costs, salaries and other staff costs including pensions, and other costs including cost of premises, depreciation and amortization related to research and development activities.

Research costs are recognized in the income statement in the period to which they relate. Development costs are recognized in the income statement when incurred if the criteria for capitalization have not been met.

A development project involves a single product candidate undergoing a high number of tests to illustrate its safety profile and effect on human beings prior to obtaining the necessary approval from the appropriate authorities. Considering the general risk related to the development of pharmaceutical products, management has concluded that the future economic benefits associated with the individual development projects cannot be estimated with sufficient certainty until the project has been finalized and the necessary market approval of the final product has been obtained. As a consequence all development costs are recognized in the income statement in the period to which they relate.

General and Administrative Expenses

General and administrative expenses comprise salaries and other staff costs including pensions, office supplies, cost of

premises, and depreciation and amortization related to administrative activities.

General and administrative expenses are recognized in the income statement in the period to which they relate.

Share-based Payment

Employees (including executive management), board members and external consultants have been granted warrants. For warrants granted after 7 November 2002 and not vested 1 January 2005, the fair value of the warrants at the grant date is recognized as an expense in the income statement over the vesting period. A corresponding amount is recognized under shareholders' equity.

Financial Income and Expenses

Financial income and expenses comprise interest income and expenses, the interest portion related to finance lease contracts and realized and unrealized exchange rate gains and losses on transactions denominated in foreign currencies.

Corporate Tax

Tax for the year, which consists of current tax for the year and changes in deferred tax, is recognized in the income statement by the portion attributable to the income for the year, and recognized directly in equity by the portion attributable to transactions recognized directly in equity. Current tax payable or receivable is recognized in the balance sheet as tax calculated on the taxable income for the year adjusted for prepaid tax.

Deferred tax is recognized and measured under the liability method on all temporary differences between the carrying amount and tax value of assets and liabilities. The tax value of the assets is calculated based on the planned use of each asset.

Deferred tax is calculated in accordance with the tax regulations and tax rates that are expected to be in effect, considering the laws in force at the balance sheet date, when the deferred tax is estimated to crystallize as current tax. Changes in deferred tax resulting from changed tax rates are recognized in the income statement.

Deferred tax assets, including the tax value of tax losses carried forward, are recognized in the balance sheet at their estimated realizable value, either as a set-off against deferred tax liabilities, if such set-off is permitted for tax purpose, or as net tax assets. Deferred tax assets which are not recognized in the balance sheet are disclosed in a note to the financial statements.

Balance Sheet

Non-Current Assets

Intangible Assets

Intangible assets comprise acquired patent rights, which are measured at cost less accumulated amortization and impairment losses. The amortization period is determined based on the expected economic and technical useful life, and amortization is recognized on a straight-line basis over the expected useful life, which is 20 years.

Tangible Fixed Assets

Tangible fixed assets comprise process plant and machinery, other fixtures and fittings, tools and equipment and leasehold improvements. Tangible fixed assets are measured at cost less accumulated depreciation and impairment losses. Cost includes expenditures that are directly attributable to the acquisition of the assets. Subsequent costs are included in the carrying amount of the asset or recognized as a separate asset, as appropriate, only when it is probable that future economic benefits associated with the assets will flow to the Company and the costs of the items can be measured reliably. All repair and maintenance costs are charged to the income statement during the financial periods in which they are incurred.

Depreciation of tangible fixed assets is calculated using the straight-line method to allocate the cost to the residual value of the assets over the expected useful life as follows:

Process plant and machinery: 7 years

Other fixtures and fittings, tools and equipment: 3-5 years

Leasehold improvements: 7-9 years

Depreciation, impairment losses and gains or losses on disposal of tangible fixed assets is recognized in the income statement as research and development costs or as general and administrative expenses, as appropriate.

Equity Interests in Subsidiaries

In the separate financial statements of the Parent Company, equity interests in subsidiaries are recognized and measured at cost. Equity interests in foreign currencies are translated to the reporting currency by use of historical exchange rates prevailing at the time of investment.

Income is recognized from the investments only to the extent that distributions from accumulated profits are received. Distributions received in excess of such profits are regarded as a recovery of the investment and recognized as a reduction to the cost of the investment.

Impairment of Long-lived Assets

The carrying amount of long-lived assets is tested for impairment whenever events or changes in circumstances indicate that the carrying amount may not be recoverable. If there are such indications, an impairment test is performed. An impairment loss is recognized for the amount by which the carrying amount of the asset exceeds its recoverable amount. The recoverable amount is determined as the higher of an asset's net selling price and its value in use. Value in use is calculated as the net present value of future cash inflow generated from the asset. For the purposes of assessing impairment, assets are grouped at the lower levels for which there are separately identifiable cash flows (cash-generating units). For corporate assets the assessment is carried out on entity level. Impairment losses are recognized in the income statement under the same line items as the related depreciation or amortization.

Current Assets

Trade Receivables

Trade receivables are measured in the balance sheet at the lower of amortized cost and net realizable value, which corresponds to the nominal value less provisions for bad debts. Provisions for bad debts are determined on the basis of an individual assessment of each receivable.

Other Receivables

Other receivables are measured at fair value on initial recognition and subsequently measured at amortized cost according to the effective interest method less provision for impairment. Impairment losses are based on an individual evaluation of each amount collectible.

Prepayments

Prepayments comprise incurred costs related to a future financial period. Prepayments are measured at nominal value.

Cash and Cash Equivalents

Cash and cash equivalents comprise cash and deposits with financial institutions. Cash and cash equivalents are measured at amortized cost.

Shareholders' Equity

The share capital comprises the nominal amount of the Company's ordinary shares, each at a nominal value of DKK 1. All shares are fully paid.

The share premium reserve includes amounts paid as premium compared to the nominal value of the shares in con-

nection with the Company's capital increases less external expenses which are directly attributable to the increases.

Translation reserves include exchange rate adjustments of equity investments in subsidiaries.

Non-Current Liabilities

Provisions

Provisions are recognized when the Company has an existing legal or constructive obligation as a result of events occurring prior to or on the balance sheet date, and it is probable that the utilization of economic resources will be required to settle the obligation. Provisions are measured at the amount expected to be paid.

Finance Leases

Leases of property, plant and equipment where the Company substantially bears all the risks and rewards of ownership are classified as finance leases. Assets under finance leases are recognized in the balance sheet at the inception of the lease term at the lower of the fair value of the asset or the net present value of the future minimum lease payments. A liability equaling the asset is recognized in the balance sheet, allocated between non-current and current liabilities. Each lease payment is separated between an interest element, recognized as a financial expense, and a reduction of the lease liability.

Assets held under finance lease are depreciated over the shorter of the asset's useful life and the lease term.

Operating Lease Commitments

Leases in which a significant portion of the risks and rewards of ownership are retained by the lessor are classified as operating leases. Payments made under operating leases (net of any incentives received from the lessor) are charged on a straight-line basis to the income statement as research and development costs or as general and administrative expenses, depending on the use of the asset.

The total commitment under operating leases is disclosed in the notes to the financial statements.

Current Liabilities

Trade Payables

Trade payables are measured at amortized cost, which is considered to be equal to the fair value due to the short-term nature of the liabilities.

Deferred Revenue

Deferred revenue reflects the part of revenue which has not been recognized as income immediately on receipt of payment and which concerns agreements with multiple components which cannot be separated. Deferred revenue is measured at the amount received.

Other Liabilities

Other liabilities are measured in the balance sheet at amortized cost, which is considered to be equal to the fair value due to the short-term nature of the liabilities.

Derivative Financial Instruments

LifeCycle Pharma does not have derivative financial instruments.

Cash Flow Statement

The cash flow statement is presented using the indirect method with basis in operating loss and shows cash flow from operating, investing and financing activities as well as the cash and cash equivalents at the beginning and end of each financial year.

Cash flows from operating activities are calculated as the operating profit/loss adjusted for non-cash operating items such as share-based payment, depreciation, amortization and impairment losses, working capital changes and financial income and expenses received or paid.

Cash flows from investing activities comprise cash flows from purchase and sale of intangible assets and property, plant and equipment.

Cash flows from financing activities comprise cash flows from issuance of shares net of costs, raising and repayment

NOTE 2. CRITICAL ACCOUNTING ESTIMATES AND JUDGMENTS

In preparing financial statements under IFRS, certain provisions in the standards require management's judgments. Such judgments are considered important to understand the accounting policies and LifeCycle Pharma's compliance with the standards. The following summarizes the areas involving higher degree of judgment or complexity, or areas where assumptions and estimates are significant to the financial statements.

of non-current loans including installments on finance lease liabilities.

Cash and cash equivalents comprise cash at hand and deposits with financial institutions.

The cash flow statement cannot be derived solely from the financial statements.

Segment Reporting

The group is managed and operated as one business unit. No separate business areas or separate business units have been identified in relation to product candidates or geographical markets. Accordingly, LifeCycle Pharma's management has concluded that it is not relevant to disclose segment information on business segments or geographical markets.

Definition of Financial Ratios

Basic EPS

Basic Earnings per share (EPS) is calculated as the net income/loss from continuing operations for the period divided by the weighted average number of ordinary shares outstanding.

Diluted EPS

Diluted earnings per share is calculated as the net income/loss from continuing operations for the period divided by the weighted average number of ordinary shares outstanding adjusted for the dilutive effect of share equivalents.

As the income statement shows a net loss, no adjustment has been made for the dilutive effect.

$$\text{Assets/Equity} = \frac{\text{Total assets}}{\text{Equity}}$$

The USD 29 million received in up-front payment from Cowen Healthcare Royalty Partners, L.P. is recognized as revenue as no obligations are connected to the payment.

The up-front payment relates to the sale of the future royalty stream of Fenoglide™ in North America. LifeCycle Pharma has no future commitments under the agreement, besides some patent prosecution and enforcement obligations. A provision of DKK 10.5 million has been made for these obligations.

Internally Generated Intangible Assets

IAS 38, "Intangible Assets" prescribes that intangible assets arising from development projects must be recognized in the balance sheet if the criteria for capitalization are met. That means (1) that the development project is clearly defined and identifiable; (2) that technological feasibility, adequate resources to complete and a market for the product or an internal use of the project can be documented; and (3) that the Company's management has the intent to produce and market the product or use it internally.

Such an intangible asset shall be recognized if it can be documented that the future income from the development project will exceed the aggregate cost of development, production, sale and administration of the product.

Management believes that future income from the development projects cannot be determined with sufficient certainty until the development activities have been completed and the necessary approvals have been obtained. Accordingly, management has decided not to recognize such internally generated intangible assets at this time.

Joint Ventures / Collaboration Agreements

Collaboration agreements within the Company's industry are often structured so that each party contributes its respective skills in the various phases of a development project. No joint control exists for such collaborations and the parties do not have any financial obligations on behalf of each other. Accordingly, the collaborations are not considered to be joint ventures as defined in IAS 31, "Financial Reporting of Interests in Joint Ventures".

Except for the above areas, assumptions and estimates are not considered to be critical to the financial statements. No estimates or judgments have been made involving a material risk of significant adjustments of the assets or liabilities at the balance sheet date.

NOTE 3. DEPRECIATION AND AMORTIZATION

(DKK'000)	Consolidated		Parent	
	2008	2007	2008	2007
Licenses and rights	50	50	50	50
Property, plant and equipment	7 627	6 060	7 548	6 048
Leasehold improvements	1 157	894	1 065	883
(Gain) / loss on sale of property, plant and equipment	0	60		60
Total	8 834	7 064	8 663	7 041
Allocated by function:				
Research and development costs	7 172	5 628	7 039	5 609
General and administrative expenses	1 662	1 436	1 624	1 432
Total	8 834	7 064	8 663	7 041

NOTE 4. STAFF COSTS

(DKK'000)	Consolidated		Parent	
	2008	2007	2008	2007
Wages and salaries	83 248	53 035	70 079	45 412
Pension contributions	5 888	3 391	4 999	3 233
Other social security costs	6 733	2 834	5 077	2 387
Share-based payment	16 879	18 017	16 244	16 299
Total	112 748	77 277	96 399	67 331
Allocated by function:				
Research and development costs	80 818	52 089	69 064	44 423
General and administrative expenses	31 930	25 188	27 335	22 908
Total	112 748	77 277	96 399	67 331
Average number of employees (FTEs)	102	64	86	58

Remuneration of board of directors, and executive management:

Board of directors				
Cash remuneration	475	213	475	213
Share-based payment	914	574	914	574
	1 389	787	1 389	787
Executive management				
Gross salary	10 467	4 610	9 998	4 137
Bonus	3 238	2 482	3 038	1 147
Pension contributions	527	239	527	239
Share-based payment	6 398	7 037	6 398	7 037
	20 630	14 368	19 961	12 560

The current Executive Management consists of Jim New, who joined LifeCycle Pharma on October 17, 2008, Karin Jexner Hamberg, who joined LifeCycle Pharma on June 1, 2008 and Peter G Nielsen, who has been with LifeCycle Pharma throughout 2008. Total remuneration related cost to the current Executive Management amounts to DKK 5.466 million in 2008.

The group senior managers have been registered with the Danish Commerce and Companies Agency and accordingly no employees are grouped as senior managers in 2008.

Members of the Board of Directors receives a fixed annual fee of DKK 100,000. The Chairman of the Board of Directors receives a supplement of DKK 50,000 to the fixed fee and the Chairman of the Audit Committee receives a supplement of DKK 25,000 to the fixed annual fee.

In addition to the fixed annual fee, the members of the Board of Directors are annually granted a fixed number of 10,000 warrants.

Upon election, each member of the Board of Directors may decide to exchange the annual fee for an additional num-

ber of 5,000 warrants. Likewise, the fixed number of warrants may be exchanged for an additional annual fee of DKK 25,000.

In addition to the notice period for the Executive Management, which varies from 6 to 12 months, the notice period shall be prolonged to 18 months for the CEO Jim New in certain cases in connection with a change of control in LifeCycle Pharma.

LifeCycle Pharma's and the group's pension schemes are defined contribution schemes and LifeCycle Pharma has no additional payment obligations.

LifeCycle Pharma has implemented a company-wide (including management) remuneration policy with a bonus element including both a cash element and a warrant based element. Hence a certain percentage of each employee's remuneration is dependent on the employee and the company specified goals and objectives agreed upon at the beginning of each year. LifeCycle Pharma has implemented Incentive Guidelines, which has been adopted by the General Assembly and are in further detailed described on page 31 and on LifeCycle Pharma's homepage www.lcpharma.com/investors.

Board of Directors and Executive Management's Holdings of Shares and Warrants

	As per 31 December 2008		As per 31 December 2007	
	Shares	Warrants	Shares	Warrants
Board of directors				
Claus Braestrup	3 000	22 175	-	10 000
Kurt Anker Nielsen	-	-	-	-
Thomas Dyrberg	15 400	22 175	8 800	10 000
Jean Deleage	-	36 307	-	17 500
Gerárd Soula	-	142 184	-	67 500
Paul Edick	-	15 000	-	-
Anders Götzche	-	-	-	-
Executive management				
Jim New	-	500 000	-	-
Peter G Nielsen	1 000	157 572	-	75 000
Karin Jexner Hamberg	-	80 000	-	-

NOTE 5. FINANCIAL INCOME

(DKK'000)	Consolidated		Parent	
	2008	2007	2008	2007
Interest income	21 843	16 586	21 827	16 575
Interest income from group companies	-	-	448	576
Exchange rate gains	23 631	1 967	23 631	1 967
Total	45 474	18 553	45 906	19 118

NOTE 6. FINANCIAL EXPENSES

(DKK'000)	Consolidated		Parent	
	2008	2007	2008	2007
Interest expenses	20	18	19	18
Interest on finance leases	1 392	1 624	1 392	1 624
Exchange rate losses	19 777	4 214	19 777	4 214
Total	21 189	5 856	21 188	5 856

NOTE 7. TAX AND DEFERRED TAX

(DKK'000)	Consolidated		Parent	
	2008	2007	2008	2007
Income tax for the year can be explained as follows:				
Income / (loss) for the year before tax	(149 779)	(160 239)	(150 055)	(157 560)
Computed tax on income / (loss) for the year	(37 119)	(40 390)	(37 514)	(39 390)
Adjustment to tax for prior year	-	795	-	795
Change in tax losses carried forward not capitalized	33 761	26 622	34 156	26 607
Change in other deferred tax assets not capitalized	2 737	(158)	2 737	(1 143)
Tax on equity postings	(3 097)	(14)	(3 097)	(14)
Other permanent adjustments	3 718	4 086	3 718	4 086
Change in tax rate	-	9 059	-	9 059
Income tax for the year	0	0	0	0
Tax rate	25 %	25 %	25 %	25 %
Calculated deferred tax asset	147 184	110 686	146 907	110 014
Write down to assessed value	(147 184)	(110 686)	(146 907)	(110 014)
Carrying amount	0	0	0	0

The components of the deferred tax asset is as follows:

Intangible assets	105	93	105	93
Property, plant and equipment	(694)	(2 579)	(694)	(2 581)
Leasehold improvements	(1 260)	(1 495)	(1 260)	(1 495)
Finance leases	5 133	6 377	5 133	6 377
Deferred income	-	429	-	429
Accrued liabilities	2 623	-	2 623	-
Tax losses carried forward	141 277	107 861	141 000	107 191
Total	147 184	110 686	146 907	110 014

The deferred tax asset has been written down, as it is uncertain whether or not the tax asset will be realized in future earnings. The deferred tax asset can be carried forward without limitations.

NOTE 8. INTANGIBLE & TANGIBLE FIXED ASSETS

Consolidated (DKK'000)	Licenses & Rights		Property, Plant & Equipment		Leasehold Improvements	
	2008	2007	2008	2007	2008	2007
Cost at 1 January	1 000	1 000	36 519	31 886	9 391	8 124
Additions	-	-	6 414	4 633	156	1 267
Exchange adjustment	-	-	7	-	9	-
Cost at 31 December	1 000	1 000	42 940	36 519	9 556	9 391
Amortization / Depreciation at 1 January	(271)	(221)	(14 682)	(8 622)	(3 171)	(2 276)
Amortization / Depreciation	(50)	(50)	(7 627)	(6 060)	(1 157)	(895)
Exchange adjustment	-	-	(3)	-	(4)	-
Amortization / Depreciation at 31 December	(321)	(271)	(22 312)	(14 682)	(4 332)	(3 171)
Net book value at 31 December	679	729	20 628	21 837	5 224	6 220
Carrying amount of assets held under finance leases included above	-	-	10 794	15 849	5 042	5 982

Parent (DKK'000)	Licenses & Rights		Property, Plant & Equipment		Leasehold Improvements	
	2008	2007	2008	2007	2008	2007
Cost at 1 January	1 000	1 000	36 306	31 886	9 142	8 124
Additions	-	-	6 382	4 420	125	1 018
Cost at 31 December	1 000	1 000	42 688	36 306	9 267	9 142
Amortization / Depreciation at 1 January	(271)	(221)	(14 670)	(8 622)	(3 160)	(2 276)
Amortization / Depreciation	(50)	(50)	(7 548)	(6 048)	(1 065)	(884)
Amortization / Depreciation at 31 December	(321)	(271)	(22 218)	(14 670)	(4 225)	(3 160)
Net book value at 31 December	679	729	20 470	21 636	5 042	5 982
Carrying amount of assets held under finance leases included above	-	-	10 794	15 849	5 042	5 982

NOTE 9. INVESTMENT IN SUBSIDIARY

(DKK'000)	2008	2007
Cost at 1 January	2 592	-
Additions	-	2 592
Cost at 31 December	2 592	2 592

LifeCycle Pharma, Inc. was established as a wholly owned subsidiary as of 2 January 2007. This subsidiary is domiciled in New York, USA and is primarily focused on clinical activities in the US and Canada on behalf of the Parent Company.

NOTE 10. SHARE CAPITAL

On 31 December 2008 the total number of outstanding shares was 56,287,507. Each share has a nominal value of DKK 1 and one vote.

In 2008, the share capital has increased by 24,516,802 shares, of which 23,987,771 shares are related to the rights issue on 17 April 2008 and 529,031 shares are related to the exercise of vested warrants by current and former employees.

Changes in Share Capital from 2004 to 2008

The table below sets forth the changes in our issued share capital since 2004:

Date	Transaction	Share Capital	Share classes after		Share price in DKK	
			capital increase		pre bonus shares	post bonus shares
22 March 2004	Cash contribution	2 634 269 ⁽¹⁾	1 508 425	A-shares		
			1 125 844	B-shares	31,54	7,8850
11 May 2005	Cash contribution	3 908 740 ⁽²⁾	1 508 425	A-shares		
			1 125 844	B-shares		
			1 274 471	C-shares	89,20	22,30
22 August 2005	Cash contribution	3 919 018 ⁽³⁾	1 518 703	A-shares		
			1 125 844	B-shares		
			1 274 471	C-shares	31,54	7,8850
5 December 2005	Cash contribution	4 428 569 ⁽⁴⁾	1 518 703	A-shares		
			1 125 844	B-shares		
			1 274 471	C-shares		
			509 551	D-shares	145,49	36,3725
23 January 2006	Cash contribution	4 429 954 ⁽⁵⁾	1 520 088	A-shares		
			1 125 844	B-shares		
			1 274 471	C-shares		
			509 551	D-shares	31,54	7,8850
27 July 2006	Issuance of 3 bonus shares per share	17 719 816	6 080 352	A-shares		
			4 503 376	B-shares		
			5 097 884	C-shares		
			2 038 204	D-shares	N/A	N/A
27 July 2006	Reclassification of share classes	17 719 816 ⁽⁶⁾	17 719 816	shares	N/A	N/A
13 November 2006	Cash contribution	11 000 000 ⁽⁷⁾	28 719 816	shares	-	44,00
23 November 2006	Cash contribution	1 650 000 ⁽⁸⁾	30 369 816	shares	-	44,00
12 March 2007	Cash contribution	144 232 ⁽⁹⁾	30 514 048	shares	-	3,79
10 September 2007	Cash contribution	1 256 657 ⁽¹⁰⁾	31 770 705	shares	-	6,78
14 Marts 2008	Cash contribution	334 469 ⁽¹¹⁾	32 105 174	shares	-	6,76
17 April 2008	Cash contribution	23 987 771 ⁽¹²⁾	56 092 945	shares	-	17,00
16 September 2008	Cash contribution	194 562 ⁽¹³⁾	56 287 507	shares	-	9,40

Notes:

- (1) Issuance of 508,425 A-shares and 379,474 B-shares in connection with subscription by Novo A/S, Nordic Biotech K/S and H. Lundbeck A/S.
- (2) Issuance of 1,274,471 C-shares in connection with subscription by Alta Partners, Lacuna, Novo A/S, Nordic Biotech K/S, H. Lundbeck A/S, Jan Møller Mikkelsen, Michael Wolff Jensen and Samuel Zucker.
- (3) Issuance of 10,278 A-shares in connection with the subscription through the exercise of employee warrants.
- (4) Issuance of 509,551 D-shares in connection with subscription by Alta Partners, Lacuna, Novo A/S, Nordic Biotech K/S, H. Lundbeck A/S and Jan Møller Mikkelsen, Michael Wolff Jensen, Samuel Zucker and Samireh Kristensen.
- (5) Issuance of 1,385 A-shares in connection with subscription through the exercise of employee warrants.
- (6) Reclassification of share classes resolved by the general meeting conditional upon completion of the IPO.
- (7) Issuance of 11 million shares in connection with the initial public offering on 13 November 2006.
- (8) Exercise of over-allotment option, leading to the issuance of an additional 1.65 million shares.
- (9) Issuance of 144,232 shares in connection with subscription through the exercise of employee warrants.
- (10) Issuance of 1,256,657 shares in connection with subscription through the exercise of employee warrants.
- (11) Issuance of 334,469 shares in connection with subscription through the exercise of employee warrants.
- (12) Issuance of 23,987,771 shares in connection with rights issue on 17 April 2008
- (13) Issuance of 194,562 shares in connection with subscription through the exercise of employee warrants.

NOTE 11. FINANCIAL RISKS**Interest Rate Risk**

LifeCycle Pharma has an investment policy with the purpose of preserving the Company's capital without significantly increasing the risks. Accordingly, the Company seeks to limit any risks related to the interest rate and the fair value of its investments. The Company is primarily exposed to interest rate risk ascribable to its cash position and to its finance lease arrangements with respect to tangible fixed assets. Based on the cash position and the lease liability at the end of 2008, a 1% change in the interest rate will impact net financial income of approximately DKK 5.5 million. Please refer to note 13 for further analysis of the interest on the finance leases.

During 2008, the Company's excess cash has been placed in short-term deposits with a major Danish bank, thereby eliminating the fair value risk. The cash position at year end and the average interest rate is presented in the following table:

(DKK'000)	Consolidated		Parent	
	2008	2007	2008	2007
Cash and cash equivalents	600 130	331 740	597 591	325 268
Average variable interest rate	4.20 %	4.05 %	4.23 %	4.07 %

Credit Risk

The credit terms on the Company's receivables are considered to be at market conditions, and the Company has not encountered any losses as a result of credit risk during the years presented. As regards cash deposits, the Company's bank has a credit rating of Aa3 according to Moody's. The credit risk ascribable to the Company's receivables is considered low as such receivables arise from collaboration agreements with large pharmaceutical companies.

Liquidity Risk

The Company is exposed to liquidity risk arising from finance lease obligations (see note 13) and short-term payables.

Currency Exposure

LifeCycle Pharma is subject to currency risk, as the Company incurs income and expenses in a number of different currencies. Changes in exchange rates of such foreign currencies towards the Company's functional currency may affect the results and cash position.

LifeCycle Pharma does not enter into hedge arrangements to reduce the foreign currency exposure. Management assesses and monitors the Company's currency exposure on a regular basis. The Company's net position (monetary items) in foreign currencies is stated below:

	Consolidated		Parent	
	2008	2007	2008	2007
USD'000	18 238	(52)	17 402	(496)
EUR'000	(1 168)	442	(1 168)	442
SEK'000	-	(11)	-	(11)
GBP'000	(32)	-	(32)	-
CAD'000	(271)	(262)	(271)	(262)
CHF'000	(25)	(23)	(25)	(23)

The carrying amount approximately equals the fair value. As it appears from the table above, the Company's net position in foreign currencies is not considered to be significant. Accordingly, the net effect on the Company's monetary items of a change in any of the listed currencies is not considered to be significant to the Company's results. Changes in currencies will, however, also affect the future income and expenses in such foreign currencies, and may have a significant impact on the Company's operating results and cash flows. The Company is primarily exposed to such risk from currency fluctuations between USD and DKK and between EUR and DKK.

NOTE 12. WARRANTS

LifeCycle Pharma has established warrant programs for board members, members of executive management, employees, consultants and advisors. All warrants have been issued by the Company's shareholders or by the board of directors pursuant to valid authorizations in LifeCycle Pharma's articles of association.

Vesting Conditions

Warrants issued during the period 2003 to 2005 and since May 2008 vest in general at 1/36 per month from the date of grant. However, some warrants are not subject to vesting conditions, but vest in full at the time of grant.

Warrants issued during the period 2006 to April 2008 generally vest at 1/48 per month from the date of grant. However, some warrants are not subject to vesting conditions but vest in full at the time of grant.

Warrants granted from May 2008 to employees in affiliates and warrants granted prior to 1 July 2004 cease to vest upon termination of the employment relationship regardless of the reason for such termination. Warrants granted after 1 July 2004 to employees employed in the parent company cease to vest from the date of termination in the event that (i) a warrant holder resigns without this being due to the Company's breach of contract, or (ii) if LifeCycle Pharma terminates the employment relationship where the employee has given the Company good reason to do so. The warrant holder will, however, be entitled to exercise vested warrants in the first coming exercise period after termination.

Exercise of warrants issued to board members, consultants and other advisors are conditional upon the warrant holder being connected to LifeCycle Pharma on the date of exercise. However, if the warrant holder's position has been terminated without this being attributable to the warrant holder's actions or omissions, the warrant holder shall be entitled to exercise vested warrants in the pre-determined exercise periods.

Exercise Periods

Vested warrants may generally be exercised during two three-week periods following publication of LifeCycle Pharma's preliminary annual report and LifeCycle Pharma's interim report for the first six months of the relevant financial year, respectively.

Adjustments

According to the terms and conditions of the Company's warrant programs, certain customary adjustment clauses apply in the event of changes to the Company's share capital at a price which does not correspond to market price. In the rights issue announced 18 March 2008, the price per offer share was below market price of the shares prior to the announcement of the rights issue. As mentioned on page I-74 in the Offering Circular published in connection with the rights issue the number of outstanding warrants as well as the exercise price of these warrants will thus be adjusted following the completion of the Offering. The adjustments calculated in the offering circular, page I-72 was based on the assumptions that the rights issue was fully subscribed.

As the rights issue was subscribed by 99.62%, the Company below announces the actual dilution after the completion of the rights issue on 17 April 2008.

Dilution following the completion of the rights issue

Issue date	Original number of warrants issued (unadjusted)	Number of warrants outstanding (unadjusted)	Number of warrants outstanding (adjusted)	Exercise Price in DKK per Share of nominal DKK 1 (unadjusted)	Exercise Price per Share of nominal DKK 1 (adjusted)	Percentage of total number of warrant outstanding	Percentage of outstanding Shares on a fully diluted basis following the Offering
April 4, 2003	591 444	0	0	2.50	2.05	0.00 %	0.00 %
August 29, 2003 -							
December 19, 2003	431 352	107 864	131 329	7.3825	6.06	2.89 %	2.89 %
March 22, 2004 -							
June 20, 2005	1 377 028	395 920	482 049	7.8850	6.48	10.62 %	10.62 %
June 20, 2005 -							
November 18, 2005	482 000	385 445	469 295	22.30	18.32	10.34 %	10.34 %
December 12, 2005 -							
June 10, 2006	1 096 000	836 750	1 018 778	36.3725	29.87	22.44 %	22.44 %
September 7, 2006	1 120 757	1 120 757	1 364 568	44.00	36.14	30.06 %	30.06 %
December 1, 2006	96 000	90 000	109 579	44.60	36.63	2.41 %	2.41 %
December 22, 2006	32 381	32 381	39 425	53.00	43.53	0.87 %	0.87 %
March 5, 2007	160 000	114 167	139 003	55.00	45.17	3.06 %	3.06 %
May 9, 2007	248 000	210 187	255 911	56.50	46.40	5.64 %	5.64 %
August 21, 2007	237 000	222 270	270 623	52.00	42.71	5.96 %	5.96 %
November 27, 2007	58 500	27 917	33 990	41.50	34.09	0.75 %	0.75 %
Februar 28, 2008	185 000	185 000	225 245	33.00	27.10	4.96 %	4.96 %
Total	6 115 462	3 728 658	4 539 797	36.20	29.73	100 %	100 %

Warrant Activity

The following table specifies the warrant activity during 2008:

	Employees	Executive management	Board of directors	Other external	Total	Weighted average exercise price DKK
Outstanding as of						
1 January 2007	2 744 762	1 875 422	50 000	153 528	4 823 712	23.44
Granted in the year	648 500	-	55 000	-	703 500	53.40
Exercised in the year	(1 272 657)	(100 000)	-	(28 232)	(1 400 889)	6.47
Cancelled in the year	(50 181)	-	-	-	(50 181)	14.87
Outstanding as of 31 December 2007	2 070 424	1 775 422	105 000	125 296	4 076 142	34.35
Granted in the year	1 744 750	646 256	110 000	177 000	2 678 006	22.77
Exercised in the year	(450 736)	-	-	(78 296)	(529 032)	4.88
Cancelled in the year	(1 260 369)	-	-	-	(1 260 369)	18.37
Adjustments following dilution rules	761 757	16 316	22 842	10 224	811 139	-
Change between categories	1 700 422	(1 700 422)	-	-	-	-
Outstanding as of 31 December 2008	4 566 248	737 572	237 842	234 224	5 775 886	26.70
Weighted average exercise price DKK	27.75	20.56	30.24	21.79	26.70	

In total, as of 31 December 2008, a total of 5,775,886 warrants were outstanding with a weighted average exercise price of DKK 26.70. 3,395,613 of these warrants had vested as of 31 December 2008. For comparison, as of 31 December 2007, a total of 4,076,142 warrants were outstanding with a weighted average exercise price of DKK 34.35.

Warrant Compensation Costs

Warrant compensation costs are calculated at the date of grant by use of the Black-Scholes valuation model with the following assumptions: (i) a volatility of 35%, determined as the average of the stock price volatility for a group of Danish and European pharma and biotech companies over 3 years; (ii) no payment of dividends; (iii) a risk free interest rate equaling the interest rate on a 5-year government bond on the date of grant; and (iv) a life of the warrants determined as the average of the date of becoming exercisable and the date of expiry.

Warrant compensation costs are recognized in the income statement over the vesting period of the warrants granted.

During 2008, a total of DKK 16.9 million was recognized as share-based compensation compared to DKK 18.0 million in 2007.

The warrant compensation costs for 2008 were allocated to research and development costs at DKK 8.2 million and to general and administrative expenses at DKK 8.7 million.

Value of Outstanding Warrants

The aggregate value of warrants granted in 2008 has been calculated at DKK 5.2 million. The aggregate value of outstanding warrants has been calculated at DKK 9.5 million using the Black Scholes Option Pricing model on the assumptions of (i) a share price of DKK 11.10 per share, the closing price as of 31 December 2008, (ii) a volatility of 35%, (iii) no payment of dividends, and (iv) a risk free interest rate of 3.08% annually.

The following table specifies the weighted average exercise price and the weighted average life of outstanding warrants:

Year of grant	Number of granted warrants	Number of outstanding warrants	Weighted average exercise price (DKK)	Weighted average exercise period (months)
2003	1 245 297	57 660	6.06	22.82
2004	1 406 295	295 258	6.48	27.30
2005	944 812	604 518	17.49	45.10
2006	2 767 640	1 864 018	33.51	55.85
2007	856 541	537 497	44.39	65.92
2008	2 718 251	2 416 936	22.77	78.49
31 December 2008	9 938 836	5 775 886	26.70	63.35

NOTE 13. FINANCE LEASES

LifeCycle Pharma has finance lease commitments regarding tangible fixed assets. The debt for these commitments is recognized in the balance sheet.

The future minimum payments and the net present value are stated below:

(DKK'000)	Consolidated		Parent	
	2008	2007	2008	2007
Within 1 year	5 416	6 294	5 416	6 294
From 1 to 5 years	17 628	20 082	17 628	20 082
After 5 years	-	2 826	-	2 826
Total	23 044	29 202	23 044	29 202
Financing components	(2 512)	(3 695)	(2 512)	(3 695)
Total	20 532	25 507	20 532	25 507
NPV for the finance lease commitments				
Within 1 year	4 450	5 092	4 450	5 092
From 1 to 5 years	16 082	18 357	16 082	18 357
After 5 years	-	2 058	-	2 058
Total	20 532	25 507	20 532	25 507

LifeCycle Pharma has the right to purchase the assets held under finance leases on expiration of the lease agreements. A weighted average internal interest rate of 5.47% (in the interval 4.29% to 6.45%) has been applied for recognition. The carrying amount of the finance lease commitment is in all material respects equal to the fair value.

NOTE 14. OTHER COMMITMENTS

(DKK'000)	Consolidated		Parent	
	2008	2007	2008	2007
Rent commitments	40 269	48 902	33 903	39 551
Operating lease commitments regarding property, plant and equipment	666	1 312	666	1 312
Total rent and operating lease commitments	40 935	50 214	34 569	40 863
Total rent and operating lease payments fall due:				
Within 1 year	10 588	10 682	7 266	7 446
From 1 to 5 years	25 714	29 296	22 670	23 182
After 5 years	4 633	10 236	4 633	10 235
Total	40 935	50 214	34 569	40 863
Expensed rent and operating lease payments	11 055	7 197	7 733	5 828

NOTE 15. RELATED PARTIES

H. Lundbeck A/S

H. Lundbeck A/S is considered a related party as it was a major shareholder until January 27, 2009.

LifeCycle Pharma has entered into an agreement with H. Lundbeck concerning maintenance and service of facilities and for use of the facilities at H. Lundbeck A/S. For the period 1 January to 31 December 2007, LifeCycle Pharma acquired services in the amount of DKK 794 thousand and for the period 1 January to 31 December 2008, LifeCycle Pharma acquired services in the amount of DKK 638 thousand.

At 31 December 2008, LifeCycle Pharma had no outstanding balances with H. Lundbeck.

Members of the Executive Management and Board of Directors

The members of the Executive Management and Board of Directors are considered related parties following their positions in the Company.

The Executive Management and the Board of Directors have received remuneration from LifeCycle Pharma, including warrants, as described in note 4 and note 12 to the financial statements.

The Company has entered into a consultancy agreement with one of the Board members, Dr. Gérard Soula. In 2008 Dr. Gérard Soula received a total of 45,000 warrants as remuneration for the consultancy agreement. During 2008, the Company has paid consultancy fees totaling DKK 165 thousand (2007: DKK 214 thousand) to Dr. Soula and reimbursed travel expenses.

LifeCycle Pharma had no outstanding balances with Dr. Soula as at 31 December 2008. LifeCycle Pharma has in addition entered into a consultancy agreement with another member of the Board of Directors, Paul Edick. During 2008, LifeCycle Pharma has paid consultancy fees totaling DKK 281 thousand to Paul Edick and reimbursed travel expenses. No consultancy fees were paid in 2007.

LifeCycle Pharma, Inc.

In the separate financial statements of the Parent Company, LifeCycle Pharma, Inc. is considered a related party, as this company is a wholly owned subsidiary of LifeCycle Pharma A/S.

During 2008, the subsidiary has performed clinical activities on behalf of the Parent Company, which has been remunerated in accordance with the service agreement between the companies. Total services amount to DKK 36,018 thousand for the year 2008. Further, the Parent Company has funded the activities of the subsidiary, thereby generating interest income of DKK 448 thousand for the period 1 January to 31 December 2008.

At 31 December 2008, the Parent Company had a net payable to LifeCycle Pharma, Inc. totaling DKK 2,216 thousand.

Other Related Parties

Other related parties may exist as the members of LifeCycle Pharma's Board of Directors and Executive Management hold positions as Board members in other companies, and as the shareholders of LifeCycle Pharma may also be shareholders of other companies. Except for the companies listed above, LifeCycle Pharma has not identified any such parties as related parties and no transactions have been identified as related party transactions as we are not aware of such relationships.

NOTE 16. CHANGES IN WORKING CAPITAL

(DKK'000)	Consolidated		Parent	
	2008	2007	2008	2007
Trade receivables	2 067	2 865	2 173	2 865
Other receivables	3 451	(8 842)	3 669	(8 865)
Prepayments	(3 870)	(2 793)	(3 887)	(2 481)
Provisions	10 492	-	10 492	-
Trade payables	10 728	1 151	8 103	554
Deferred revenue	(1 716)	1 343	(1 716)	1 343
Other payables	6 103	9 834	4 947	7 806
Exchange gains/(losses)	(3 884)	1 436	(3 734)	1 183
Total	23 371	4 994	20 047	2 405

NOTE 17. FEES TO AUDITORS APPOINTED BY THE ANNUAL GENERAL MEETING

(DKK'000)	Consolidated		Parent	
	2008	2007	2008	2007
PricewaterhouseCoopers				
Audit	375	275	300	275
Other services	1 257	633	1 257	633
Total	1 632	908	1 557	908





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