

# Interim Report for the period 1 January to 30 June 2008

## Santaris Pharma – Interim Report for the period 1 January to 30 June 2008

The board of directors of Santaris Pharma has approved the interim report for the period 1 January to 30 June 2008.

- As per July 1<sup>st</sup>, Santaris Pharma's President and CEO since 2003 Keith McCullagh retired and his successor Søren Tulstrup took over. Søren Tulstrup was previously Vice President, Global Human Health at Merck & Co, Inc. Keith McCullagh will remain a member of the Board of Directors of the Company.
- The loss after tax realised in the period was 65,6m DKK (8,8m EUR) compared to 49,9m DKK (6,7m EUR) in 2007.
- At June 30 the capital resources totalled 233,7m DKK (31,4m EUR).

During the second quarter of 2008 Santaris Pharma continued to make satisfactory progress in each of its research and development programs within the therapeutic areas of Oncology, Metabolic Disorders and Infectious Diseases. Key milestones achieved and other events during the quarter were as follows.

### Development

- **SPC3649**  
In May 2008, Santaris Pharma initiated a Phase I **First-in-Man** volunteer study of SPC3649. The study was accomplished in the beginning of August and the data monitoring will be finalised in Q4 2008. SPC3649 is the Company's first microRNA antagonist to complete a phase I trial development. SPC3649 is a potent and specific inhibitor of microRNA-122, a liver specific regulatory RNA known to be involved in cholesterol metabolism and in hepatitis virus replication in the liver. SPC3649 is being developed as a potential new therapy for Hepatitis C Virus infection. The clinical study was the **first ever** human trial of a drug targeting a **microRNA**.
- **SPC2996**  
An open label Phase II multicentre safety and exploratory efficacy combination study with SPC2996 and rituximab in rituximab-relapsed Non-Hodgkin's Lymphoma is planned to commence later in 2008. SPC2996 also has potential in solid tumors and a Phase I/II study is being planned for this indication.
- **SPC3833**  
The ApoB Antagonist, SPC3833 has in rodent and primate studies been shown to lower LDL cholesterol and triglycerides effectively at both 2 mg/kg and 8 mg/kg without side effects when given once a week for 5 weeks. A 'First-in-Man' Phase I human volunteer study of SPC3833 is planned to commence in Q4 2008.

## Collaborations

- **GlaxoSmithKline Collaboration**

Under the terms of the collaboration with GlaxoSmithKline (GSK) on new drugs for the treatment of viral diseases, Santaris Pharma is responsible for the discovery and development of RNA antagonist drug candidates through to completion of Phase IIa ("Clinical Proof of Concept") for 4 viral targets, at which point GlaxoSmithKline will have an exclusive option to license each compound for further development and commercialisation on a worldwide basis.

During the second Quarter of 2008 Santaris Pharma continued the discovery research aimed at identifying novel and potent RNA Antagonists against the first viral target selected by GSK.

- **Enzon Collaboration**

During the second Quarter of 2008 Enzon Pharmaceuticals continued the clinical development of EZN/SPC2968 – a HIF-1 $\alpha$  Antagonist – which is currently being evaluated in two separate Phase I/II clinical trials in patients with advanced solid tumors. Further, in July 2008, Santaris received a progress milestone payment from Enzon for the drug candidate EZN/SPC3042 – a Survivin Antagonist.

Enzon has now received four cancer drug candidates (the HIF-1 $\alpha$  Antagonist EZN/SPC2968, the Survivin Antagonist EZN/SPC3042 and two novel drug candidates). The last 4 novel drug candidates will be delivered to Enzon in the 2<sup>nd</sup> half of 2008.

According to the parties' collaboration agreement, Enzon will fund and manage the further development of these 8 drug candidates and file for regulatory approvals outside Europe. Santaris Pharma has maintained all commercial rights for all 8 drug candidates in Europe.

Enzon has announced plans to spin out its biotech R&D activities, including the 8 programs relating to the collaboration agreement with Santaris Pharma, into a new public biotechnology company. Enzon expects to capitalize the new company with sufficient cash to fund approximately two to three years of operations, including appropriate milestone commitments to Santaris Pharma and other third parties. Enzon has announced that it expects to complete the transaction in the fourth quarter. Enzon has furthermore announced that its management and financial advisors have continued to review a variety of strategic alternatives including a potential sale of Enzon's specialty pharmaceutical business, and that Enzon has received confidential, non-binding, preliminary indications of interest for the purchase of all or a portion of the specialty pharmaceutical business, which are subject to various conditions. Enzon currently intends to continue evaluating the sale process.

## Pipeline Summary

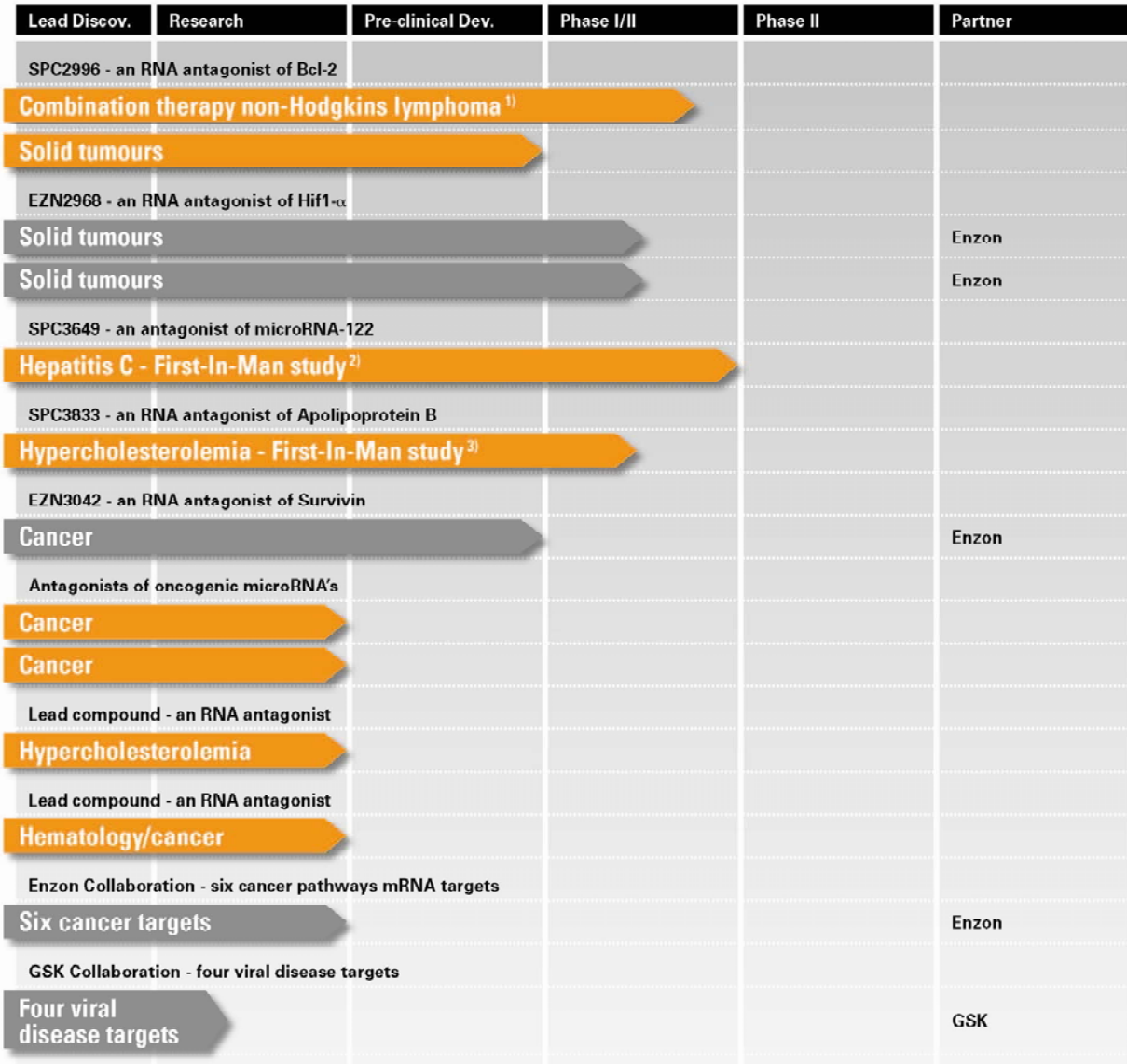
In Q2 Santaris Pharma's activities continued to show very satisfactory progress for both the drug discovery programs and the drug development pipeline. As shown in the pipeline diagram below, the Company had at the end of the quarter three drugs in clinical development and one more, the Apo-B Antagonist SPC3833, coming up:

- SPC2996, a Bcl-2 Antagonist, being developed for the treatment of Non-Hodgkin's Lymphoma
- EZN/SPC2968, a HIF-1 $\alpha$  Antagonist, being developed for the treatment of various solid tumors
- SPC3649, an LNA-antimiR against microRNA-122, being developed for the treatment of HCV infections.
- SPC3833 will reach clinical development in Q4 2008

The Survivin Antagonist EZN/SPC3042 is in preclinical development. Santaris Pharma is pursuing research in 11 new drug discovery projects including 6 anti-cancer drug discovery projects being conducted with Enzon, the first of up to 4 viral research programs in collaboration with GSK, and 4 un-partnered drug discovery programs.

Eight oncology programs are funded under partnership agreements with Enzon Pharmaceuticals and the viral disease program is funded under the partnership agreement with GlaxoSmithKline.

## Santaris Pharma Product Pipeline



Legend: Own compounds Partnered compounds

- 1) Initialized in Q3 08
- 2) Data ready in Q4 08
- 3) Initialized in Q4 08

## Research

- **Nature publication**

On March 26 2008 Nature published a study by Santaris Pharma scientists and collaborators regarding LNA-mediated microRNA silencing in African Green Monkeys. This paper was the first demonstration of microRNA silencing in non-human primates and it was an important validation of the Company's emerging clinical program to develop a new class of LNA based therapeutics capable of silencing disease associated microRNAs. The study showed a dose depending lowering of plasma cholesterol and an efficient long-lasting silencing of microRNA-122 in the primates following three intravenous doses of 3mg/kg.

- **The Advanced Technology Foundation**

In May Santaris Pharma announced that the Danish National Advanced Technology Foundation (ATF) has awarded a major program grant of DKK 45m (€6m) towards the development of a high-throughput drug discovery platform for novel RNA medicines. The project will be based on Santaris Pharma's proprietary LNA drug chemistry and the screening platform will be developed by a collaborative Research Consortium led by Santaris Pharma and the Biotech Research & Innovation Centre (BRIC) at the University of Copenhagen. Other members of the Consortium are the Nucleic Acid Centre (NAC), University of Southern Denmark, H. Lundbeck A/S, the Danish headquartered pharmaceutical company and RiboTask A/S, the Danish reagents company.

## Corporate matters

- In June, Santaris Pharma as the only biotech company outside USA was named to the annual FierceBiotech "Fierce 15" list, designated as one of the top biotech companies of 2008. The editors of FierceBiotech evaluated hundreds of privately-held firms based on company vision, revenue potential, quality of deals, strength of technology, partnerships, and competitive market position. Santaris Pharma was determined to be one of the "fiercest," proven by their creativity and innovations in the industry. An internationally recognized daily newsletter reaching more than 65,000 biotech and pharma industry professionals, FierceBiotech provides subscribers with a quick authoritative briefing on the day's top stories, with a special focus on drug discovery and clinical trials.

Santaris Pharma has revised its guidance for the year ending 31 December 2008 to a loss before tax in the region of DKK 160 – 170 million. The forecast includes various success-based milestone payments that may or may not be realized during the year.

Flemming Ørnkov  
Chairman of the Board

Søren Tulstrup  
President and CEO

## FINANCIAL REVIEW

The Financial Statements in this interim report are presented in accordance with IAS 34 as adopted by the EU and additional Danish disclosure requirements for interim reports of listed companies. The accounting policies are consistent with those applied in the annual report for 2007. The interim report is un-audited and un-reviewed.

### Income Statement (1 January – 30 June 2008)

The loss after tax was 65,6m DKK (8,8m EUR) compared to 49,9m DKK (6,7m EUR) in 2007.

Revenues from partnerships were recognised with a value of 29,8m DKK (4,0m EUR) compared to 2,0m DKK (0,3m EUR) in 2007.

The costs totalled 101,7m DKK (13,6m EUR) compared to 54,6m DKK (7,3m EUR) in 2007. The costs include the calculated non-cash costs of Warrants granted to management, employees and directors. The costs can be sub-divided into Research & Development Costs of 92,7m DKK (12,4m EUR) and Administrative costs of 9,0m DKK (1,2m EUR). The Research & Development costs mainly relate to the development programmes SPC2996, SPC3833 and SPC3649.

The Financial Income was 6,3m DKK (0,8m EUR) compared to 2,8m DKK (0,4m EUR) in 2007.

Resultatopgørelse (Income Statement)	1/4 - 30/6		1/1 - 30/6		1/1 - 30/6		Full Year 2007	
	2008	2008	2008	2008	2007	2007	2007	2007
(All amounts in '000)	DKK	EUR	DKK	EUR	DKK	EUR	DKK	EUR
Indtægter (Revenues)	23.051	3.093	29.818	4.000	1.955	262	37.828	5.077
Forsknings- og udviklingsomkostninger (Research and development costs)	-51.228	-6.873	-92.703	-12.438	-47.177	-6.332	-132.481	-17.781
Administrationsomkostninger (Administrative costs)	-4.976	-668	-9.005	-1.208	-7.452	-1.000	-16.980	-2.279
<b>Driftsresultat (Loss from operating activities)</b>	<b>-33.153</b>	<b>-4.448</b>	<b>-71.891</b>	<b>-9.645</b>	<b>-52.673</b>	<b>-7.070</b>	<b>-111.633</b>	<b>-14.983</b>
Finansielle indtægter (Financial income)	3.404	457	6.447	865	2.770	372	9.267	1.244
Finansielle omkostninger (Financial expenditures)	-51	-7	-191	-26	-18	-2	-94	-13
<b>Resultat før skat (Loss before tax)</b>	<b>-29.800</b>	<b>-3.998</b>	<b>-65.635</b>	<b>-8.806</b>	<b>-49.921</b>	<b>-6.700</b>	<b>-102.461</b>	<b>-13.752</b>
Skat af årets resultat (Tax on the results of the year)	0	0	0	0	0	0	0	0
<b>Årets resultat (Underskud) (Loss for the year (Loss))</b>	<b>-29.800</b>	<b>-3.998</b>	<b>-65.635</b>	<b>-8.806</b>	<b>-49.921</b>	<b>-6.700</b>	<b>-102.461</b>	<b>-13.752</b>

## Balance Sheet

At June 30 2008, the Company had total assets of 305,5m DKK (41,0m EUR) of which the Cash & Cash Equivalents amounts to 233,7m DKK (31,4m EUR). This cash position is, subject to the Company's receipt of certain milestone payments related to its ongoing collaboration activities, expected to be sufficient to finance the Company's operation until approximately the end of 2009.

The total Equity amounts to 264,4m DKK (35,5m EUR) and consist of the Nominal Share Capital of 85,4m DKK (11,5m EUR) and Retained Earnings of 179,0m DKK (24,0m EUR). Together with Long Term Debts (Operative Leases) of 1,8m DKK (0,3m EUR) and other short term debts of 39,2m DKK (5,3m EURO) the total Liabilities amounts to 305,5m DKK (41,0m EUR). 9,6m DKK (1,3m EUR) of the short term debts is related to accruals and deferred income related to the strategic alliances with Enzon and GSK.

### Balance (Balance Sheet)

	30/6 2008		30/6 2007		Full Year 2007	
	DKK	EUR	DKK	EUR	DKK	EUR
(All amounts in '000)						
<b>Aktiver (Assets)</b>						
Immaterielle aktiver (Intangible assets)	20.208	2.711	22.085	2.963	21.414	2.874
Materielle aktiver (Tangible assets)	13.791	1.850	6.031	809	12.301	1.651
Finansielle aktiver (Long term financial assets)	2.364	317	122	16	2.364	317
<b>Langfristede aktiver (Non-current assets)</b>	<b>36.363</b>	<b>4.879</b>	<b>28.238</b>	<b>3.789</b>	<b>36.080</b>	<b>4.843</b>
Varebeholdning (Inventory)	18.495	2.481	9.616	1.290	9.825	1.319
Tilgodehavender (Accounts receivable)	16.932	2.272	3.926	527	41.122	5.519
Likvide beholdninger (Cash and cash equivalents)	233.664	31.350	183.440	24.611	276.820	37.154
<b>Kortfristede aktiver (Current assets)</b>	<b>269.091</b>	<b>36.103</b>	<b>196.982</b>	<b>26.428</b>	<b>327.768</b>	<b>43.992</b>
<b>Aktiver i alt (Total assets)</b>	<b>305.454</b>	<b>40.981</b>	<b>225.220</b>	<b>30.217</b>	<b>363.847</b>	<b>48.835</b>
<b>Passiver (Equity and liabilities)</b>						
Selskabskapital (Share Capital)	85.387	11.456	60.014	8.052	85.387	11.460
Overført resultat m.v. (Retained earnings etc.)	179.000	24.015	155.028	20.799	241.908	32.468
<b>Egenkapital (Equity)</b>	<b>264.386</b>	<b>35.471</b>	<b>215.042</b>	<b>28.851</b>	<b>327.295</b>	<b>43.929</b>
<b>Langfristet gældsforpligtelse (Long-term debt)</b>	<b>1.823</b>	<b>245</b>	<b>1.088</b>	<b>146</b>	<b>1.468</b>	<b>197</b>
<b>Kortfristet gældsforpligtelse (Short-term debt)</b>	<b>39.244</b>	<b>5.265</b>	<b>9.090</b>	<b>1.220</b>	<b>35.084</b>	<b>4.709</b>
<b>Passiver i alt (Total equity and liabilities)</b>	<b>305.454</b>	<b>40.981</b>	<b>225.220</b>	<b>30.217</b>	<b>363.847</b>	<b>48.835</b>

## Udvikling i egenkapital (Statement of change in Equity)

1. januar - 30. juni (1 January - 30 June)

(All amounts in '000)	Selskabs-	Overført	Total	Total
	kapital (Share capital)	resultat, etc. (Retained earnings, etc)		
	DKK	DKK	DKK	EUR
<b>Egenkapital 31. december 2006 (Equity 31 December 2006)</b>	<b>40.641</b>	<b>62.871</b>	<b>103.513</b>	<b>13.893</b>
Kapitaludvidelse, netto (Net Capital Increase)	44.745	275.722	320.467	43.013
Aktiebaseret vedlæggelse (Sharebased payments)	-	5.776	5.776	775
Periodens resultat (Result for the period)	-	-102.461	-102.461	-13.752
<b>Egenkapital 31. december 2007 (Equity 31 December 2007)</b>	<b>85.387</b>	<b>241.908</b>	<b>327.295</b>	<b>43.929</b>
Kapitaludvidelse, netto (Net Capital Increase)	-	-	-	-
Aktiebaseret vedlæggelse (Sharebased payments)	-	2.783	2.783	374
Periodens resultat (Result for the period)	-	-65.635	-65.635	-8.825
Regulering af overført resultat (Adjustment to Retained earnings etc.)		-57	-57	-8
<b>Egenkapital 30. juni 2008 (Equity 30 June 2008)</b>	<b>85.387</b>	<b>179.000</b>	<b>264.386</b>	<b>35.471</b>

Weighted Conversion rate for information purposes only:

7,438

Udvikling i aktiekapital (Development in share capital)	DKK
Aktiekapital pr. 1. januar 2002 (Share capital as per 1 January)	1.296
Kapitaludvidelse 2003 (Capital increase 2003)	6.062
Kapitaludvidelse 2006 (Capital increase 2006)	33.283
Kapitaludvidelse 2007 (Capital increase 2007)	44.745
<b>Aktiekapital pr. 30. juni 2008</b>	<b>85.387</b>

## MANAGEMENT'S STATEMENT

The board of directors and executive management today considered and approved the interim report for the period 1 January to 30 June 2008. The interim report, which is unaudited and unreviewed, is presented in accordance with international accounting standards. We consider the accounting policies to be appropriate to the effect that the interim report gives a true and fair view of the Group's assets and liabilities, financial position, results of operations and cash flows. Furthermore, we consider the management report to give a true and fair statement of the developments in the Group's activities and financial affairs, results of operations and the Group's financial position as a whole as well as a description of the significant risks and uncertainties the Group faces.

Hørsholm, August 25, 2008

### Board of Executives

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Søren Tulstrup  
President & CEO

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Henrik Stage  
Vice President & CFO

### Board of Directors

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Flemming Ørnskov  
Chairman

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Linda Sjöström  
Vice Chairman

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Claus Braestrup  
Director

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Søren Carlsen  
Director

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Edwin W. de Graaf  
Director

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Keith McCullagh  
Director

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Martien van Osch  
Director

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Holger Reithinger  
Director

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Walter Wenninger  
Director

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**Santaris Pharma forward looking statements**

*This written announcement contains forward-looking statements, identified by the use of words such as "believes," "expects," "may," "will," "should", "potential," "anticipates," "plans" or "intends" and similar expressions. Such forward-looking statements involve risks, uncertainties and other factors that may cause actual results, events or developments to be materially different from the future results, events or developments indicated in this announcement. Such factors include, but are not limited to the timing, success and cost of clinical studies; the ability to obtain regulatory approval of products, market acceptance of and future demand for Santaris Pharma products and the impact of competitive products and pricing. These factors should be considered carefully and readers are cautioned not to place undue reliance on such forward-looking statements. No assurance can be given that the future results covered by the forward-looking statements will be achieved. All information in this press release is as of the date of this press release and Santaris Pharma does not intend to update this information.*