

ChronTech develops the therapeutic DNA-vaccines ChronVac-C® and ChronVac-B drugs against chronic hepatitis C virus and hepatitis B virus infections, i.e. chronic infections with jaundice causing viruses which can lead to liver cirrhosis and liver cancer. ChronTech has also developed and further develops a patent pending new type of injection needle for a more effective uptake of DNA vaccines. ChronTech also have part ownership in the wound healing therapy ChronSeal®, and in the new platform technology RAS®. The ChronTech share is admitted to trade on First North. Remium AB is Certified Adviser for ChronTech.

For more information, please visit: www.chrontech.se

## **INTERIM REPORT CHRONTECH PHARMA JANUARY-SEPTEMBER 2010**

- o Research and development costs amounted to SEK 6.2 (4.5) m
- o The loss after tax was SEK -9.6 (-8.7) m
- Earnings per share were SEK -0.13 (-0.22)
- o The company had no net sales for the period
- o The patients from the completed ChronVac-C® study are enrolled on treatment according to standard of care, i.e. interferon in combination with ribavirin. As previously reported, of those who started standard of care therapy, >70% have responded to the treatment with <50 virus copies/mL blood already after 4 weeks (so called rapid viral response). This is an unusually rapid reduction of virus in the blood of patients with HCV genotype 1, indicating a role for ChronVac-C® in combination therapy
- o Industrial development of IVIN, the new injection needle for DNA vaccination, has started through the consulting firm Team Consulting.
- o As was made public earlier the multi-center study conducted in Sweden and Norway on ChronSeal® for the treatment of chronic leg wounds is completed. Kringle Pharma, Inc. in Japan has given ChronTech Pharma a six months' extension, i.e. until the 31st of December 2010, of its option to buy back in ownership of the ChronSeal®

# Events after the end of the reporting period

- o Six out of seven (85%) of the patients from the ChronVac-C® phase I/IIa study who have started standard of care therapy were negative for HCV RNA in blood already at treatment week 24. This further supports a role for ChronVac-C® in combination therapy.
- o The Board of Directors has decided to prolong the time for subscription for shares in the ongoing rights issue with three weeks until the 19th of November 2010.

In the event of any discrepancy between the Swedish an English Interim Reports, the Swedish version will take precedence.

### **Clinical studies**

### ChronVac-C° – Therapeutic Vaccine against Hepatitis C

In the clinical study on ChronVac-C® for the treatment of chronic hepatitis C virus infection previously untreated patients chronically infected with hepatitis C virus of genotype 1 were enrolled. Each patient received four vaccinations at one-month intervals, after which they were monitored for six months. The main purpose of the study was to demonstrate the safety of the treatment. The study also tested if the treatment boosted the host immune response to hepatitis C, as well as if it had an effect on virus replication. This is the first study in the world where a DNA vaccine is being administered by *in vivo* electroporation to treat patients with chronic hepatitis C virus infection. These results showed a transient reduction of virus levels in the blood lasting for less than 2 to more than 10 weeks. This has provided a proof of concept that ChronVac-C® therapy has antiviral effect.

The original vaccination study is ended but has now gone into a second phase where all patients will be offered standard of care therapy, i.e. a 24-48 weeks' treatment with interferon and ribavirin. Preliminary data from the first patients whom after vaccination have started standard of care treatment show that hepatitis C virus had disappeared rapidly and cautiously indicate that it could be advantageous to combine ChronVac-C® with standard of care treatment. Five of the patients (71%) had a viral count <50 virus copies/ ml of blood. Also, five (71%) patients were negative for HCV at week 12 indicating a so-called complete early viral response in all. In addition, six out of seven (85%) of the patients were negative for HCV RNA in blood already at treatment week 24. This good treatment effect is unusual for patients infected with HCV genotype 1. Generally approximately 10-15% of patients infected with HCV genotype 1 respond on standard of care treatment with a viral count <50 virus copies/ml of blood after four weeks and approximately 40-50% with virus disappearance after completed treatment. Data from the follow up treatment will be reported consecutively during 2010 and 2011. In view of these promising results a better controlled study where ChronVac-C® is combined with standard of care is planned to commence early in 2011.

In parallel with the ongoing study ChronTech has also developed further ChronVac-C® and increased its activity considerably. The new versions showed a strong immune response in an animal model resembling a chronically infected patient. Thus, ChronVac-C® will be developed in two parallel clinical schemes, one as a part of a combination therapy and one as a monotherapy (new version of ChronVac-C®).

### **ChronSeal® - Treating Chronic Wounds**

ChronSeal®, the patent applied therapy for the treatment of chronic wounds in the skin, based on hepatocyte growth factor (HGF) protected in an unique patent applied antibiotic free formulation has been tested in a multi-center study in Sweden and Norway. In the study two different dose levels were evaluated versus placebo. The patients were treated for one week with ChronSeal® as an add on to regular dressing and were thereafter followed for another 11 weeks. Only those patients were included in the study whose wounds did not heal by more than 50% during a 14 day's run in period with standard dressing. The study is now completed. No drug related serious adverse events were reported. The healing was significantly better for the two groups receiving active substance as compared to placebo (mean for reduction of wound sizes was 34% and 30%, respectively as compared to -6% for placebo). This gives proof-of-concept for ChronSeal® as treatment of chronic leg wounds. At follow up no appreciable further healing were observed in the two treatment groups.

ChronSeal® has from the start been developed in collaboration with the Japanese company Kringle Pharma Inc. which produces recombinant human HGF at high biological activity. The agreeement with Kringle Pharma not only provided availability to recombinant HGF of highest quality but it has also given the project accessibility to their entire preclinical evaluation of the recombinant HGF. In addition the collaboration has resulted in an improved patent protection of the project.

The clinical development has been conducted in Kringle Pharma Europe AB collectively owned by ChronTech and Kringle Pharma Inc. In connection with the renegotiation of the original agreement during 2008 Kringle Pharma Inc. took on itself all further financing of the project. In return ChronTech's ownership in the project was reduced from 60% to 10%. ChronTech now has a right to buy back up to 40% ownership before December 31st 2010. Should ChronTech chose not to buy back further ownership in the project, ChronTech will all the same retain 10% of all revenues from the project. This means that ChronTech at present bares no economical risk in this project.

### **Other Research Projects**

### IVIN, a new injection needle for DNA vaccinations

A considerable problem when performing DNA vaccinations is that when injected with a regular injection needle the DNA is not taken up by the muscle cells and that they thereby produce too small amounts of the vaccine proteins. Advanced electronic or mechanical devices as *in vivo* electroporation or a "gene gun" are usually needed for a good effect. To solve this problem in a much simpler way the researchers at ChronTech have developed a new type of injection needle which through a concentrated direction of injection result in a considerable stronger production of the vaccine protein as compared to what is achieved with regular injection needles. Apart from the new needle commercially available syringes are only needed for an efficacious DNA vaccination to be performed.

ChronTech has applied for patent for this new injection needle. During the third quarter industrial development of IVIN has started through the consulting firm Team Consulting in England. They have specialized in the development of medical devise products, in particular in delivery systems. Among other things they have earlier on a consulting basis developed auto injectors. The first prototypes of IVIN have been delivered during the month of October and needles for clinical studies are estimated to be delivered during the second quarter of 2011. Team Consulting will also deliver an entire production.

### ChronVac-B - Therapeutic Vaccine against Hepatitis B

During 2009 the work with selecting a candidate drug progressed to the stage of a final selection of vaccine candidates. ChronTech has previously signed a letter of intent with Inovio Biomedical, USA, regarding the joint development of ChronVac-B, a therapeutic vaccine against chronic hepatitis B viral infection where ChronVac-B is administered using Inovio's *in vivo* electroporation technology.

An estimated 400 million people suffer from chronic infection, and these are exposed to an increased risk of serious liver damage and cancer. Currently approved drugs have problems with side effects or the development of antiviral resistance, implying a considerable need for improving treatment of patients with chronic hepatitis B viral infection. A therapeutic vaccine is intended to improve the infected individual's chances of gaining control of the infection through the specific activation of the immune defense. Currently, there are only preventative vaccines against hepatitis B on the market.

### RAS®

ChronTech has out licensed an exclusive right to the RAS® technology to a newly started American company, Opsonic Therapeutics, and in return has received 20% of outstanding Opsonic stock. Opsonic Therapeutics has also received a license for a so called mRNA library from the German company Cosmix, also for a 20% ownership. With the mRNA library, originally invented by last year's Nobel laureate in Medicine Dr. Jack Szostak, peptides can be found that bind to any target molecule, which allows for a rational design of new RAS® molecules.

During the period work has been performed in collaboration with Karolinska Institutet to optimize the glycopeptides which earlier have been shown to have an effect on HIV in test tube experiments.

### **Collaboration Agreements**

During 2008 ChronTech renegotiated the agreement with its Japanese partner Kringle Pharma Inc. regarding the wound healing project ChronSeal®. ChronTech has reduced its share in the project but retains a right to buy back an increased share in the project. This means that currently ChronTech carries no risk in the project. ChronTech received an upfront payment of app. SEK 3.8 m. The value of the agreement corresponds to slightly more than SEK 19 m in saved costs for the ChronSeal® project which is now taken over by Kringle Pharma, Inc. In return ChronTech's share in the project was lowered from 60% to 10%, but with a right to buy back into the project with up to 40% until the 31st of December 2010. Should ChronTech chose not to buy back sharing in the project ChronTech will still retain 10% of all revenue from the project. There are ongoing discussions with Kringle Pharma, Inc. whether Kringle Pharma Europe AB is needed for continued development of the ChronSeal® project. Hence Kringle Pharma Europe may be closed down.

In addition, ChronTech has a collaboration agreement with US Corporation Inovio regarding the joint development of ChronTech's therapeutic vaccine ChronVac-C®. This collaboration has given the company access to world-leading technology for administering DNA vaccines.

Moreover, ChronTech signed a letter of intent with Inovio Inc. regarding the joint development of ChronVac-B.

### **Patents**

ChronTech's strategy is to secure patent protection in the regions significant to the company, i.e. North America, Europe and Asia. The patent portfolio consists of 57 approved patents and 34 patents pending.

### **Employees**

The company had 3 (3) employees at the end of the period.

### **Profit/Loss**

The company had no net sales for the period. SEK 0.7 m under other operating income relates to Management fees related to the ChronSeal® project and SEK 0.1 m EU subsidies received and gain on the sale of tangible assets

Operating costs were SEK 3.0 (2.6) m for the third quarter 2010 and SEK 10.3 (10.2) m for the period January-September 2010.

The loss after financial items was SEK -2.9 (-2.3) m for the third quarter 2010 and SEK -9.6 (-8.7) m for the period January-September 2010.

Research and development costs were SEK 2.0 (1.4) m for the third quarter 2010, of which external researchers and subcontractors were SEK 2.0 (1.3) m. Research and development costs were SEK 6.2 (4.5) m for the period January-September 2010, of which external researchers and subcontractors were SEK 5.9 (4.1) m.

### **Investments**

Investments in tangible fixed assets

Net investments in equipment amounted to SEK -0.0 (0.0) m during the third quarter 2010 and SEK -0.0 (0.0) m for the period January-September 2010.

### **Financial Position**

The company's liquid assets amounted to SEK 3.8 (3.2) m as of 30 September 2010.

As of 30 September 2010, shareholders' equity was SEK 2.3 (-2.2) m. As of 30 September 2010 the company share capital amounts to SEK 2,134,518.84.

As of 30 September 2010 the number of shares was 71,150,628. Each share has a nominal value of SEK 0.03.

Long-term liabilities were SEK - (1.1) m as of 30 September 2010, this is a commitment that ChronTech undertook coincident with the acquisition of the ChronSeal® wound healing project.

Current liabilities amounted to SEK 3.2 (5.8) m as of 30 September 2010.

### **New Issues**

The company has carried out a rights issue during the fourth quarter 2009 which was fully subscribed, raising the company SEK 17.0 m before transaction costs (SEK 0.8 m) as of December 31 2009. The remaining SEK 0.8 m has been paid in January 2010.

The Board of Directors of ChronTech Pharma AB has on the 27th of September 2010, based on the authorization by the Annual General Meeeting resolved to carry out a rights issue. Three existing shares entitles to subscribe for two new shares at the subscription price SEK 0.50 per share. If the rights issue is subscribed in full it will give the company a capital injection of SEK 23.7 m before transaction costs which is estimated to SEK 0.8 m. After the end of the reporting period the time for subscription has been prolonged with three weeks until the 19th of November 2010.

### **Stock Option Plan**

The company has one staff stock option plan involving 262,500 staff stock options in one serie (D) with expiry on 30 June 2011. Series A (150,000),

B (150,000) and C (187,500) has expired without any options being exercised. As a consequence of the rights issue the exercise price have been recalculated: the exercise price for warrants series D was SEK 21.19, and has been recalculated to SEK 14.56. 10 options confers the right to subscribe for 1.99 shares.

# Authorisation to issue shares, convertibles debentures and warrants

The Annual General Meeting on March 10, 2010, authorized the Board of Directors to resolve, at one or more occasions until the next Annual General Meeting and with pre-emption right for the shareholders, to issue new shares, convertible debentures and/or warrants with consideration in cash and/or in kind or by set-off or otherwise with conditions. The authorization has partly been exercised by the Board of Directors.

### **Risks and Uncertainty Factors**

The risks are primarily associated with ChronTech's business risk and possibilities to finance development.

For ChronVac-C $^{\circ}$ , the biggest risk is assessed to be that the main product ChronVac-C $^{\circ}$ , at the dosages administered, will not activate a human immune response of sufficient strength.

ChronSeal® is subject to the risk that the positive clinical effects of ChronSeal® cannot be repeated in future clinical trials.

In addition, there can be no guarantee that the clinical trials conducted by ChronTech are able to demonstrate with sufficient clarity that potential products are sufficiently safe and effective. In such case, approval may not be forthcoming for these products, which would adversely affect ChronTech's operations, financial position and earnings.

Another risk ChronTech is exposed to lies in its competitive market, with the risk of new and better pharmaceuticals from competing companies.

For a more in-depth discussion of the company's exposure to risk, please refer to the Risk Factors section in ChronTech's Prospectus September 2010 and Risk Factors section (pages 23-24) and note 19 of ChronTech's Annual Report 2009 (only available in Swedish).

### **Events after the End of the Reporting Period**

Of 7 patients who participated in the recently finished phase I/IIa study with the treatment vaccine ChronVac-C® and who thereafter received standard of care treatment for chronic hepatitis C virus infection 6 became virus free after 24 weeks of treatment. These results support the earlier reported good results from these patients. Based on these results ChronTech Pharma will, as has been announced previously, during Q4 2010 apply to the Swedish Medical Product Agency for performing a phase IIb study where patients will receive ChronVac-C® followed by standard of care treatment and will be compared with patients who will receive standard of care alone.

The Board of Directors has decided to prolong the time for subscription for shares in the onging rights issue with three weeks until the 19th of November 2010.

### **Accounting Policies**

This Interim Report has been compiled in accordance with the Swedish Accounting Standards Board's general recommendations for voluntary interim reporting, BFNAR 2007:1. The accounting policies applied are consistent with those applied when preparing the 2009 Annual Report.

### **Forthcoming Financial Reports**

Year-end Report 2010 28 January 2011
Annual Report 2010 March 2011
Annual General Meeting March 2011

The Board of Directors and the Chief Executive Officer hereby declare that the Interim Report gives a true and fair view of the company's operations, financial position and results, and that it accurately reviews the material risks and uncertainties facing the company.

Huddinge, Sweden, 5 November 2010

Thomas Lynch Anders Vahlne William Hall Matti Sällberg
Chairman CEO and Board member Board member Board member

This Interim Report has not been subject to review by the company's auditors

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## **INCOME STATEMENT**

	3 mth.	3 mth.	9 mth.	9 mth.	12 mth.
SEK m	Jul-Sep 2010	Jul-Sep 2009	Jan-Sep 2010	Jan-Sep 2009	Jan-Dec 2009
Net sales	-	-	-	0.4	0.4
Other operating income	0.1	0.4	0.7	1.2	1.5
Total operating income	0.1	0.4	0.7	1.6	1.9
Operating costs					
Other external costs 1)	-2.4	-1.8	-8.1	-6.5	-9.1
Payroll costs	-0.6	-0.7	-2.2	-3.5	-4.1
Depreciation of tangible fixed assets	-0.0	-0.1	-0.0	-0.2	-0.2
Total operating costs	-3.0	-2.6	-10.3	-10.2	-13.4
Operating profit/loss	-2.9	-2.2	-9.6	-8.6	-11.5
Profit/loss from financial investments					
Interest income and similar profit/loss items	0.0	0.0	0.0	0.0	0.0
Interest costs and similar profit/loss items	-0.0	-0.1	-0.0	-0.1	-0.1
Total profit/loss from financial investments	-0.0	-0.1	-0.0	-0.1	-0.1
Profit/loss after financial items	-2.9	-2.3	-9.6	-8.7	-11.6
Tax on net profit/loss	-	-	-	-	-
Net profit/loss for the period	-2.9	-2.3	-9.6	-8.7	-11.6

<sup>1)</sup> R&D costs specified under key figures on p. 6  $\,$ 

## **EARNINGS PER SHARE**

	3 mth.	3 mth.	9 mth.	9 mth.	12 mth.
SEK	Jul-Sep 2010	Jul-Sep 2009	Jan-Sep 2010	Jan-Sep 2009	Jan-Dec 2009
Earnings per share	-0.04	-0.05	-0.13	-0.22	-0.26
Earnings per share after dilution	-0.04	-0.05	-0.13	-0.22	-0.26
Outstanding average number of shares	71,150,628	49,572,321	71,150,628	39,997,562	43,883,656

Earnings per share: net profit/loss divided by the average number of shares. Earnings after dilution: net profit/loss divided by the average number of shares after dilution. No outstanding options give rise to any dilution effect when calculating earnings per share. Conversion has been affected for the bonus issue element of consummated rights issues.

# **NUMBER OF OUTSTANDING SHARES**

	3 mth.	3 mth.	9 mth.	9 mth.	12 mth.
	Jul-Sep 2010	Jul-Sep 2009	Jan-Sep 2010	Jan-Sep 2009	Jan-Dec 2009
No. of outstanding shares, opening balance	71,150,628	23,575,314	71,150,628	19,950,412	19,950,412
Rights issue	-	-	-	3,624,902	3,624,902
Private placement	-	12,000,000	-	12,000,000	12,000,000
Rights issue 1)	-	-	-	-	35,575,314
Outstanding number of shares, closing balance	71,150,628	35,575,314	71,150,628	35,575,314	71,150,628

A statement of changes in equity is presented on page 20 in ChronTech's Annual Report 2009, and in ChronTech's Prospectus September 2010, page 39 (only available in Swedish)

<sup>1)</sup> of which 34,064,000 paid-up but not registered at the Swedish Companies Registrations Office on December 31 2009, and 1,511,314 subscribed (paid 8 January 2010). Registration took place 14 January 2010.

## **WARRANTS**

	Number	Of which the company owns	Of which the staff	Exercise Price, SEK	Subscription Period
Series D	350,000	87,500	262,500	14.56	1-30 June 2011

Series A has expired on 30 June 2008 without any options being exercised.

Series B has expired on 30 June 2009 without any options being exercised. Series C has expired on 30 June 2010 without any options being exercised.

Series D - ten options confers the right to subscribe for 1.99 shares. As a consequence of the rights issues and the reverse stock split the terms have been recalculated. At the end of the period, there were 157,500 staff stock options, because 105,000 had expired due to terminated employment, and 150,000 series A has expired on 30 June 2008, 150,000 series B has expired on 30 June 2009 and 187,500 series C has expired on 30 June 2010 without being exercised.
TO2 - has expired on 30 September 2009 without any options being exercised.

## **BALANCE SHEET**

SEK m	30 Sep 2010	30 Sep 2009	31 Dec 2009
Subscribed not yet paid capital	-	-	0.8
Tangible fixed assets	0.0	0.2	0.2
Financial fixed assets	0.1	0.1	0.1
Current receivables	1.6	1.1	1.3
Cash & bank balances <sup>1)</sup>	3.8	3.2	14.4
Total assets	5.5	4.7	16.8
Shareholder's equity (see note below)	2.3	-2.2	11.9
Long-term liabilities	-	1.1	0.8
Current liabilities	3.2	5.8	4.2
Total liabilities and shareholder's equity	5.5	4.7	16.8

<sup>1)</sup> of which SEK 0.2 m is blocked funds for rent

# STATEMENT OF CHANGES TO SHAREHOLDERS' EQUITY

SEK m	30 Sep 2010	30 Sep 2009	31 Dec 2009
Shareholder's equity, opening balance	11.9	-1.1	-1.1
Rights issue, 9,786,224 shares 1)	-	1.7	1.7
Private placement, 12,000,000 shares <sup>2)</sup>	-	5.9	5.9
Rights issue, 35,575,314 shares <sup>3)</sup>	-	-	17.0
Options	0.0	0.0	0.0
Net profit/loss	-9.6	-8,7	-11.6
Shareholders' equity, closing balance	2.3	-2.2	11.9

<sup>1)</sup> Of which 6,161,322 shares were issued 2008, and 3,624,902 were issued 2009. Includes issue costs of SEK 0.5 m.

# SHAREHOLDERS' EQUITY PER SHARE

SEK	30 Sep 2010	30 Sep 2009	31 Dec 2009
Shareholders' equity per share	0.03	-0.04	0.17

Shareholders' equity per share: shareholders' equity divided by the number of outstanding shares at the end of the period.

Conversion has been affected for the bonus issue element of consummated rights issues, including the right issue registered in January 2010.

<sup>2)</sup> Includes issue costs of SEK 0.1 m

<sup>3)</sup> Includes issue costs of SEK 0.8 m

# **CASH FLOW STATEMENTS**

	9 mth.	9 mth.	12 mth.
SEK m	Jan-Sep 2010	Jan-Sep 2009	Jan-Dec 2009
Cash flow from operating activities			
Net profit/loss	-9.6	-8.7	-11.6
Depreciation	0.0	0.2	0.2
Profit/Losses on sale/disposal of tangible fixed assets	0.1	-	-
Change in long-term liabilities <sup>1)</sup>	-0.8	-0.7	-1.1
Cash flow from operating activities before change in working capital	-10.2	-9.3	-12.5
Cash flow from change in working capital			
Decrease/increase (-) in receivables	-0.2	2.1	1.9
Decrease(-)/increase in current liabilities	-1.0	-0.5	-2.1
Net cash flow used in operating activities	-11.4	-7.7	-12.7
Net cash flow used in investment activities	0.0	-	-
Cash flow from financing activities			
New issue/capital contribution	0.8	7.6	23.8
Cash flow from financing activities	0.8	7.6	23.8
Cash flow for the period	-10.6	-0.1	11.1
Liquid assets, at start of period	14.4	3.3	3.3
Liquid assets, at end of period	3.8	3.2	14.4

<sup>1)</sup> A commitment that Tripep undertook coincident with the acquisition of the ChronSeal wound healing project

# **KEY FIGURES**

	3 mth.	3 mth.	9 mth.	9 mth.	12 mth.
	Jul-Sep 2010	Jul-Sep 2009	Jan-Sep 2010	Jan-Sep 2009	Jan-Dec 2009
Return on capital employed, %	neg	neg	neg	neg	neg
Return on equity, %	neg	neg	neg	neg	neg
Equity/assets ratio, %	41.8	neg	41.8	neg	70.8
Debt/equity ratio	0.0	neg	0.0	neg	0.07
Liquid assets, SEK m	3.8	3.2	3.8	3.2	14.4
Share risk-bearing capital, %	41.8	neg	41.8	neg	70.8
Cash flow for the period, SEK m	-4.3	2.8	-10.6	-0.1	11.1
Net investment in tangible fixed assets, SEK m	-0.0	0.0	-0.0	0.0	0.0
Internal research and development (written off), SEK m	0.0	0.1	0.3	0.4	0.5
External research and development (written off), SEK m	2.0	1.3	5.9	4.1	5.9
Salaries, benefits and social sequrity costs, SEK m	0.6	0.7	2.2	3.5	4.1
Average No. of employees	2	3	2	3	3