

ChronTech develops the therapeutic DNA-vaccines ChronVac-C<sup>®</sup> 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<sup>®</sup>, and in the new platform technology RAS<sup>®</sup>. 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-MARCH 2011**

- o Research and development costs amounted to SEK 3.8 (1.8) m
- o The loss after tax was SEK -5.0 (-2.7) m
- o Earnings per share were SEK -0.06 (-0.04)
- The company had no net sales for the period
- Of six patients with genotype 1 chronic hepatitis C virus infection treated with standard of care treatment following participation in a clinical trial with four ChronVac-C<sup>®</sup> vaccinations, five have been cured, i.e. are virus free six months after completed treatment. These are unusually good treatment results for patients carrying the hard-to-treat variant of hepatitis C-virus called genotype 1.
- ChronTech has received permission for starting a controlled phase IIb clinical study of ChronVac-C<sup>®</sup> in combination with standard-of-care
- ChronTech has entered as a partner in a collaborative project to improve on HCV vaccines with
  Karolinska Institutet, University of Gothenburg, and Vecura, which is funded by Vinnova by up to SEK
  4.5 m. The project started in November 2010 and lasts for three years.

## Events after the end of the reporting period

 ChronTech Pharma AB has signed a collaboration agreement with Transgene S.A. (Euronext Paris: FR0005175080) and Inovio Pharmaceuticals, Inc. (NYSE Amex: INO) to evaluate a novel therapeutic vaccination strategy against genotype 1 hepatitis C virus (HCV) in a phase I clinical study.

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

### **OPERATIONS**

#### **Clinical studies**

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

In the clinical study on ChronVac-C<sup>®</sup> 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. Patients were shown to have had 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<sup>®</sup> therapy has antiviral effect.

### ChronVac-C° in combination with standard-of-care therapy

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. Data from those patients who after the vaccination 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, which means a good prognosis for total recovery. At week 24, six out of seven (85%) of the patients were negative for HCV RNA in blood. 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. Furthermore, of those six patients with genotype 1 chronic hepatitis C virus infection treated with standard of care treatment following the four ChronVac-C® vaccinations, five have been cured, i.e. are virus free six months after completed treatment.

Based on these results, ChronTech filed an application to the Swedish Medical Products Agency to conduct a follow up phase IIb clinical study where vaccination and standard-of-care treatment are given according to a organized scheme. In March all permits for this study were received.

In the study a group of patients with chronic infection of hepatitis C-virus genotype 1 will receive two vaccinations with ChronVac-C<sup>®</sup> administered with Inovios Medpulser DDS and thereafter will receive standard-of-care treatment of ribavirin and Interferon. A control group will receive standard-of-care alone without prior vaccinations with ChronVac-C<sup>®</sup>.

# ChronVac-C<sup>®</sup> in combination with Transgene's vaccine TG-4040 against Hepatitis C virus

ChronTech Pharma AB has signed a collaboration agreement with Transgene S.A. (Euronext Paris: FR0005175080), one of Europe's largest biotech companies who's largest shareholder is bioMériuex, and Inovio Pharmaceuticals, Inc. (NYSE Amex: INO) to evaluate a novel therapeutic vaccination strategy against genotype 1 hepatitis C virus (HCV) in a phase I clinical study. ChronTech/Inovio and Transgene have both developed different kinds of therapeutic vaccines against chronic infection with hepatitis C which have been tested in clinical studies with good results. It is common to follow an initial "prime" (first dose) vaccination with a "boost" (further doses) of the same vaccine to achieve the required level and durability of immune protection. In this collaboration, the strategy is to use different prime and boost vaccines with the goal of obtaining a clinical effect by inducing different immune responses. A Phase I study, to be started during Q3 of this year, will use ChronTech's ChronVac-C® plasmid DNA vaccine delivered by in vivo electroporation using Inovio's Medpulser® DDS as the "prime" and Transgene's therapeutic vaccine TG4040, a modified vaccinia Ankara (MVA), as the "boost". ChronTech och Transgene have together in substantial pre-clinical studies been able to show that the effect will be better with this "prime/boost" than when just one of the vaccines is being used. In the planned phase I clinical study, each company will contribute their respective products and equally share study related costs. The study will enroll 12 treatment-naive patients with chronic hepatitis C at a site in Germany.

### ChronVac-C° as a monotherapy

In parallel with the ongoing study ChronTech has also developed further ChronVac-C<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup>). This is a part of collaborative project to improve on HCV vaccines with Karolinska Institutet, University of Gothenburg, and Vecura, which is funded by Vinnova by up to SEK 4.5 m. The project started in November 2010 and lasts for three years. All IP related to ChronVac-C<sup>®</sup> belongs to ChronTech.

### 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 line.

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

During 2010 the work with selecting a candidate drug progressed to the stage of a final selection of vaccine candidates.

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.

#### ChronSeal® - Treating Chronic Wounds

ChronSeal<sup>®</sup>, the patent applied therapy for the treatment of chronic wounds in the skin, is based on hepatocyte growth factor (HGF) has been tested in a multi-center study in Sweden and Norway. The clinical development has been conducted in Kringle Pharma Europe AB collectively owned by ChronTech and Kringle Pharma Inc. As the study now is completed Kringle Pharma Europe has started to be liquidated. 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 had a right to buy back up to 40% ownership before December 31st 2010. ChronTech has chosen not to buy back further ownership in the project at present, 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. However, Kringle Pharma, Inc. has indicated that it is open for negotiations on continued collaboration with ChronTech and the terms for increasing ChronTech's ownership in the project.

#### **RAS**<sup>®</sup>

ChronTech has out licensed an exclusive right to the RAS<sup>®</sup> 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 2009 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<sup>®</sup> molecules.

Continued work is being 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<sup>®</sup>. In this agreement 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. ChronTech has chosen not to buy back sharing in the project but ChronTech will still retain 10% of all revenue from the project. As there is no longer a need for Kringle Pharma Europe AB in the further development of ChronSeal<sup>®</sup>, the company is now being closed down.

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

#### 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 59 approved patents and 27 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 0.0 m under other operating income relates to funding from Vinnova.

Operating costs were SEK 5.0 (3.0) m for the first quarter 2011.

The loss after financial items was SEK -5.0 (-2.7) m for the first quarter 2011. Research and development costs were SEK 3.8 (1.8) m for the first quarter 2011, of which external researchers and subcontractors were SEK 3.8 (1.6) m.

#### Investments

Investments in tangible fixed assets

Net investments in equipment amounted to SEK 0.0 (0.0) m during the first quarter 2011.

#### Financial fixed assets

The company's holding in associated company Kringle Pharma Europe AB has been written down in full since Kringle Pharma Europe AB is closing down.

### **Financial Position**

The company's liquid assets amounted to SEK 0.9 (11.9) m as of 31 March 2011.

As of 31 March 2011, shareholders' equity was SEK -2.6 (9.2) m.

As of 31 March 2010 the company share capital amounts to SEK 2,466,597.90.

As of 31 March 2011 the number of shares was 82,219,930. Each share has a nominal value of SEK 0.03. On March 17 the shares in ChronTech was placed on the observation segment due to uncertainty regarding the Company's financial situation.

Long-term liabilities were SEK - (0.6) m as of 31 March 2011, this is a commitment that ChronTech undertook coincident with the acquisition of the ChronSeal® wound healing project.

Current liabilities amounted to SEK 4.3 (3.7) m as of 31 March 2011.

The short-term financing has been solved through a bridge loan. The Board intends to finance the companys operations through additional new issues, including private placements towards new investors. The company has a negative equity as of March 31, 2011. The Board has made a judgement that there are surplus values in the company's projects and therefore considers it to be under no obligation to prepare a balance sheet for liquidation purposes.

#### **New Issues**

The Board of Directors of ChronTech Pharma AB has on the 27th of September 2010, based on the authorization by the AGM, resolved to carry out a rights issue with a maximum of 47,433,752 shares. In the rights issue 11,069,302 shares were subscribed for and raised approx. SEK 5.5 m before transaction costs. 21.5 %, 10,201,910 shares, have been subscribed for by using first rights. 1.8 %, 867,392 shares, have been subscribed for without rights.

#### **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 and exercise price SEK 14.56. Series A (150,000), B (150,000) and C (187,500) has expired without any options being exercised. 10 options confers the right to subscribe for 1.99 shares. The Board resolved not to recalculate the terms for outstanding warrants as a consequence of the newly carried out rights issue.

### **Annual General Meeting (AGM)**

The Annual General Meeting on March 30, 2011 resolved:

Election of Board of Directors and Chairman of the Board and compensation to the Board

Thomas Lynch, Anders Vahlne, Matti Sällberg and William Hall were re-elected as members of the Board. Thomas Lynch was re-elected as Chairman of the Board. The Meeting resolved that directors' fees of in total SEK 200,000 shall be payable.

Authorisation to issue new shares, warrants and convertible debentures The Meeting resolved to authorize the Board to resolve, at one or more occasions prior to the next Annual General Meeting, to issue new shares, warrants and/or convertible debentures with or without preferential rights for the shareholders. Payment shall be made in cash, by set-off or through payment in kind. The Meeting resolved a limit of USD 4 million with respect to issues without preference rights for existing shareholders. The existing shareholders shall within six months be offered to subscribe for new shares (or warrants/convertible debentures) at the same terms but limited to 50 per cent of the number of shares (or warrants/convertible debentures) that are issued without preferential rights.

#### Amendments of the Articles of Association

The Meetings resolved to amend the Articles of Association to include new provisions regarding notice of shareholders' meetings. Notice of shareholders' meetings shall be published in the Official Swedish Gazette (Post och Inrikes Tidningar) as well as on the Company's website. At the time of the notice, an announcement with information that the notice has been issued shall be published in Svenska Dagbladet. Notice of the Annual General Meeting and of any Extraordinary General Meeting at which a proposal for amendment of the Articles of Association will be considered shall be issued no more than six and no less than four weeks prior to the Meeting. Notice of any other Extraordinary General Meeting at more than six weeks and no less than three weeks prior to the Meeting.

#### **Risks and Uncertainty Factors**

The risks are primarily associated with ChronTech's business risk and possibilities to finance development. For ChronVac-C®, the biggest risk is assessed to be that the main product ChronVac-C®, 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 section (pages 23-24) and note 19 of ChronTech's Annual Report 2010 and ChronTech's Prospectus September 2010 (only available in Swedish).

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

ChronTech Pharma, Transgene, and Inovio Pharmaceuticals to Collaborate on Prime-Boost Therapeutic Vaccination Against Hepatitis C. A new issue is necessary for funding during 2011.

### **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 2010 Annual Report.

#### **Forthcoming Financial Reports**

26 August 2011
28 October 2011
27 January 2012

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, 29 April 2011			
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.	12 mth.
SEK m	Jan-Mar 2011	Jan-Mar 2010	Jan-Dec 2010
Net sales		-	-
Other operating income	0.0	0.3	0.7
Total operating income	0.0	0.3	0.7
Operating costs			
Other external costs <sup>1)</sup>	-4.4	-2.4	-12.4
Payroll costs	-0.6	-0.6	-2.9
Depreciation of tangible fixed assets	-0.0	-0.0	-0.0
Total operating costs	-5.0	-3.0	-15.3
Operating profit/loss	-5.0	-2.7	-14.6
Profit/loss from financial investments			
Interest income and similar profit/loss items	0.0	0.0	0.0
Write-down of financial fixed assets	-0.0	-	-
Interest costs and similar profit/loss items	-0.0	-0.0	-0.0
Total profit/loss from financial investments	-0.0	-0.0	-0.0
Profit/loss after financial items	-5.0	-2.7	-14.6
Tax on net profit/loss	-	-	-
Net profit/loss for the period	-5.0	-2.7	-14.6

1) R&D costs specified under key figures on p. 6

# **EARNINGS PER SHARE**

	3 mth.	3 mth.	12 mth.
SEK	Jan-Mar 2011	Jan-Mar 2010	Jan-Dec 2010
Earnings per share	-0.06	-0.04	-0.20
Earnings per share after dilution	-0.06	-0.04	-0.20
Outstanding average number of shares	82,219,930	72,032,240	72,419,785

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.	12 mth.
	Jan-Mar 2011	Jan-Mar 2010	Jan-Dec 2010
No. of outstanding shares, opening balance	82,219,930	71,150,628	71,150,628
Rights issue 1)	-	-	11,069,302
Outstanding number of shares, closing balance	82,219,930	71,150,628	82,219,930

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

1) Paid-up but not registered at the Swedish Companies Registration Office on 31 December 2010. Registration took place 11 January 2011.

# **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 - the 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	31 Mar 2011	31 Mar 2010	31 Dec 2010
Tangible fixed assets	0.1	0.1	0.1
Financial fixed assets	0.1	0.1	0.1
Current receivables	0.6	1.4	0.9
Cash & bank balances	0.9	11.9	5.7
Total assets	1.7	13.5	6.8
Shareholder's equity (see note below) Long-term liabilities	-2.6	9.2 0.6	2.4
Current liabilities	4.3	3.7	4.4
Total liabilities and shareholder's equity	1.7	13.5	6.8

1) of which SEK 0.2 m is blocked funds for rent 2010-03-31

# **STATEMENT OF CHANGES TO SHAREHOLDERS' EQUITY**

SEK m	31 Mar 2011	31 Mar 2010	31 Dec 2010
Shareholder's equity, opening balance	2.4	11.9	11.9
Rights issue, 11,069,302 shares <sup>1)</sup>	-	-	5.0
Options	0.0	0.0	0.0
Net profit/loss	-5.0	-2.7	-14.6
Shareholders' equity, closing balance	-2.6	9.2	2.4

1) Includes issue costs of SEK 0.5 m

# SHAREHOLDERS' EQUITY PER SHARE

SEK	31 Mar 2011	31 Mar 2010	31 Dec 2010
Shareholders' equity per share	-0.03	0.13	0.03

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 2011.

# **CASH FLOW STATEMENTS**

	3 mth.	3 mth.	12 mth.
SEK m	Jan-Mar 2011	Jan-Mar 2010	Jan-Dec 2010
Cash flow from operating activities			
Net profit/loss	-5.0	-2.7	-14.6
Depreciation and write-downs	0.0	0.0	0.0
Profit/Losses on sale/disposal of tangible fixed assets	-	-	0.1
Change in long-term liabilities <sup>1)</sup>	-	-0.2	-0.8
Cash flow from operating activities before change in working capital	-5.0	-2.8	-15.3
Cash flow from change in working capital			
Decrease/increase (-) in receivables	0.3	-0.0	0.5
Decrease(-)/increase in current liabilities	-0.1	-0.5	0.2
Net cash flow used in operating activities	-4.8	-3.3	-14.6
Net cash flow used in investment activities		-0.0	0.0
Cash flow from financing activities			
New issue/capital contribution	-0.0	0.8	5.8
Cash flow from financing activities	-0.0	0.8	5.8
Cash flow for the period	-4.8	-2.5	-8.7
Liquid assets, at start of period	5.7	14.4	14.4
Liquid assets, at end of period	0.9	11.9	5.7

1) A commitment that ChronTech undertook coincident with the acquisition of the ChronSeal wound healing project

# **KEY FIGURES**

	3 mth.	3 mth.	12 mth.
	Jan-Mar 2011	Jan-Mar 2010	Jan-Dec 2010
Return on capital employed, %	neg	neg	neg
Return on equity, %	neg	neg	neg
Equity/assets ratio, %	neg	68.1	35.3
Debt/equity ratio	neg	0.07	0.0
Liquid assets, SEK m	0.9	11.9	5.7
Share risk-bearing capital, %	neg	68.1	35.3
Cash flow for the period, SEK m	-4.8	-2.5	-8.7
Net investment in tangible fixed assets, SEK m	0.0	0.0	0.0
Internal research and development (written off), SEK m	0.0	0.2	0.3
External research and development (written off), SEK m	3.8	1.6	9.3
Salaries, benefits and social sequrity costs, SEK m	0.6	0.6	2.9
Average No. of employees	2	2	2

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