

# INTERIM REPORT JANUARY-JUNE 2009 TRIPEP AB (PUBL)

- Research and development costs amounted to SEK 3.1 (11.8) m
- The loss after tax was SEK -6.4 (-18.1) m
- Earnings per share were SEK -0.28 (-1.92)
- Net sales SEK 0.4 (-) m
- All patients in the ChronVac-C® study have now received all vaccinations. A total of 12 patients has now been treated with ChronVac-C® and no severe adverse events have been recorded. Virological and immunological analyses are ongoing and results are scheduled to be made public during the 4th quarter of 2009
- Data from the ChronVac-C<sup>®</sup> study was presented as oral presentations at the annual meeting of the European Association for the Study of the Liver in Copenhagen, Denmark, April 23rd, and at the annual meeting of the American Society for Gene Therapy in San Diego May 28th
- The multi-center study on ChronSeal® is ongoing in Sweden and Norway. An interim analysis of the treatment effect will be performed no later than October 31st and published shortly thereafter

### Events after the end of the reporting period

- The company has carried out two private placements after the end of the reporting period raising SEK 6 m through the placements
- Tripep has out licensed the RAS® technology to Opsonic Therapeutics

Tripep develops drugs against chronic disease based on proprietary and other parties' patented and patent pending technologies. The company's main focuses are: the wound healing therapy ChronSeal®, the therapeutic vaccine against Hepatitis C named ChronVac-C® plus the RAS® technology platform. The Tripep share is admitted to trade on First North. Remium AB is Certified Adviser for Tripep AB. For more information, please visit: www.tripep.se

#### **OPERATIONS**

#### Clinical studies

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

After an interim analysis performed in November 2008 the last three patients have now completed their treatment with the highest dose of ChronVac-C\*. Tripep has earlier reported on the first nine patients that had completed therapy in ongoing open phase I/II trial. In the low dose group a short lived T-cell activation was observed in 2 out of 3 patients which did not reduce the viral levels in the blood. In the high- and intermediate dose groups, in 2 out of 3 patients in each group, a significant lowering if viral levels, often coinciding with a T-cell activation was observed. These reductions in viral load lasted for 2 to more than 10 weeks. This is a proof-of-concept that ChronVac-C\* therapy has a clear antiviral effect. No unexpected or serious side effects have been noted. These results were presented as oral presentations at the annual meeting of the European Association for the Study of the Liver in Copenhagen, Denmark, April 23rd, and at the annual meeting of the American Society for Gene Therapy in San Diego May 28.

This study involved previously untreated patients with chronic hepatitis C virus infection with low levels of genotype 1 virus. Each patient received four vaccinations at one-month intervals, after which they were monitored for six months. The main purpose of the study is 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 used to treat patients with chronic Hepatitis C virus infection. It is also the first time a DNA vaccine against an infectious agent is being administered by *in vivo* electroporation in humans. Virological and immunological analyses are ongoing and results are scheduled to be made public during the 4th quarter of 2009.

#### 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 is now being tested in a multicenter study in Sweden and Norway. In the study two different dose levels will be evaluated versus placebo. 75 patients will be enrolled. The patients are treated for one week with ChronSeal\* as an add on to regular dressing and are thereafter followed for another 11 weeks to monitor if a sustained healing of the wounds has been achieved. Since HGF's mechanism is to start the healing process, longer treatment periods are not expected to give additional healing effects. Only those patients will be included in the study whose wounds do not heal by more than 50% during a 14 day's run in period with standard dressing. The main purpose of the study, which now is ongoing in both Norway and Sweden, is to demonstrate the safety of ChronSeal\* but also to evaluate the clinical efficacy. An interim analysis of the treatment effect will be performed no later than October 31st and published shortly thereafter.

#### Other Research Projects

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

Tripep signed a letter of intent with Inovio Inc. of San Diego regarding the joint development of ChronVac-B, a therapeutic vaccine against chronic hepatitis B viral infection. During 2008 the work with selecting a candidate drug progressed. The new partnership between Tripep and Inovio is based on the combination of Tripep's ChronVac-B technology, which 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 defence. Currently, there are only preventative vaccines against hepatitis B on the market.

#### RAS

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. Trippe has out licensed the RAS\* technology to a newly started American company, Opsonic Therapeutics, and in return has received 20% of outstanding Opsonic stock. Opsinic 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 peptides can be found that bind to any target molecule, which allows for a rational design of new RAS\* molecules.

#### **Collaboration Agreements**

Tripep has renegotiated the agreement with its Japanese partner Kringle Pharma Inc. regarding the wound healing project ChronSeal\*. According to the new agreement Kringle Pharma takes on the economic responsibility, including Tripep's internal costs, for the upcoming clinical study. Tripep reduces its share in the project but retains a right to buy back an increased share in the project. This means that currently Tripep carries no risk in the project. Tripep received an upfront payment of ca 3.8 MSEK. The value of the agreement corresponds to slightly more SEK 19 m in saved costs for the ChronSeal\* project which is now taken over by Kringle Pharma, Inc. In return Tripep'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 30th of June 2010. Should Tripep chose not to buy back sharing in the project Tripep will still retain 10% of all revenue from the project.

Through Tripep's partner Kringle Pharma an option agreement has been signed with the Japanese specialty pharma company Maruho regarding ChronSeal\*, Tripep's and Kringle Pharma's jointly owned product for the treatment of chronic leg wounds. The option agreement gives Maruho the first right to evaluate the results from the ongoing phase I/II study and to negotiate the rights for sale in the Japanese market.

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

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

#### **Patents**

Tripep'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 61 approved patents and 31 patents pending.

#### Scientific publications

ChronVac-C

T Ahlén G, Weiland M, Derk E, Jiao J, Rahbin N, Aleman S, Peterson DL, Pokrovskaja K, Grandér D, Frelin L, and Sällberg M.. Cleavage of the IPS-1/Cardif/MAVS/VISA does not inhibit T cell-mediated elimination of hepatitis C virus non-structural 3/4A-expressing hepatocytes. Gut 2009 Apr;58(4):560-9.

Brenndörfer ED, Karthe J, Frelin L, Cebula P, Erhardt A, Schulte am Esch J, Hengel H, Bartenschlager R, Sällberg M, Häussinger D and Bode JG. 2009. The non-structural 3/4A protease of HCV activates EGF-induced signal-transduction by cleavage of the T-cell protein tyrosine phosphatase. Hepatology 2009 Jun; 49(6):1810-20.

#### ChronVac-B

Lee BO, Tucker A, Frelin L, Sallberg M, Jones J, Peters C, Hughes J, Whitacre D, Darsow B, Peterson DL, Milich DR. Interaction of the hepatitis B core antigen and the innate immune system. J Immunol. 2009 Jun 1;182(11):6670-81.

#### **Employees**

The company had 4 (7) employees at the end of the period. This number includes CEO Jan Nilsson who's employment ends on September 30th 2009.

CEO

In a mutual understanding with the Tripep Board CEO Jan Nilsson left the Company on the 31st of March. Head of Research Anders Vahlne became the new CEO on April 1st 2009.

#### Profit/Loss

During the second quarter the company has received a license fee from the option agreement with Maruho amounting to SEK 0.4 m. SEK 0.8 m under other operating income relates to Management fees related to the ChronSeal® project.

Operating costs were SEK 3.6 (8.3) m for the second quarter 2009 and SEK 7.6 (18.2) m for the period January-June 2009.

The loss after financial items was SEK -2.9 (-8.2) m for the second quarter 2009 and SEK -6.4 (-18.1) m for the period January-June 2009.

Research and development costs were SEK 2.0 (5.2) m for the second quarter 2009, of which external researchers and subcontractors were SEK 1.8 (4.9) m. Research and development costs were SEK 3.1 (11.8) m for the period January-June 2009, of which external researchers and subcontractors were SEK 2.8 (11.2) m.

#### Investments

Net investments in equipment amounted to SEK 0.0 (0.0) m during the second quarter 2009 and SEK 0.0 (0.0) m for the period January-June 2009.

#### Financial Position

The company's liquid assets amounted to SEK 0.4 (2.9) m as of 30 June 2009. In addition to the private placements amounting to SEK 6 m carried out in July-August, the company is planning a rights issue during the second half-year 2009.

As of 30 June 2009, shareholders' equity was SEK -5.8 (-4.8) m. As of 31 December 2008 the Board of Directors has prepared a balance sheet for liquidation purposes showing that the equity is intact. The balance sheet for liquidation purposes has been reviewed by the company auditor.

As of 30 June 2009 the company share capital amounts to SEK 707,259.42, after a reduction of share capital to cover deficits, as resolved by the AGM, has been carried out.

As of 30 June 2009 the number of shares was 23,575,314. Each share has a nominal value of SEK 0.03.

Long-term liabilities were SEK 1.4 (2.5) m as of 30 June 2009, this is a commitment that Tripep undertook coincident with the acquisition of the ChronSeal\* wound healing project.

Current liabilities amounted to SEK 6.3 (7.7) m as of 30 June 2009.

#### Warrants

There are 32,418,905 TO2 warrants. Twenty TO2 confers the right to subscribe for 1.2 shares with an exercise price of SEK 8.35 per share during the period 1 April 2008 to 30 September 2009. TO2 warrants are traded on First North. Upon full exercise of TO2 the company would raise app. SEK 16.2 m and another 1,945,134 shares will be issued.

#### Stock Option Plan

The company has one staff stock option plan involving 450,000 staff stock options in two series (C-D) with expiry on 30 June 2010 and 2011. Series A (150,000) and B (150,000) has expired without any options being exercised. As a consequence of the reverse stock split 1:10 and the rights issue in November 2008 the exercise price for warrants C-D have been recalculated: exercise price for series C was SEK 2.29 and has been recalculated to SEK 19.11, exercise price for series D was SEK 2.54 and has been recalculated to SEK 21.19. After the reverse stock split 10 options (series C-D) confers the right to subscribe for 1.37 shares.

#### Risks and Uncertainty Factors

The financial risks are primarily associated with Tripep'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 Tripep 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 Tripep's operations, financial position and earnings.

Another risk Tripep 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 (pages 22-23) and note 19 of Tripep's Annual Report 2008 (only available in Swedish).

#### Annual General Meeting (AGM) on 1 April 2009

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

Thomas Lynch, Anders Vahlne and Matti Sällberg were appointed to the Board of Directors, (all re-elected). Thomas Lynch was re-elected as Chairman of the Board. The Meeting resolved that no directors' fees shall be payable.

Authorisation to issue shares, convertibles debentures and warrants

The Meeting authorized the Board of Directors to resolve, at one or more occasions until the next Annual General Meeting, to issue new shares, convertible debentures and/or warrants with consideration in cash or in kind or by set-off or otherwise with conditions and thereby be able to resolve to disapply the shareholders pre-emption rights.

Reduction of the share capital and new articles of association

The meeting resolved to reduce the share capital for covering of losses and to adopt new articles of association which reflects the lower share capital.

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

In July-August the company has carried out two new issues without preferential rights for existing shareholders raising SEK 6 m. The new issues of 12,000,000 shares will increase the number of shares in the company to 35,575,314.

Tripep has out licensed the RAS\* technology to a newly started American company, Opsonic Therapeutics, and in return has received 20% of outstanding Opsonic stock. Opsinic 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 peptides can be found that bind to any target molecule, which allows for a rational design of new RAS\* molecules. Among the founders of Opsonic are the inventors behind the two technologies Dr Peter Wagner, Prof Matti Sällberg and Prof Anders Vahlne, and the CEO Albert Collinson.

#### **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 2008 Annual Report.

#### Forthcoming Financial Reports

Third-quarter Interim Report Year-end Report 2009 23 October 2009 29 January 2010

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, 26 August 2009

Thomas Lynch Chairman Anders Vahlne CEO and Board member Matti Sällberg 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.	6 mth.	6 mth.	12 mth.
SEK m	Apr-Jun 2009	Apr-Jun 2008	Jan-Jun 2009	Jan-Jun 2008	Jan-Dec 2008
Net sales	0.4	-	0.4	-	3.8
Other operating income	0.3	0.0	0.8	0.0	0.7
Total operating income	0.7	0.0	1.2	0.0	4.5
Operating costs					
Other external costs 1)	-2.4	-6.2	-4.7	-13.6	-20.9
Payroll costs	-1.2	-2.0	-2.8	-4.5	-8.3
Depreciation of tangible fixed assets	-0.0	-0.1	-0.1	-0.1	-0.2
Total operating costs	-3.6	-8.3	-7.6	-18.2	-29.4
Operating profit/loss	-2.9	-8.3	-6.4	-18.2	-24.9
Profit/loss from financial investments					
Interest income and similar profit/loss items	0.0	0.1	0.0	0.1	0.2
Interest costs and similar profit/loss items	-0.0	-0.0	-0.0	-0.0	-0.2
Total profit/loss from financial investments	-0.0	0.1	-0.0	0.1	0.0
Profit/loss after financial items	-2.9	-8.2	-6.4	-18.1	-24.9
Tax on net profit/loss	-	-	-	-	-
Net profit/loss for the period	-2.9	-8.2	-6.4	-18.1	-24.9

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

## **EARNINGS PER SHARE**

	3 mth.	3 mth.	6 mth.	6 mth.	12 mth.
SEK	Apr-Jun 2009	Apr-Jun 2008	Jan-Jun 2009	Jan-Jun 2008	Jan-Dec 2008
Earnings per share	-0.13	-0.79	-0.28	-1.92	-2.14
Earnings per share after dilution	-0.13	-0.79	-0.28	-1.92	-2.14
Outstanding average number of shares	23,575,314	10,426,283	23,057,471	9,438,655	11,639,665

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 issue.

Conversion has been affected for the reverse stock split 1:10 carried out in June 2008.

# NUMBER OF OUTSTANDING SHARES

	3 mth.	3 mth.	6 mth.	6 mth.	12 mth.
	Apr-Jun 2009	Apr-Jun 2008	Jan-Jun 2009	Jan-Jun 2008	Jan-Dec 2008
No. of outstanding shares, opening balance	23,575,314	7,946,658	19,950,412	4,826,087	4,826,087
Rights issue	-	121,320	-	3,241,891	3,241,891
Rights issue	-	-	-	-	1,718,246
Private placement	-	-	-	-	4,000,000
Rights issue	-	-	3,624,902	-	6,161,322
New issue, TO3	-	-	-	-	2,866
Outstanding number of shares, closing balance	23,575,314	8,067,978	23,575,314	8,067,978	19,950,412

A statement of changes in equity is presented on page  $\overline{19}$  in Tripep's Annual Report 2008

Conversion has been affected for the reverse stock split 1:10 carried out in June 2008

## **WARRANTS**

	Number	Of which the company owns	Of which the staff	Exercise Price, SEK	Subscription Period
Series C	250,000	62,500	187,500	19.11	1-30 June 2010
Series D	350,000	87,500	262,500	21.19	1-30 June 2011
TO2	32,418,905		Rights issue	8.35	1 Apr 2008-30 Sep 2009

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-D - ten options confers the right to subscribe for 1.37 shares. As a consequence of the rights issue and the reverse stock split the terms have been recalculated. At the end of the period, there were 390,000 staff stock options, because 60,000 had expired due to terminated employment, and 150,000 serie A has expired on 30 June 2008 and 150,000 serie B has expired on 30 June 2009 without being exercised.

TO2 - twenty options confer the right to subscribe for 1.2 shares.

### **BALANCE SHEET**

SEK m	30 Jun 2009	30 Jun 2008	31 Dec 2008
Tangible fixed assets	0.3	0.4	0.4
Financial fixed assets	0.1	-	0.1
Current receivables	1.1	2.0	3.3
Cash & bank balances <sup>1)</sup>	0.4	2.9	3.3
Total assets	1.9	5.4	7.1
Shareholder's equity (see note below)	-5.8	-4.8	-1.1
Long-term liabilities	1.4	2.5	1.9
Current liabilities	6.3	7.7	6.3
Total liabilities and shareholder's equity	1.9	5.4	7.1

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

## STATEMENT OF CHANGES TO SHAREHOLDERS' EQUITY

SEK m	30 Jun 2009	30 Jun 2008	31 Dec 2008
Shareholder's equity, opening balance	-1.1	-1.6	-1.6
Rights issue, 3,241,891 shares 1,2)	-	14.9	14.9
Rights issue, 1,718,246 shares 3)	-	-	2.8
Private placement, 4,000,000 shares	-	-	5.0
Rights issue, 9,786,224 shares 4)	1.7	-	2.7
New issue, 2,866 shares	-	-	0.0
Options	0.0	0.0	0.1
Net profit/loss	-6.4	-18.1	-24.9
Shareholders' equity, closing balance	-5.8	-4.8	-1.1

<sup>1)</sup> Includes issue costs of SEK 1.6 m

# SHAREHOLDERS' EQUITY PER SHARE

SEK	30 Jun 2009	30 Jun 2008	31 Dec 2007
Shareholders' equity per share	-0.25	-0.47	-0.06

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 issue.

Conversion has been affected for the reverse stock split 1:10 carried out in June 2008.

<sup>2)</sup> Conversion has been affected for the reverse stock split 1:10 carried out in June 2008.

<sup>3)</sup> Includes issue cost of SEK 0.7 m. 4) Includes issue cost of SEK 0.5 m.

## **CASH FLOW STATEMENTS**

	6 mth.	6 mth.	12 mth.
SEK m	Jan-Jun 2009	Jan-Jun 2008	Jan-Dec 2008
Cash flow from operating activities			
Net profit/loss	-6.4	-18.1	-24.9
Depreciation	0.1	0.0	0.2
Change in long-term liabilities <sup>1)</sup>	-0.5	-0.5	-1.1
Cash flow from operating activities before change in working capital	-6.8	-18.6	-25.8
Cash flow from change in working capital			
Decrease/increase(-) in receivables	2.2	0.1	-1.2
Decrease(-)/increase in current liabilities	0.0	1.2	-0.2
Net cash flow used in operating activities	-4.6	-17.3	-27.2
Cash flow from investment activities			
Acquisition of subsidiary/associated company	-	-	-0.1
Acquisition of tangible fixed assets	-	-0.0	-0.1
Net cash flow used in investment activities	-	-0.0	-0.2
Cash flow from financing activities			
New issue/capital contribution	1.7	14.9	25.4
Cash flow from financing activities	1.7	14.9	25.4
Cash flow for the period	-2.9	-2.4	-2.0
Liquid assets, at start of period	3.3	5.3	5.3
Liquid assets, at end of period	0.4	2.9	3.3

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

## **KEY FIGURES**

	3 mth.	3 mth.	6 mth.	6 mth.	12 mth.
	Apr-Jun 2009	Apr-Jun 2008	Jan-Jun 2009	Jan-Jun 2008	Jan-Dec 2008
Return on capital employed, %	neg	neg	neg	neg	neg
Return on equity, %	neg	neg	neg	neg	neg
Equity/assets ratio, %	neg	neg	neg	neg	neg
Debt/equity ratio	neg	neg	neg	neg	neg
Liquid assets, SEK m	0.4	2.9	0.4	2.9	3.3
Share risk-bearing capital, %	neg	neg	neg	neg	neg
Cash flow for the period, SEK m	-1.4	-6.2	-2.9	-2.4	-2.0
Investment in tangible fixed assets, SEK m	0.0	0.0	0.0	0.0	0.1
Internal research and development (written off), SEK m	0.2	0.3	0.3	0.6	0.9
External research and development (written off), SEK m	1.8	4.9	2.8	11.2	16.2
Salaries, benefits and social sequrity costs, SEK m	1.2	2.0	2.8	4.5	8.3
Average No. of employees	3	5	4	5	5