



## MEDIVIR AB – INTERIM REPORT, JANUARY – JUNE 2016

### *Financial summary*

#### Second quarter 2016

- Net turnover totalled SEK 81.3 million (245.8 m), of which SEK 24.2 million (165.6 m) comprised royalties for simeprevir.
- Revenues from Medivir's own pharmaceutical sales totalled SEK 50.1 million (55.1 m), of which SEK 5.6 million (13.2 m) derived from sales of OLYSIO® and SEK 44.5 million (41.9 m) from sales of other pharmaceuticals.
- The profit after tax was SEK -39.8 million (64.1 m).
- Basic and diluted earnings per share totalled SEK -1.48 (2.21) and SEK -1.47 (2.19), respectively.
- The cash flow from operating activities amounted to SEK -37.1 million (64.3 m).

#### Six months 2016

- Net turnover totalled SEK 156.3 million (461.7 m), of which SEK 42.3 million (294.2 m) comprised the first six months' royalties for simeprevir.
- Revenues from Medivir's own pharmaceutical sales totalled SEK 106.4 million (141.9 m), of which SEK 7.4 million (47.4 m) derived from sales of OLYSIO® and SEK 99.0 million (94.5 m) from sales of other pharmaceuticals.
- The profit after tax was SEK -80.2 million (130.7 m).
- Basic and diluted earnings per share totalled SEK -2.98 (4.50) and SEK -2.97 (4.46), respectively.
- The cash flow from operating activities amounted to SEK -73.5 million (269.6 m).

#### Summary of the Group's figures, continuing operations (SEK m)

	Q2		Q1-Q2		Full year
	2016	2015	2016	2015	2015
Net turnover	81.3	245.8	156.3	461.7	657.9
Gross profit	55.7	214.9	110.4	397.7	548.6
Operating profit before depreciation and amortisation (EBITDA)	-40.1	104.9	-72.4	189.6	155.0
Operating profit (EBIT)	-48.1	96.1	-88.9	172.2	114.8
Profit/loss before tax	-43.6	85.4	-81.7	168.2	102.0
Profit/loss after tax	-39.8	64.1	-80.2	130.7	75.1
Operating margin, %	-59.2	39.1	-56.9	37.3	17.4
Basic earnings per share, SEK	-1.48	2.21	-2.98	4.50	2.59
Diluted earnings per share, SEK	-1.47	2.19	-2.97	4.46	2.56
Net worth per share, SEK	50.8	55.7	50.8	55.7	53.8
Return on equity	-3.1	5.8	-5.8	9.7	5.9
Cash flow from operating activities	-37.1	64.3	-73.5	269.6	307.4
Liquid assets and short-term investments at the period end	997.5	1 043.4	997.5	1 043.4	1 077.9
R&D spending/total opex, %	71.5	60.2	73.0	61.1	64.2

## CEO's comments

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An important event in Q2 was the decision to investigate the possibility of dividing Medivir's operations into two independent companies – a dedicated research and development company and a commercial pharmaceutical company. The separation of the businesses would enable the existing operations to be conducted by two clearly focused, specialised companies where both companies' potential can be maximised in line with their different objectives and capabilities. This aims to highlight shareholder values of both the commercial operations and the pharmaceutical projects that make up the R&D portfolio.

Our in-house research portfolio is based on our established and successful technology platform, and all of the projects developed according to plan during the quarter. The MIV-711 osteoarthritis project continued its recruitment of patients according to plan and our previous estimate that we will be able to report the results of the study in the second half of 2017 remains unchanged. Negotiations with potential partners on the MIV-802 project for the treatment of hepatitis C also continued during the quarter.

We are also delighted to note that our partner, Janssen Research & Development, has decided to initiate a phase IIb study investigating the efficacy, safety and pharmacokinetics of different treatment regimens of a triple combination using simeprevir together with AL-335 and odalasvir in patients with chronic Hepatitis C virus (HCV).

Royalties attributable to the hepatitis C pharmaceutical, OLYSIO® (simeprevir), totalled SEK 24.2 million during the quarter, reflecting the lower level of global net sales of OLYSIO® that we are also seeing in the Nordic region.

The Xerclear (Zoviduo) product has been registered by GlaxoSmithKline in Spain, triggering milestone revenues of SEK 6.5 million in the quarter.

Our Nordic pharmaceutical sales saw the Nordic Brands portfolio continue to grow with sales reaching SEK 44 million during the quarter, corresponding to an increase of 6.7 per cent in comparison with the same period in 2015.

Administrative costs are continuing to decrease as a result of the efficiency enhancing measures that we have implemented, in spite of the increased investments in the phase IIa study of MIV-711.

The corporate separation investigation, coupled with the ongoing progress of our projects and continued commercial development, give me every confidence in our efforts to continue creating long-term value.

**Niklas Prager**  
*President and CEO*

### Medivir in brief

Medivir is a research based pharmaceutical company with a research focus on oncology and infectious diseases. We have market-leading expertise in protease inhibitor design and nucleotide/nucleoside science and we are dedicated to developing innovative pharmaceuticals that meet great unmet medical needs. Our commercial organisation supplies the Nordic market with a portfolio of specialty care pharmaceuticals. Medivir is listed on the Nasdaq Stockholm Mid Cap List.

*For more information about Medivir, please visit [www.medivir.com](http://www.medivir.com).*

## Significant events during the second quarter

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In April, new clinical data for simeprevir, an NS3 / 4A protease inhibitor for the treatment of hepatitis C virus infection was presented by our partner, Janssen Sciences Ireland UC (Janssen), in conjunction with The International Liver Congress™ 2016 of the European Association for the Study of the Liver (EASL) in Barcelona. A total of nine presentations were made, including one "late breaker" presentation. The presentations covered the efficacy, safety and tolerability of simeprevir used as a component of various combination therapies in a number of different adult patient populations, and was based on data from phase II and phase III studies and from on-going clinical use (so-called "real-world data").

In May, Medivir's partner, Janssen Research & Development, LLC., decided to initiate a phase IIb study investigating the efficacy, safety and pharmacokinetics of different treatment regimens of AL-335, odalasvir, and simeprevir in treatment-naïve and treatment-experienced patients with chronic Hepatitis C Virus (HCV) genotype 1-6 infection, with and without cirrhosis. This global phase IIb study is a randomized, open-label, four-arm study of AL-335, a nucleotide-based HCV NS5B polymerase inhibitor, odalasvir, an HCV NS5A inhibitor and simeprevir. The primary endpoint of the study is the percentage of chronic HCV-infected subjects who achieve a sustained virologic response 12 weeks after the end of treatment (SVR12).

In June, the Board of Directors tasked the company management with reviewing the possibility of dividing the company's operations into two independent companies and achieving a separate listing for the commercial pharmaceutical portfolio. The Board believes that a division of Medivir's operations into a dedicated research and development company and a

commercial pharmaceutical company could be advantageous for the company's shareholders. The objective is to highlight the value of both the commercial operations and the pharmaceutical projects that make up the R&D portfolio. In addition, the split would enable the existing operations to be conducted by two clearly focused, specialised companies where both companies' potential can be maximised in line with their different prerequisites and preconditions.

### Annual General Meeting

The 2016 AGM resolved to authorise the Board to adopt decisions, whether on one or several occasions and whether with or without pre-emption rights for the shareholders, to issue new class B shares up to an amount not exceeding in total 10 per cent of the total number of outstanding class B-shares in the company following utilization of the authorisation.

The AGM also resolved to authorise the Board of Directors to resolve to transfer (sell) own shares. The purpose of the authorisation to transfer own shares is to enable the Board of Directors to make acquisitions of companies and products with a view to broadening the ownership of the company, or for use in the context of the company's incentive programmes.

Anders Ekblom, Anders R Hallberg, Johan Harmenberg, Helena Levander and Anna Malm Bernsten were re-elected as Board Members and Thomas Axelsson was elected as a new Board Member. Anna Malm Bernsten was elected as the new Chairman of the Board.

Öhrlings PricewaterhouseCoopers AB was re-elected as Auditor.

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## Financial overview, second quarter 2016

### Revenues

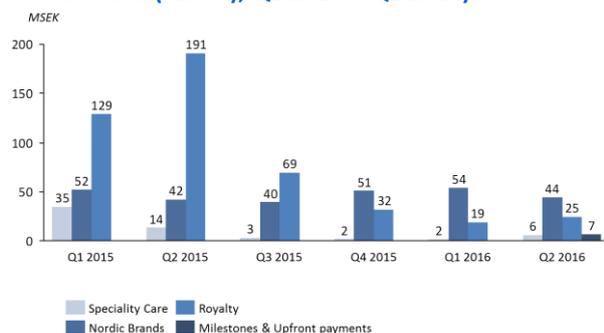
Net turnover totalled SEK 81.3 million (245.8 m), corresponding to a decrease of SEK 164.5 million. Revenues from Medivir's own pharmaceutical sales in the Nordic region totalled SEK 50.1 million (55.1 m), of which SEK 44.5 million (41.9 m) was generated by the Nordic Brands portfolio. The Innovative Specialty Care portfolio achieved sales of SEK 5.7 million (13.5 m).

Janssen's global sales of simeprevir totalled USD 43 million (264m), generating royalties during the quarter of SEK 24.2 million (190.7 m). Royalties based on GSK's global sales of Xerclear (Zoviduo) during the second quarter amounted to SEK 0.5 million. In addition, a milestone payment of SEK 6.5 million (0 m) was received in the quarter due to the registration for sale of the product in Spain by our partner, GlaxoSmithKline.

## Breakdown of net turnover (SEK m)

	Q2		Q1-Q2		Full year
	2016	2015	2016	2015	2015
Milestone payments	6.5	0.0	6.5	0.0	0.0
Pharmaceutical sales, where of	50.1	55.1	106.4	141.9	237.5
<i>Nordic brands</i>	44.4	41.6	98.8	93.9	183.6
<i>Innovative specialty care</i>	5.7	13.5	7.5	48.0	53.9
Royalties	24.7	190.7	43.4	319.8	420.4
<b>Total</b>	<b>81.3</b>	<b>245.8</b>	<b>156.3</b>	<b>461.7</b>	<b>657.9</b>

## Net turnover (SEK m), Q1 2015 – Q2 2016



## Results

### Gross profit

The cost of goods sold was SEK -25.6 million (-30.9 m), corresponding to a decrease of SEK 5.3 million. The gross profit amounted to SEK 55.7 million (214.9 m), corresponding to a decrease of SEK 159.2 million and equating to a gross margin of 68% (87%), explained by the shift from royalties to pharmaceutical sales.

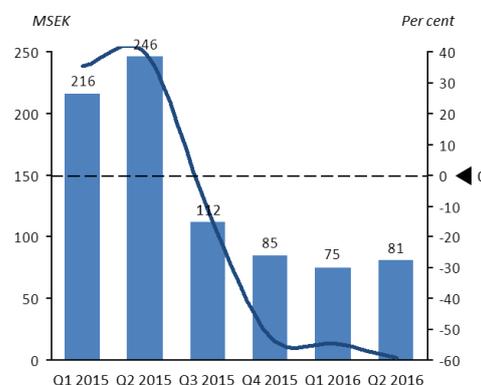
### Operational expenses

The reorganisation of the sales organisation last year has resulted in a decrease in selling expenses of SEK 10.0 million. Administrative expenses have, furthermore, decreased by SEK 6.1 million. Research and development costs increased by SEK 2.8 million, primarily as a result of the ongoing phase IIa study of MIV-711. Other operating income/expenses have increased by SEK 1.5 million, largely due to exchange rate effects. Overall, operating expenses totalled SEK -103.8 million (-118.7 m), corresponding to a decrease of SEK 14.9 million.

The operating profit/loss totalled SEK -48.1 million (96.1 m), corresponding to a decrease of SEK 144.2 million.

Net financial items totalled SEK 4.5 million (-10.7 m), corresponding to an increase of SEK 15.2 million, and due to unrealised gains driven by market valuation of short-term interest-bearing investments.

## Net turnover and operating margin (SEK m)



## Taxes

Tax for the second quarter totalled SEK 3.7 million (-21.3 m), corresponding to a decrease of SEK 25.0 million. The decrease in taxes is a result of reduced profits.

The Groups' income and deferred tax are calculated using the legally stipulated tax rate of 22%, which is expected to be the effective rate.

### Revenues

Net turnover totalled SEK 156.3 million (461.7 m), corresponding to a decrease of SEK 305.4 million. Revenues from Medivir's own pharmaceutical sales in the Nordic region totalled SEK 106.4 million (141.9 m), of which SEK 98.8 million (93.9 m) was generated by the Nordic brands. Innovative specialty care reached sales of SEK 7.5 million (48.0 m) as a result of the decrease in sales of OLYSIO®.

Janssen's global sales of simeprevir totalled USD 75 million (498m), which has generated royalties of SEK 42.3 million (319.8 m) during the period.

Royalties based on GSK's global sales of Xerclear (Zoviduo) during the first six months amounted to SEK 1.2 million (1.3 m). In addition, a milestone payment of SEK 6.5 million (0 m) was received during the period.

### Results

#### Gross profit

The cost of goods sold was SEK -46.0 million (-64.0 m), corresponding to a decrease of SEK 18.0 million. The gross profit amounted to SEK 110.4 million (397.7 m), corresponding to a decrease of SEK 287.3 million and equating to a gross margin of 71% (86%), explained by the shift from royalties to pharmaceutical sales.

#### Operational expenses

The reorganisation of the sales organisation last year has resulted in a decrease in selling expenses of SEK 17.8 million. Administrative expenses have, furthermore, decreased by SEK 10.7 million. Research and development costs increased by SEK 7.8 million, primarily as a result of the ongoing phase IIa study of MIV-711 and the progress of discovery projects, such as the RSV fusion inhibitor and the HCC nucleotide. Other operating income/expenses are positive and decreased by SEK 5.4 million, largely due to exchange rate effects. Overall, operating expenses totalled SEK -199.3 million (-225.4 m), corresponding to a decrease of SEK 26.1 million.

The operating profit/loss totalled SEK -88.9 million (172.2 m), corresponding to a decrease of SEK 261.1 million.

Net financial items totalled SEK 7.2 million (-4.0 m), corresponding to an increase of SEK 11.2 million, and due to market valuation of short-term interest-bearing investments.

#### Taxes

Tax for the period totalled SEK 1.5 million (-37.5 m), corresponding to a decrease of SEK 39.0 million. The decrease in taxes is a result of reduced profits. The

Group's income and deferred tax are calculated at the tax rate of 22%.

### Cash flow, Investments and Financial Position

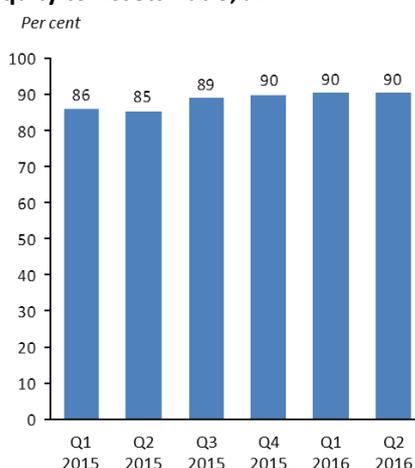
Liquid assets, including short-term investments with a maximum term of three months, amounted to SEK 997.5 million (1,043.4 m) at the end of the period, compared to 1,077.9 million (1,395.6 m) at the beginning of 2016 and corresponding to a decrease of SEK 80.4 million. Royalty revenues for the second quarter totalled SEK 24.2 million and are not included in liquid assets at the period end. Pledged assets at the end of the period totalled SEK 54.3 million (54.3 m). Medivir's financial assets are, in accordance with its financial policy, invested in low-risk, interest-bearing securities.

Cash flow from operating activities totalled SEK -73.5 million (269.6 m), with changes in working capital accounting for SEK 17.9 million (92.3 m) of this total.

Cash flow from investing activities totalled SEK -6.8 million (-10.5 m). Investments in research and facility equipment and IT systems totalled SEK -6.8 million (-5.4 m), and the revenues from the sales of operations amounted to SEK 0.0 million (2.5 m).

Cash flow from financing activities totalled SEK 0.0 million (-611.6 m).

### Equity to Assets Ratio, %



Investments in tangible fixed assets during the period amounted to SEK -8.5 million (-7.6 m) and comprised investments in research, facilities and IT equipment.

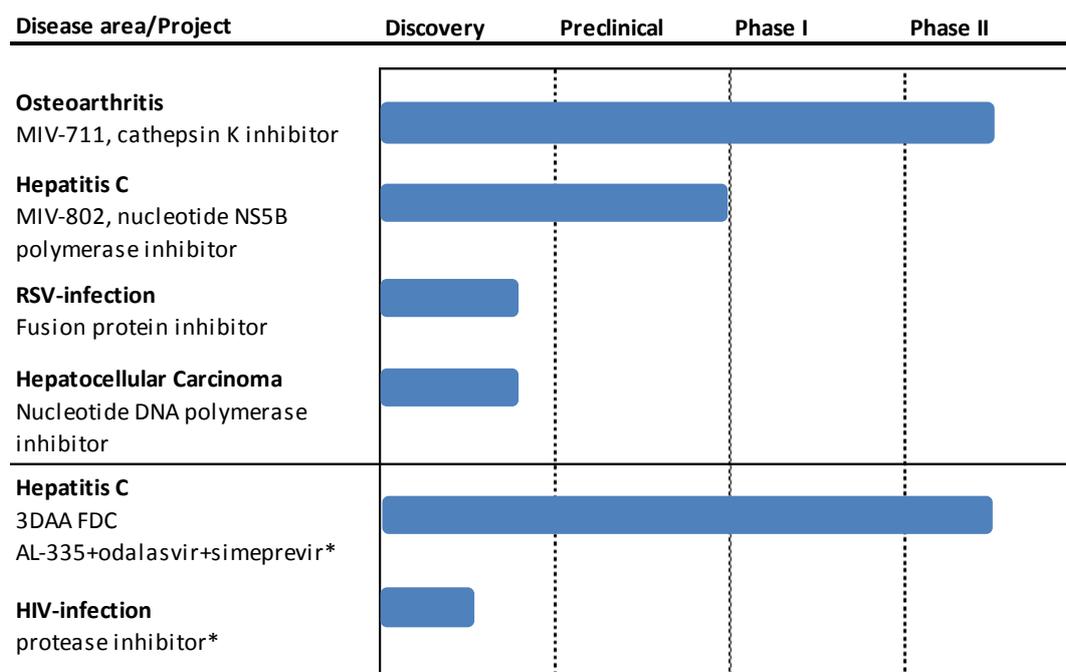
Depreciation of tangible fixed assets and intangible fixed assets totalling SEK -5.4 million (-5.4 m) and SEK -11.2 million (-11.7 m), respectively, were charged to the profit/loss for the period.

## Research and development

Medivir's pharmaceutical product research and development portfolio is based on the company's expertise in the design of protease inhibitors and in the science of nucleotides and nucleosides. The focus is both on oncology and infectious diseases, and on the ongoing clinical project in the area of osteoarthritis.

Medivir has successfully developed products all the way from concept to marketed products. In 2009, Xerclear (Zoviduo®) was approved for the treatment of labial herpes. The marketing rights to Xerclear in the USA, Canada and Mexico was divested in 2010, while the corresponding rights in Europe and the rest of the world have been out-licensed to GlaxoSmithKline, with the exception of Israel and China, where Medivir has appointed local distributors, and South America where Medivir has retained the rights.

In 2013, simeprevir (OLYSIO®) was approved in the USA, and in May 2014, it was granted marketing authorisation in the EU. Subsequent marketing authorisations have followed in several other countries around the world. Simeprevir is approved for the treatment of hepatitis C infection as part of an antiviral treatment regimen in adults without cirrhosis or with compensated cirrhosis who are chronically infected with HCV genotype 1 or 4, (indications vary by market). Janssen is responsible for the global clinical development of simeprevir and has exclusive, worldwide marketing rights, except in the Nordic countries. Medivir retains marketing rights for simeprevir in these countries under the marketing authorisation held by Janssen-Cilag International NV.



\* Partner Janssen

For further information about our projects, please visit [www.medivir.com](http://www.medivir.com)

## **MIV-711**

MIV-711 is a cathepsin K inhibitor in clinical development for the treatment of osteoarthritis. Cathepsin K is a protease, which can break down the collagen in bone and cartilage, and hence an inhibitor of cathepsin K has the potential to reduce joint structural disease progression and attenuate pain. In support of this, MIV-711 has been demonstrated to exert joint protective effects in preclinical models of osteoarthritis. In a phase I study including postmenopausal women, MIV-711 reduced biomarkers for bone resorption and cartilage degradation by up to 98 per cent and 62 per cent, respectively, compared with placebo.

### **Status/significant events:**

A phase IIa study of MIV-711 in patients with moderate knee osteoarthritis was initiated early in the first quarter, with the first patient enrolled into the study in January. We continue to make good progress with patient enrolment. Medivir therefore continues to expect that all patients will have completed their six months of dosing during the first half of 2017, and that results from the study will be available in the second half of 2017. Details of the trial can be found at [www.clinicaltrials.gov/ct2/show/NCT02705625](http://www.clinicaltrials.gov/ct2/show/NCT02705625).

## **MIV-802**

MIV-802 is a potent, pan-genotypic nucleotide-based inhibitor of the HCV NS5B polymerase, which is currently in preclinical development. Hepatitis C treatment comprises a combination of several pharmaceuticals with different mechanisms. Nucleotides are regarded as the most important component of any such combination, due to their potent and broad spectrum antiviral effect on multiple HCV genotypes and high barriers to the emergence of resistance. Preclinical data indicate that MIV-802 can be used effectively in combination with other classes of antiviral agents for the treatment of HCV, including protease inhibitors and NS5A inhibitors.

### **Status/significant events:**

Preclinical safety testing to enable phase I clinical studies has been completed successfully. Partnership discussions are currently in progress.

## **RSV fusion protein inhibitor**

The aim of the project is to develop an oral inhibitor of the RSV fusion protein. Respiratory syncytial virus (RSV) can cause life-threatening pulmonary and respiratory tract infections, particularly in children, the elderly, and the immunocompromised. The RSV fusion protein is a mediator of viral entry into host cells and an important target for new medicines. Medivir has an in-licensing agreement for the RSV programme with Boehringer Ingelheim. The agreement offers exclusive, global rights to a drug programme for the treatment and prevention of RSV infections.

### **Status/significant events:**

The programme licensed from Boehringer Ingelheim included several series of molecules that inhibit the RSV fusion protein. These substances are being further optimised to ensure broad coverage against clinical isolates of RSV and good pharmacokinetic properties in order to ensure that the candidate drug that emerges from this project for further development has a highly competitive profile.

## **HCC nucleotide based DNA polymerase inhibitor**

The objective of the nucleotide project for hepatocellular carcinoma is to deliver an anticancer therapeutic selectively to the liver. Non-surgical approaches to managing HCC rely to a large extent on the targeting of drugs to the liver. Medivir has developed substantial capabilities to selectively deliver the active metabolites of nucleoside and nucleotide analogues to the liver, based on its long-standing interests in discovering improved treatments for chronic hepatitis B virus and hepatitis C virus infection. These approaches are now being applied to HCC. The intention is to develop an orally administered drug that is liver specific for the treatment of hepatocellular carcinoma.

### **Status/significant events:**

Medivir has identified molecules with excellent activity against a range of HCC cell lines and with the required distribution properties to enable them to be delivered selectively to the liver. Compounds are currently being profiled in disease-relevant models. Medivir will make a first public presentation of the profiles of molecules from this project at the 10th Annual Conference of the International Liver Cancer Association in Vancouver, Canada on 9-11 September 2016.

## PARTNERED PROJECT

### Simeprevir

Simeprevir is an NS3/4A protease inhibitor jointly developed by Janssen Sciences Ireland UC and Medivir AB and indicated for the treatment of chronic hepatitis C infection as a component of a combination antiviral treatment regimen.

#### Status/significant events:

In mid-October 2015, Janssen started a phase IIa clinical trial to evaluate the combination of simeprevir, the NS5A inhibitor, odalasvir, and the nucleotide analogue AL-335. This trial is due to be completed by the end of 2016.

In May, Janssen announced its intention to initiate a phase IIb study to investigate the efficacy, safety and pharmacokinetics of different treatment regimens of AL-335, odalasvir, and simeprevir in treatment-naïve and treatment-experienced patients with chronic Hepatitis C Virus (HCV) genotype 1-6 infection, with and without cirrhosis.

### Patents

Securing patent protection is the foundation for all new pharmaceutical projects, whether a project derives from our own laboratories or is in-licensed. Patents and other exclusive rights, such as data exclusivity and trademark protection are crucial to companies' future commercial prospects. Medivir currently has around 50 active patent families, with over 200 national patents awarded. During the second quarter, Medivir filed one new patent within RSV and advanced the MIV-802 patent family in Europe and over 30 other countries.

### Royalty undertakings

A significant percentage of Medivir's research and development project work has been carried out exclusively in-house and Medivir is consequently entitled to all revenues in respect of these inventions. Some of Medivir's research and development projects also originate from Swedish universities and pharmaceutical companies, and Medivir is consequently entitled to the revenues generated by these projects but obliged to pay royalties on their commercialisation. Certain projects have been progressed with patented research tools which are in-licensed from other companies and for which royalties are payable. The combined royalty costs for the period were SEK 3.1 million (20.0 m).

## Other disclosures (six months period)

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### Employees

Medivir had 120 (138) employees (FTEs) at the period end, 53% (57%) of whom were women.

### Share-related incentive plans

The objective of share-related incentive plans is to promote the company's long-term interests by motivating and rewarding the company's senior executives and other members of staff. Medivir currently has one active share-related incentive plan, LTI 2014. The LTI 2013 plan was finalized during the second quarter 2016 and approximately 80,500 of the shares from the buyback programme were distributed to the participants. The cost of the current plan, including social security contributions, based on certain assumptions such as share price performance, participation and staff turnover, was charged to the profit/loss for the period in the sum of SEK 0.6 million.

### The Parent Company in brief

Medivir AB (publ.), corporate ID no. 556238-4361, is the Parent Company of the Group. Its operations consist of research and development, marketing and sales, and administrative and company management functions. The Parent Company's net turnover totalled SEK 58.5 million (380.3 m). Intra-Group sales amounted to SEK 13.2 million (12.5 m).

The gross profit amounted to SEK 39.1 million (336.2 m). Combined operating expenses totalled SEK -175.6 million (-179.6 m). The operating profit/loss was SEK -136.6 million (156.6 m), corresponding to a decrease of SEK 293.2 million. Net financial items totalled SEK 4.3 million (-2.5 m), corresponding to an increase of SEK 6.8 million, and due to unrealised gains driven by market positive valuation of short-term interest-bearing investments.

The tax for the period totalled SEK -0.1 million (-34.5 m). The net profit/loss for the period was SEK -132.4 million (119.6 m), corresponding to a decrease of SEK 252.0 million, primarily due to decreases in royalty income.

Liquid assets, including short-term investments with a maximum term of three months, amounted to SEK 883.6 million (941.4 m).

Please see the section entitled “Financial Overview” for further comments on the operations.

### Transactions with related parties

Transactions with related parties are on market terms. There are existing agreements between companies owned by senior executives and Medivir, dating from 2005, which entitle the senior executives to royalties on products that the company may develop based on patented inventions that the company has purchased from the parties in question. During the period, transactions with related parties totalled SEK 1.3 million (9.4 m) whereof royalty payments to Uppsala Hallbechem AB (Board Member, Anders Hallberg) totalled SEK 0.3 million (2.5 m) and those to Sybesam AB (Board Member, Bertil Samuelsson) totalled SEK 1.0 million (6.9 m). No other services were purchased from related parties.

### Significant risks and uncertainty factors

An effective risk assessment reconciles Medivir’s business opportunities and results with the requirements of shareholders and other stakeholders for stable, long-term value growth and control. The process of research and pharmaceutical development, all the way up to approved registration, is both high-risk and capital-intensive. The majority of projects initiated will never achieve market authorisation. If competing pharmaceuticals take market shares, or competing research projects achieve better efficacy and reach the market more quickly, the future value of Medivir’s product and project portfolio may be lower than expected. Medivir’s ability to produce new candidate drugs, to enter into partnerships for its projects, to successfully develop its projects to market launch and continued sales, and to secure funding for its operations, are decisive in terms of the company’s future.

#### Medivir is exposed to the following main risk categories:

**Exogenous risks** – such as regulatory approval risk, competition, price changes, external seasonality and patent protection.

**Operating risks** – such as integration risk, production risk, and a reliance on key employees and partnerships.

**Financial risks** – such as liquidity, interest, currency and credit risk.

A more detailed description of the exposure to risk, and of the ways in which Medivir manages it, is provided in the 2015 Annual Report, see pages 27 and 62 (Note 8). The Annual Report is available at; [www.medivir.com](http://www.medivir.com).

### Significant events after end of Q2

In August, Medivir announced that new clinical data from an ongoing phase IIa study of simeprevir, odalasvir and AL-335, being conducted by Alios BioPharma Inc., part of the Janssen Pharmaceutical Companies of Johnson & Johnson (Janssen), will be presented at the European Association for the Study of the Liver (EASL)/American Association for the Study of Liver Diseases (AASLD) Special Conference on Friday September 23<sup>rd</sup> 2016. It will include interim data which aims to establish the safety, pharmacokinetics and efficacy (SVR12) of different combination regimens consisting of three directly acting antiviral agents (DAAs), simeprevir, odalasvir, an HCV NS5A inhibitor, and AL-335, a nucleotide inhibitor of the HCV NS5B polymerase, for the treatment of GT 1 HCV infection in eight weeks or less.

### Outlook

The Board of Directors has decided to investigate the possibility of dividing Medivir’s operations into two independent companies – a dedicated research and development company and a commercial pharmaceutical company.

Medivir will continue to exploit its leading expertise in the design of protease inhibitors and nucleotide and nucleoside research, and possesses attractive in-house projects both in development phase and in early discovery. Intensified external business development activities aim to balance the research operations with additional clinical phase projects.

A number of studies of simeprevir in combination with other direct-acting antiviral agents are also being conducted in parallel, under the aegis of Janssen, with the aim of developing interferon-free treatment alternatives for different patient groups with hepatitis C.

## Attestation

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The Board of Directors and the President & CEO hereby affirm that the Interim Report constitutes a faithful representation of the company's and the Group's operations, position and profit/loss, and that it describes the significant risks and uncertainty factors faced by the company and the companies that make up the Group.

Stockholm, 17 August 2016

**Thomas Axelsson**  
*Member of the Board*

**Susana Ayesa Alvarez**  
*Member of the Board,  
Employee Representative*

**Anders Ekblom**  
*Member of the Board*

**Anders Hallberg**  
*Member of the Board*

**Johan Harmenberg**  
*Member of the Board*

**Helena Levander**  
*Member of the Board*

**Anna Malm Bernsten**  
*Chairman of the Board*

**Veronica Werlinder**  
*Member of the Board,  
Employee Representative*

**Niklas Prager**  
*President and CEO*

*This report has not been subject to auditors' review.*

*The information in this report comprises the information that Medivir is obliged to disclose under the provisions of the Swedish Securities Markets Act.*

*This information was released for publication at 08.30 AM CET on 17 August 2016.*

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### For further information, please contact

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### Conference call for investors, analysts and the media

The Interim Report, January – June 2016 will be presented by Medivir's President & CEO, Niklas Prager.

Time: Wednesday, 17 August 2016, at 14.00 (CET).

Phone numbers for participants from:  
Sweden + 46 8 566 426 96  
Europe + 44 20 3008 9817  
USA + 1 855 831 5946

**The conference call will also be streamed via a link on the website: [www.medivir.com](http://www.medivir.com)**

The presentation will be available on Medivir's website after completion of the conference.

#### Financial calendar:

**Interim Report (January – September 2016)**  
10 November 2016

**Financial Statement (January – December 2016)**  
17 February 2017

**Interim Report (January – March 2017)**  
28 April 2017

## Consolidated Income Statement, summary (SEK m)

	Q2		Q1-Q2		Full year
	2016	2015	2016	2015	2015
<b>Continuing operations</b>					
Net turnover	81.3	245.8	156.3	461.7	657.9
Cost of goods sold	-25.6	-30.9	-46.0	-64.0	-109.3
<b>Gross profit</b>	<b>55.7</b>	<b>214.9</b>	<b>110.4</b>	<b>397.7</b>	<b>548.6</b>
Selling expenses	-17.6	-27.6	-34.7	-52.5	-98.4
Administrative expenses	-12.1	-18.2	-20.8	-31.5	-60.3
Research and development costs	-74.2	-71.4	-145.5	-137.7	-278.4
Other operating income/expenses	0.1	-1.5	1.7	-3.7	3.2
<b>Operating profit/loss</b>	<b>-48.1</b>	<b>96.1</b>	<b>-88.9</b>	<b>172.2</b>	<b>114.8</b>
Net financial items	4.5	-10.7	7.2	-4.0	-12.8
<b>Profit/loss after financial items</b>	<b>-43.6</b>	<b>85.4</b>	<b>-81.7</b>	<b>168.2</b>	<b>102.0</b>
Tax	3.7	-21.3	1.5	-37.5	-26.9
Net profit/loss for the period from continuing operations	-39.8	64.1	-80.2	130.7	75.1
Net profit/loss for the period from discontinued operations	0.0	0.0	0.0	0.0	0.0
<b>Net profit/loss for the period</b>	<b>-39.8</b>	<b>64.1</b>	<b>-80.2</b>	<b>130.7</b>	<b>75.1</b>
<b>Net profit/loss for the period attributable to:</b>					
Parent Company shareholders	-39.8	64.1	-80.2	130.7	75.1
<b>Earnings per share, calculated from the net profit/loss attributable to Parent Company shareholders during the period</b>					
Earnings per share (SEK per share)					
- Total operations, basic earnings	-1.48	2.21	-2.98	4.50	2.59
- Total operations, diluted earnings	-1.47	2.19	-2.97	4.46	2.56
Average number of shares, '000	26 941	29 048	29 048	29 048	29 048
Number of shares at period end, '000	26 917	26 836	26 836	26 836	26 836

## Notes

### Accounting principles

Medivir applies International Financial Reporting Standards (IFRS) as endorsed by the European Union. Significant accounting and valuation principles are presented on pages 50-57 of the 2015 Annual Report. The Group's Interim Report has been prepared in accordance with IAS 34. The Parent Company applies the principles recommended by the Swedish Financial Reporting Board in its recommendation, RFR 2. Other new or revised IFRS standards and IFRIC interpretations that have come into force since 31 December 2015 have had no significant effect on the Group's or Parent Company's financial position or results.

## Consolidated Statement of Comprehensive Income (SEK m)

	Q2		Q1-Q2		Full year
	2016	2015	2016	2015	2015
<b>Net profit/loss for the period</b>	<b>-39.8</b>	<b>64.1</b>	<b>-80.2</b>	<b>130.7</b>	<b>75.1</b>
<b>Other comprehensive income</b>					
<i>Items that may be reclassified in the Income Statement</i>					
Exchange rate differences	0.3	0.0	0.1	0.8	2.2
<b>Total other comprehensive income for the period, net after tax</b>	<b>0.3</b>	<b>0.0</b>	<b>0.1</b>	<b>0.8</b>	<b>2.2</b>
<b>Total comprehensive income for the period</b>	<b>-39.5</b>	<b>64.1</b>	<b>-80.1</b>	<b>131.5</b>	<b>77.3</b>
<b>Total net profit/loss</b>	<b>-39.5</b>	<b>64.1</b>	<b>-80.1</b>	<b>131.5</b>	<b>77.3</b>

## Consolidated Balance Sheet, summary (SEK m)

	2016	2015	2015
	30 June	30 June	31 Dec
<b>Assets</b>			
Intangible fixed assets	386.9	410.9	398.0
Tangible fixed assets	29.4	29.1	26.3
Financial fixed assets	0.0	2.5	0.0
Inventories	21.5	23.8	18.7
Current receivables	82.3	253.9	95.4
Short-term investments	841.6	862.4	860.4
Cash and bank balances	155.8	181.0	217.5
<b>Total assets</b>	<b>1 517.7</b>	<b>1 763.8</b>	<b>1 616.3</b>
<b>Shareholders' equity and liabilities</b>			
Shareholders' equity	1 370.7	1 502.5	1 450.1
Long-term liabilities	32.7	16.8	30.8
Current liabilities	114.4	244.4	135.4
<b>Total shareholders' equity and liabilities</b>	<b>1 517.7</b>	<b>1 763.8</b>	<b>1 616.3</b>

## Consolidated Statement of Changes in Shareholders' Equity (SEK m)

	Share capital	Other paid-in capital	Exchange rate difference	Accumulated loss	Total shareholders' equity
<b>Opening balance, 1 January 2015</b>	<b>156.3</b>	<b>1 761.8</b>	<b>-4.0</b>	<b>68.5</b>	<b>1 982.6</b>
Total comprehensive income for the period	0.0	0.0	2.2	75.1	77.3
Share incentive plan: value of employee service	0.0	2.9	0.0	0.0	2.9
Redemption program	-21.5	-579.7	0.0	0.0	-601.2
Stock dividend issue	22.3	-22.3	0.0	0.0	0.0
Transaction costs	0.0	0.0	0.0	-1.4	-1.4
Tax effect on transaction costs	0.0	0.0	0.0	0.3	0.3
Repurchase of own shares	0.0	-10.4	0.0	0.0	-10.4
<b>Closing balance, 31 December 2015</b>	<b>157.1</b>	<b>1 152.3</b>	<b>-1.7</b>	<b>142.5</b>	<b>1 450.2</b>
<b>Opening balance, 1 January 2015</b>	<b>156.3</b>	<b>1 761.8</b>	<b>-4.0</b>	<b>68.5</b>	<b>1 982.6</b>
Total comprehensive income for the period	0.0	0.0	0.8	130.7	131.5
Share incentive plan: value of employee service	0.0	1.1	0.0	0.0	1.1
Redemption program	-21.5	-579.7	0.0	0.0	-601.2
Stock dividend issue	22.3	-22.3	0.0	0.0	0.0
Transaction costs	0.0	0.0	0.0	-1.4	-1.4
Tax effect on transaction costs	0.0	0.0	0.0	0.3	0.3
Repurchase of own shares	0.0	-10.4	0.0	0.0	-10.4
<b>Closing balance, 30 June 2015</b>	<b>157.1</b>	<b>1 160.9</b>	<b>-3.2</b>	<b>198.1</b>	<b>1 502.6</b>
<b>Opening balance, 1 January 2016</b>	<b>157.1</b>	<b>1 152.3</b>	<b>-1.7</b>	<b>142.5</b>	<b>1 450.2</b>
Total comprehensive income for the period	0.0	0.0	0.1	-80.2	-80.1
Share incentive plan: value of employee service	0.0	0.4	0.0	0.0	0.4
<b>Closing balance, 30 June 2016</b>	<b>157.1</b>	<b>1 152.7</b>	<b>-1.6</b>	<b>62.3</b>	<b>1 370.5</b>

## Consolidated Cash Flow Statement, summary (SEK m)

	Q2		Q1-Q2		Full Year
	2016	2015	2016	2015	2015
<b>Cash flow from operating activities before changes in working capital</b>	<b>-42.0</b>	<b>92.8</b>	<b>-91.4</b>	<b>177.3</b>	<b>107.6</b>
Changes in working capital	4.9	-28.4	17.9	92.3	199.8
<b>Cash flow from operating activities</b>	<b>-37.1</b>	<b>64.3</b>	<b>-73.5</b>	<b>269.6</b>	<b>307.4</b>
<b>Investing activities</b>					
Acquisition/sale of fixed assets	-5.0	-9.0	-6.8	-13.0	-20.1
Sale of operations	0.0	0.0	0.0	2.5	5.0
<b>Cash flow from investing activities</b>	<b>-5.0</b>	<b>-9.0</b>	<b>-6.8</b>	<b>-10.5</b>	<b>-15.0</b>
<b>Financing activities</b>					
Redemption program	0.0	0.0	0.0	-601.2	-601.2
Repurchase of own shares	0.0	-10.4	0.0	-10.4	-10.4
<b>Cash flow from financing activities</b>	<b>0.0</b>	<b>-10.4</b>	<b>0.0</b>	<b>-611.6</b>	<b>-611.6</b>
<b>Cash flow for the period</b>	<b>-42.0</b>	<b>44.9</b>	<b>-80.3</b>	<b>-352.5</b>	<b>-319.2</b>
Liquid assets at beginning of period	1 040.0	998.4	1 077.9	1 395.6	1 395.6
Change in liquid assets	-42.0	44.9	-80.3	-352.5	-319.2
Exchange rate difference, liquid assets	-0.4	0.1	-0.2	0.2	1.6
<b>Liquid assets at period end</b>	<b>997.5</b>	<b>1 043.4</b>	<b>997.5</b>	<b>1 043.4</b>	<b>1 077.9</b>

## Parent company income statement, summary (SEK m)

	Q2		Q1-Q2		Full year
	2016	2015	2016	2015	2015
Net turnover	43.5	210.5	70.7	380.3	500.8
Cost of goods and services sold	-13.2	-23.2	-20.4	-44.1	-57.8
<b>Gross profit</b>	<b>30.3</b>	<b>187.3</b>	<b>50.3</b>	<b>336.2</b>	<b>443.0</b>
Selling expenses	-10.3	-14.2	-19.9	-28.8	-57.8
Administrative expenses	-9.3	-15.1	-14.1	-26.5	-53.7
Research and development costs	-73.3	-60.4	-144.5	-119.9	-257.8
Other operating income/expenses	0.0	-2.1	2.9	-4.4	9.8
<b>Operating profit/loss</b>	<b>-62.7</b>	<b>95.5</b>	<b>-125.2</b>	<b>156.6</b>	<b>83.4</b>
Net financial items	3.4	-10.0	4.3	-2.5	-32.3
<b>Profit/loss after financial items</b>	<b>-59.3</b>	<b>85.5</b>	<b>-120.9</b>	<b>154.1</b>	<b>51.2</b>
Appropriations	0.0	0.0	0.0	0.0	-37.9
Tax	0.1	-19.4	-0.1	-34.5	-9.8
<b>Net profit/loss for the period</b>	<b>-59.1</b>	<b>66.1</b>	<b>-121.0</b>	<b>119.6</b>	<b>3.4</b>

## Parent company statement of comprehensive income (SEK m)

	Q2		Q1-Q2		Full year
	2016	2015	2016	2015	2015
Net profit/loss for the period	-59.1	66.1	-121.0	119.6	3.4
Other comprehensive income for the period, net after tax	0.0	0.0	0.0	0.0	0.0
<b>Total comprehensive income for the period</b>	<b>-59.1</b>	<b>66.1</b>	<b>-121.0</b>	<b>119.6</b>	<b>3.4</b>

## Parent company balance sheet, summary (SEK m)

	2016	2015	2015
	30 June	30 June	31 Dec
<b>Assets</b>			
Intangible fixed assets	17.1	19.0	17.1
Tangible fixed assets	29.3	28.9	26.1
Financial fixed assets	626.7	624.5	628.5
Inventories	2.0	2.1	2.3
Current receivables	59.2	231.2	80.3
Short-term investments	841.6	862.4	860.4
Cash and bank balances	41.9	79.1	80.9
<b>Total assets</b>	<b>1 617.9</b>	<b>1 847.2</b>	<b>1 695.6</b>
<b>Shareholders' equity and liabilities</b>			0.0
Shareholders' equity	1 202.0	1 436.6	1 322.2
Appropriations	37.9	0.0	37.9
Provisions	0.0	0.0	0.0
Long-term liabilities	75.3	0.0	0.0
Current liabilities	302.2	410.6	335.5
<b>Total shareholders' equity and liabilities</b>	<b>1 617.9</b>	<b>1 847.2</b>	<b>1 695.6</b>

## Key ratios, share data, options

	Q2 2016	Q1-Q2 2015	Full year 2015
Return on:			
- shareholders' equity, %	-3.1	9.7	5.9
- capital employed, %	-2.3	7.6	5.3
- total capital, %	-2.6	8.7	5.9
Number of shares at beginning of period, '000	26 966	31 260	31 260
Number of shares at period end, '000	26 966	26 966	26 966
- of which class A shares	606	606	606
- of which class B shares	26 230	26 230	26 230
- of which repurchased B shares	130	130.0	130
Average number of shares, '000	26 941	29 048	29 048
Outstanding warrants, '000	73	250	238
Share capital at period end, SEK m	157.2	156.3	157.2
Shareholders' equity at period end, SEK m	1 370.7	1 502.5	1 450.1
Earnings per share, SEK			
- Earnings per share, basic earnings	-2.98	4.50	2.59
- Earnings per share, diluted earnings	-2.97	4.46	2.56
Shareholders' equity per share, SEK	50.9	56.0	54.0
Net worth per share, SEK	50.9	56.0	54.0
Cash flow per share after investments, SEK	-1.6	8.9	10.1
Equity/assets ratio, %	90.3	85.2	89.7
EBITDA	-31.6	189.6	155.0
EBIT	-48.1	172.2	114.8
Operating margin, %	-59.2	37.3	17.4
R&D spending/total opex, %	73.0	61.1	64.2

### Key ratio definitions

**Average number of shares.** The unweighted average number of shares during the year.

**Basic earnings per share.** Profit/loss per share after financial items divided by the average number of shares.

**Capital employed.** Balance Sheet total less non-interest-bearing liabilities including deferred tax liabilities.

**Cash flow per share after investments.** Cash flow after investments divided by the average number of shares.

**Diluted earnings per share.** Profit/loss per share after financial items divided by the average number of shares and outstanding warrants adjusted for any dilution effect.

**EBIT (Earnings before interest and taxes).** Operating profit/loss after depreciation and amortisation.

**EBITDA (Earnings before interest, taxes, depreciation and amortisation).** Operating profit/loss before depreciation and amortisation.

**Equity/assets ratio.** Shareholders' equity in relation to the Balance Sheet total.

**Net worth per share.** Shareholders' equity plus hidden assets in listed equities divided by the number of shares at the period end.

**Operating margin.** Operating profit/loss as a percentage of net turnover.

**R&D spending/total OPEX.** Research and development costs divided by total operating costs.

**Return on capital employed.** Profit/loss after financial items plus financial expenses as a percentage of the average capital employed.

**Return on shareholders' equity.** Profit/loss after financial items as a percentage of the average shareholders' equity.

**Return on total assets.** Profit/loss after financial items plus financial expenses as a percentage of the average Balance Sheet total.

**Shareholders' equity per share.** Shareholders' equity divided by the number of shares at the period end.