Hansa Medical

Interim report July – September 2017

Positive data demonstrating potential of IdeS published in The New England Journal of Medicine

July-September in brief

- Combined data from three independent clinical Phase II studies with Hansa Medical's lead candidate IdeS was published in The New England Journal of Medicine 2017;377:442-53, August 3, 2017 issue. Data from these studies show that IdeS effectively reduces HLA antibodies and enables patients with very poor prognosis, who are unlikely to find a kidney donor, to be transplanted. Importantly, patients were doing well with good kidney function at last follow up.
- Patient enrollment on target to have all patients recruited and treated by the end of 2017 in two ongoing Phase II studies with lead candidate IdeS in highly sensitized patients in the US and Europe. All treated patients will be monitored for six months post treatment.
- Continued strengthening of the organization in preparation for additional Phase II studies with lead candidate IdeS.

Significant events after the end of the reporting period

- On November 8, 2017, Hansa Medical announced the sudden and unexpected passing of CEO Göran Arvidson. Ulf Wiinberg, chairman of Hansa Medical, will serve as acting CEO and board member Birgit Stattin Norinder will take over the role as chairman of the board until further notice.
- Updates on the clinical progress of IdeS in kidney transplant program were presented at Hansa Medical's well attended Capital Markets Days in Stockholm (October 3) and London (October 4). As of October 3, the number of patients treated with IdeS prior to kidney transplantation was 42. Follow-up data on the first patient transplanted after desensitization with IdeS in 2014 was presented, demonstrating continuous normalized creatinine levels three years' post kidney transplantation.
- Continued patient enrollment in the investigator initiated Phase II study with IdeS in anti-GBM, a rare kidney disease. As of November 14, five patients had been included in the study. Limited follow-up data is currently available from three of these five patients who have responded favorably. IdeS appears to be well tolerated in these patients so far. Patients enrolled in the study will be monitored for six months.

Ulf Wiinberg
Acting CEO

"Göran will be greatly missed by all of us, as a true professional and as a warm and inspiring person. We are firmly dedicated to continue the development of our company in the direction outlined by Göran and the board of directors. Göran's work in collaboration with the team in Lund and in the US, has taken us to a very strong position in the development of innovative immunomodulatory enzymes. I am very encouraged by the significant progress that has been made in the clinical development of IdeS in recent months. Our studies continue to demonstrate the potential of immunomodulatory enzymes both in transplant-related indications and in serious autoimmune diseases. Hansa is well positioned to be a pioneer in this field and we are pursuing our strategy of bringing important, life-saving products to patients."

Financial summary for the Group (KSEK)

	Q3		January–September		Year
KSEK, unless otherwise stated	2017	2016	2017	2016	2016
Net revenue	678	907	2,429	2,036	2,579
Operating profit/loss	-37,434	-26,954	-127,162	-77,573	-111,135
Net profit/loss	-37,527	-26,926	-127,672	-77,573	-111,129
Earnings per share before and after dilution (SEK)	-1,07	-0,83	-3,64	-2,39	-3,39
Shareholders' equity	167,890	138,806	167,890	138,806	283,693
Cash flow from operating activities	-38,427	-27,775	-120,963	-67,378	-94,563
Cash and cash equivalents including short term investments	130,871	103,948	130,871	103,948	253,578

CEO statement

We are very grateful for the time we had Göran at the helm of Hansa Medical. Through his inspiring and genuine commitment, he has built a strong growing biopharmaceutical company with clear and ambitious strategic plans and a dedicated organization capable of executing and delivering on milestone targets. Göran will be greatly missed by all of us, as a true professional and as a warm and inspiring person. We are firmly dedicated to continue the development of our company in the direction outlined by Göran and the board of directors. Göran's work in collaboration with the team in Lund and in the US, has taken us to a very strong position in the development of innovative immunomodulatory enzymes.

During the third quarter, we received further evidence that IdeS has great potential as a new and innovative treatment to enable life-saving kidney transplantation. In our ongoing clinical Phase II studies with IdeS a total of 42 patients have been transplanted, which reinforces our view that IdeS could represent an entirely new approach for eliminating HLA antibodies to enable transplantation for highly sensitized patients.

In line with the clinical progress, we have also gained increased attention from in the medical research community and among other stakeholders. In August, data was published from three independent clinical Phase II studies with IdeS in the high impact medical journal The New England Journal of Medicine. The article, titled *IgG Endopeptidase in Highly Sensitized Patients Undergoing Transplantation*, concludes that treatment with IdeS effectively reduces donor-specific antibodies (DSAs) to levels that enable life-saving transplantation for highly sensitized kidney transplant patients. This is a very important milestone for highly sensitized patients awaiting a kidney transplant and for us as a company.

In October, we hosted Capital Markets Days in Stockholm and in London, where we shared these important study results with our shareholders and provided details of our strategy for the company's next phase of development. During the events, senior management from Hansa Medical and leading transplant experts gave an update on our projects and the latest research findings. The interest from both our shareholders and the research community, further supports the relevance and medical importance of our research and development of immunomodulatory enzymes.

This year, in parallel with our innovative work in organ transplantation, we have taken the first important clinical steps to broaden the use of IdeS. We believe there is significant therapeutic potential for the fast and efficient IgG cleaving mechanism of action of IdeS in both serious transplant-related indications and acute autoimmune diseases, such as anti-GBM antibody disease.

As of today (November 14, 2017) five patients have been treated with IdeS in an ongoing investigator-initiated Phase II study in severe anti-GBM antibody disease, a rare and acute autoimmune disease in which the kidneys often are irreversibly damaged resulting in the need for dialysis treatment or kidney transplantation. Limited follow-up data is currently available from three of these five patients, who have responded favorably. IdeS appears to be well tolerated so far in these patients. In addition, prior to initiation of this clinical study, three patients with anti-GBM antibody disease were treated on a named patient basis in Sweden. Hence, a total of eight patients with anti-GBM disease have been treated with IdeS as of November 14, 2017.

In total, approximately 15 patients will be recruited to the anti-GBM study at up to 15 clinics in Europe. This may provide evidence that IdeS has the potential to be an important treatment in additional serious, acute IgG-mediated diseases for which no approved treatments exist today.

During this year, we have continued to build a strong and committed team expanding broadly in both R&D and marketing as well as in the medical department to which we recently hired two seasoned senior medical science liaisons in the US, to support our increasing presence in this important market for future anticipated launches. We have increased the number of co-workers significantly and are now around 40.

We have made significant investments in the IdeS production process during 2017 and we continue to prepare product supply for commercialization of IdeS. The processes have been transferred to manufacturers in Europe suitable for commercialization and the product we are preparing for launch is going to be a lyophilized product for easy off the shelf use and for convenient and effective world-wide distribution.

Naturally, we still have several milestones to achieve until we have a product on the market, but the overall progress in recent months is very encouraging and has further strengthened our belief in the future of IdeS. Our position to become a pharmaceutical company with important, life-saving products on the market is becoming more prominent for every milestone we reach and I look forward to updating you on our continued development.

Ulf Wiinberg
Acting CEO

Hansa Medical in brief

Hansa Medical is a biopharmaceutical company developing novel immunomodulatory enzymes for transplantation and acute autoimmune diseases. The lead product, IdeS, is a proprietary antibody-degrading enzyme currently in late-stage clinical development for kidney transplant patients, with significant potential for further development in other solid organ transplants and in acute autoimmune indications. The company also has a strong pipeline of preclinical projects that may provide a second wave of potential drugs. Under the project name NiceR, novel immunoglobulin cleaving enzymes are developed for repeat dosing with the objective of treating relapsing autoimmune diseases and cancer. Hansa Medical is based in Lund, Sweden, and its shares are listed on Nasdaq Stockholm (ticker: HMED).

Business overview

IdeS is an enzyme, currently in late stage clinical development, that specifically cleaves immunoglobulin G (IgG). Our strategy takes advantage of the ability of IdeS to specifically and efficiently inactivate IgG to prevent and treat patients who have developed pathogenic IgG. IdeS-mediated IgG elimination constitutes a novel therapeutic principle for the treatment of IgG-mediated acute human diseases.

NiceR is a program developing novel IgG inactivating drug candidates for repeat dosing, which may translate to wider usage in relapsing autoimmune diseases and oncology.

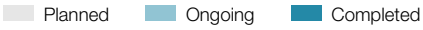
EndoS is an IgG-modulating enzyme that has proven efficacious in a range of autoimmune models. Preclinical research and development aiming at enabling clinical trials with EndoS in autoimmune diseases is ongoing.

EnzE is a preclinical research- and development program under which the combination use of approved antibody-based cancer treatments with IgG-modulating enzymes is explored in order to potentiate presently available antibody-based cancer therapies.

HBP-assay is a novel diagnostic method to help predict severe sepsis in patients with symptoms of infectious disease. The method has been evaluated in two clinical studies and is available on the market. HBP-assay has been out-licensed to UK-based Axis-Shield Diagnostics and the agreement is associated with royalties to Hansa Medical.

Pipeline

Candidate/ Method/Project	Indication	Research/ Preclinical	Phase I[1]	Phase I/II	Phase II	Pivotal	Registration
THERAPEUTICS							
IdeS	Kidney transplantation in sensitized patients[2]						
	Other kidney transplant indications (ABMR, ABOi)[3]						
	Anti-GBM antibody disease						
	Other acute autoimmune diseases[4]						
NiceR	Recurring treatment in autoimmune disease						
EndoS	Autoimmune disease						
EnzE	Cancer immunotherapy						
DIAGNOSTICS							
HBP-assay (IVD)	Prediction of severe sepsis[5]						



[1] Present and future IdeS Phase II studies to be based on the same Phase I study. Results from the Phase I study have been published, Winstedt el al. (2015) PLOS ONE 10(7).

[2] Two separate Phase II studies with IdeS in sensitized patients are currently ongoing. Results from finalized and partly ongoing Phase II studies have been published in N Engl J Med 2017;377:442-53.

[3] Phase II studies in antibody mediated rejection (ABMR) post kidney transplantation and blood-group incompatible (ABOi) kidney transplantation are being planned.

[4] Phase II studies in rare autoimmune conditions like GBS are being planned.

[5] Out-licensed to Axis-Shield Diagnostics Ltd.

Lead candidate IdeS

IdeS – A novel therapeutic principle

Our lead candidate drug, IdeS, represents a unique and novel approach to rapidly and effectively eliminate pathogenic IgG-antibodies. IdeS, Immunoglobulin G-degrading enzyme of Streptococcus pyogenes, specifically cleaves immunoglobulin G (IgG). Several autoimmune diseases are characterized by pathogenic IgG-antibodies and, in organ and tissue transplantation, pathogenic IgG-antibodies can prohibit patients from being transplanted or cause organ rejection after transplantation. Hansa Medical develops IdeS as a single intravenous treatment for fast and effective elimination of pathogenic IgG-antibodies in transplantation and acute autoimmune diseases.

Overview of Hansa Medical's clinical program with IdeS

The clinical development program is currently focused on treatment prior to kidney transplantation. The long-term vision for Hansa Medical is to establish IdeS as a therapy for fast and efficient elimination of pathogenic IgG in several transplant related indications and acute autoimmune diseases.

IdeS has been evaluated in a Phase I study [1] in healthy subjects and in three Phase II studies in sensitized patients awaiting kidney transplantation [2]. The results from these studies demonstrate that IdeS is highly effective in reducing anti-HLA antibodies to levels acceptable for transplantation and is well tolerated.

The efficacy and safety of IdeS is currently being investigated in two ongoing Phase II studies in highly sensitized kidney transplantation patients. We are planning additional Phase II studies within kidney transplantation in acute antibody mediated rejection (ABMR) post-kidney transplantation and desensitization prior to blood group incompatible (ABOi) kidney transplantation.

An investigator-initiated Phase II study with IdeS in the rare and acute autoimmune kidney disease anti-GBM antibody disease has been initiated in collaboration with several European nephrology clinics. In addition, we are planning a Phase II study with IdeS in Guillain-Barré syndrome (GBS), a rare and acute autoimmune disease.

Ongoing clinical studies with IdeS

IdeS – Desensitization prior to kidney transplantation

Latest developments

Combined data from three independent clinical Phase II studies with Hansa Medical's lead candidate IdeS was published in The New England Journal of Medicine 2017;377:442-53, August 3, 2017 issue. In the article *IgG Endopeptidase in Highly Sensitized Patients Undergoing Transplantation*, it is demonstrated that treatment with IdeS is effective in reducing donor specific HLA-antibodies (DSAs) to levels allowing kidney transplantation of highly sensitized patients. Data from these studies show that IdeS effectively reduces DSAs and enables patients with very poor prospects and who are unlikely to find a donor to be transplanted.

The studies, performed in Sweden and the US, included 25 HLA-sensitized patients who received IdeS immediately before kidney transplantation. All HLA-antibodies were eliminated in all patients after IdeS treatment prior to surgery. Of the 25 treated

and transplanted patients, 24 patients had good kidney function at last follow-up. One graft loss occurred in the U.S. study due to non-HLA IgM and IgA antibodies. Five biopsy confirmed episodes of acute antibody-mediated rejection (meeting the Banff criteria, Loupy et al., American Journal of Transplantation 2017; 17: 28–41) occurred in the 24 patients but all responded well to treatment. The article concludes that IdeS is generally well tolerated and effective in eliminating HLA antibodies including DSAs, thus enabling successful transplantation in highly sensitized patients.

The New England Journal of Medicine publication may be found online at: www.nejm.org, DOI: 10.1056/NEJMoa1612567

Currently, patient enrollment is ongoing in two open label single arm Phase II clinical studies with IdeS in highly sensitized patients, an investigator-initiated study at Cedars-Sinai Medical Center and the ongoing Hansa Medical-sponsored multicenter study named Highdes, initiated in October 2016. Highdes is enrolling highly sensitized patients at three US clinics and two European clinics. The primary objective of the Highdes study is to assess the efficacy of IdeS in creating a negative crossmatch test in highly sensitized patients with antibodies to the donor. As demonstrated in the recent publication in The New England Journal of Medicine above, IdeS effectively remove donor-specific antibodies and enables transplantation in patients who would otherwise not qualify for transplantation.

The objective is to have all patients recruited and treated in the two separate studies by the end of 2017. All treated patients will be monitored for six months post treatment.

IdeS – Treatment of anti-GBM antibody disease

Anti-GBM antibody disease, also known as Goodpasture disease, is a rare and acute autoimmune disease where autoantibodies directed against type IV collagen cause acute inflammation of the kidney and/or the lungs. In severe anti-GBM, the disease may progress to renal failure or death. Anti-GBM antibody disease is a rare disease affecting one in a million annually[3].

Latest developments

In June 2017, an investigator initiated Phase II study in severe anti-GBM antibody disease was initiated. The study (ClinicalTrials.gov identifier NCT03157037) is an open label investigator initiated Phase II study in severe anti-GBM antibody disease with Professor Mårten Segelmark at Linköping University Hospital, Sweden, as sponsor/coordinating principal investigator. Approximately 15 patients will be recruited to the study at up to 15 clinics in Europe. The primary objective of this study is to evaluate the safety and tolerability of IdeS in patients with severe anti-GBM antibody disease in addition to standard-of-care consisting of pulse-methyl- prednisolone, oral prednisolone and intravenous cyclophosphamide (CYC) combined with plasma exchange (PLEX). IdeS efficacy will be assessed by evaluating renal function at six months after IdeS treatment.

As of November 14, five patients have been included in the study. Limited follow-up data is currently available from three of these five patients, who have responded favorably. IdeS appears to be well tolerated so far in these patients. In addition, prior to site initiation of this ongoing study, three patients were treated on a named patient basis in Sweden. Hence, a total of eight patients with anti-GBM disease have been treated with IdeS as of November 14, 2017.

Overview of completed and ongoing clinical trials with lead candidate IdeS

Study	Study site	Subjects	Status
Phase I	Lund University Hospital, Sweden	29 healthy subjects, randomized placebo controlled dose-escalation study.	● Completed 2014. Conclusion: IdeS is efficacious and well tolerated with a favorable safety profile.
Phase II in kidney transplantation	Uppsala University Hospital, Sweden	8 sensitized patients, dose finding study.	● Completed 2015. Conclusion: IdeS treatment resulted in HLA levels acceptable for transplantation in all patients.
Phase II in kidney transplantation	Uppsala University Hospital, Sweden Karolinska University Hospital, Sweden	10 sensitized patients, with transplantation.	● Completed 2016. Conclusion: IdeS enabled kidney transplantation for all patients with a favourable safety profile.
Phase II in kidney transplantation (Investigator initiated)	Cedars Sinai Medical Center, Los Angeles, USA	20 sensitized patients, with transplantation.	● Ongoing. Top line results demonstrates that IdeS completely eliminates donor specific IgG antibodies and enables transplantation for HLA-sensitized patients.
Highdes – Phase II in kidney transplant-ation	Cedars Sinai Medical Center, Los Angeles, USA NYU Langone Medical Center, New York, USA Johns Hopkins Medicine, Baltimore, USA Uppsala University Hospital, Sweden Necker Hospital, Paris, France	20 refractory HLA sensitized patients, with transplantation.	● Ongoing. Recruitment to be completed in 2017.
Phase II in anti-GBM (Investigator initiated)	Europe. Several sites.	15 patients with anti-GBM antibody disease.	● Ongoing.

Table A. IdeS has been evaluated in a Phase I study in healthy subjects and in two Phase II studies in sensitized patients awaiting kidney transplantation. The results in these studies indicate that IdeS is highly effective in reducing anti-HLA antibodies to levels acceptable for transplantation with a favorable safety profile. Currently, two additional Phase II studies are ongoing with IdeS in sensitized patients prior to kidney transplantation – an investigator-initiated US Phase II study at Cedars-Sinai Medical Center in Los Angeles, and a Hansa Medical-sponsored multi-center study in the US, Sweden and France. In addition, a Phase II in the rare autoimmune disease anti-GBM is ongoing.

Manufacturing of IdeS

The IdeS drug product being evaluated in the ongoing studies is a frozen 10 mg/ml solution. During 2016 and 2017, Hansa Medical has made significant investments in process development and the processes have been transferred to manufacturers in Europe suitable for commercialization. The product being prepared for commercialization is a lyophilized product. The first GMP batch for further clinical studies and commercial supply is being produced in the fourth quarter of 2017. Full process characterization and validation for commercial supply is scheduled to be completed in the third quarter of 2018.

Regulatory strategy for IdeS in desensitization

The Highdes study is recruiting patients who have either failed on previous attempts of desensitization, are likely to fail desensitization with currently available methods or patients for whom it is highly unlikely to identify a suitable donor organ. Hansa Medical will seek to gain accelerated approval and aims to obtain market authorization in the US and Europe for IdeS for this category of patients as soon as possible. In May 2017 the European Medicines Agency (EMA) granted IdeS access to its Priority Medicines (PRIME) scheme for desensitization of highly sensitized kidney patients. Under the PRIME scheme, Hansa Medical is working in close collaboration with EMA for accelerated development of IdeS towards submission of a Market Authorization Application (MAA) for EU marketing authorization. Similarly, Hansa Medical will seek scientific advise from the US Food and Drug Administration through an end of Phase II meeting during 2018 for accelerated development of IdeS towards submission of a Biologics License Application (BLA) in the US.

Provided that the results from the Highdes study demonstrates that it is possible to transplant these patients and to achieve a reasonable outcome i.e. a functioning kidney at 6 months post transplantation, it is anticipated that the Highdes study, together with the results of the completed and ongoing studies, will provide data to support a BLA and an MAA.

Planned clinical studies with IdeS in additional indications

Treatment of kidney transplant antibody-mediated rejection (ABMR)

Approximately 10 percent[4] of all transplant patients experience ABMR post-transplant. Although different experimental protocols are used in the treatment of ABMR, there is currently no approved treatment.

Blood-group incompatible (ABOi) kidney transplantation

ABOi transplantations have increased worldwide in order to shorten the long waiting times for transplantation[5]. If levels of preformed antibodies to donor blood group antigens are not decreased to low levels prior to ABOi transplantation they will result in severe ABMR and early graft loss.

Treatment of Guillain-Barré syndrome (GBS)

GBS is an acute autoimmune disease in which the peripheral nervous system is attacked by the immune system and IgG-antibodies. It affects one in 100,000 annually[6]. In February 2017, preclinical data demonstrating the treatment potential of IdeS in GBS were published[7]. In a model of GBS, inactivation of IgG by IdeS treatment significantly promoted the recovery and reduced the degeneration of peripheral nerves. The data show that treatment with IdeS could potentially become a novel therapeutic strategy for the treatment of GBS.

Preclinical development projects

NiceR

Hansa Medical develops novel IgG-degrading enzymes under the project name NiceR (Novel Immunoglobulin Cleaving Enzymes for Repeat dosing). The aim of project NiceR is to create novel IgG-inactivating biopharmaceuticals which can be used for repeated dosing in acute autoimmune conditions where patients would benefit from more than one dose of an IgG-modulating enzyme. Several novel IgG-eliminating enzymes have been designed and the program is currently in preclinical development.

EnzE – Enzyme-based antibody Enhancement

Recently published findings[8] demonstrate how pre-treatment with IdeS in tumor animal models can increase the efficacy of currently available antibody based cancer therapies. This treatment concept is investigated under the project name EnzE, Enzyme-based antibody Enhancement. The published data demonstrate the potential of an IgG-clearing agent as a pre-treatment for cancer patients. High levels of plasma IgG have been shown to limit the efficacy of therapeutic antibodies, as plasma IgG can saturate the receptors of the patient's immune cells preventing them from efficiently killing the tumor cells. Removing inhibiting IgG antibodies with IdeS or novel IgG-clearing enzymes prior to dosing the patient with a therapeutic antibody can potentially increase the efficacy of the given cancer therapy.

The publication entitled *Enzymatic inactivation of endogenous IgG by IdeS enhances therapeutic antibody efficacy*[8] show that IdeS is a potent tool to reboot the human antibody repertoire and to generate a window to preferentially load therapeutic antibodies onto effector cells. Pre-treatment with IdeS could be a potential new treatment to unblock the receptors of immune cells thereby enabling the full potential of the therapeutic antibodies. Hansa Medical is currently evaluating strategic options for EnzE.

EndoS – Treatment of autoimmune diseases

EndoS, Endoglycosidase of *Streptococcus pyogenes*, is an enzyme that specifically hydrolyzes the functionally important glycan in IgG. EndoS has proven to be active in a range of preclinical autoimmune models, including rheumatoid arthritis (RA), immune thrombocytopenic purpura (ITP), autoimmune hemolysis, multiple sclerosis (MS) and autoimmune blistering skin disorder. Given the importance, we believe that EndoS may have the potential to become a novel therapy for autoimmune diseases.

Out-licensed royalty generating programs

HBP – Prediction of severe sepsis

The HBP-assay for measurement of Heparin Binding Protein in plasma is a novel diagnostic method originally developed and patented by Hansa Medical to assist in predicting severe sepsis in patients with infectious disease symptoms at emergency departments[9]. Hundreds of thousands of patients die every year due to severe sepsis as a complication to infections, e.g. urinary tract infection and pneumonia. Many of these infections can be effectively treated with antibiotics in order to prevent progression to severe sepsis although early prediction of risk patients is crucial for successful treatment. Severe sepsis affects 300 of 100,000 people annually[10].

The HBP-assay has been out-licensed by Hansa Medical to UK-based Axis-Shield Diagnostics, a subsidiary to Alere Inc. and Hansa Medical holds the right to royalty payments from Axis-Shield. Axis-Shield is engaged in further product development and clinical development with the HBP-assay. For more information, please visit: www.heparinbindingprotein.com

Financial review January–September 2017

Net revenue

Net revenue for the third quarter 2017 amounted to SEK 0.7m (0.9) and to SEK 2.4m (2.0) year to date 2017 and is comprised of royalty income from Axis-Shield Diagnostics and re-invoiced expenses.

Other operating income

Other operating income amounted to SEK 2.8m for the third quarter 2017 and to SEK 2.0m year to date 2017 and is comprised mainly of a grant from Vinnova.

Sales, general and administration expenses

Sales, general and administration expenses for the third quarter 2017 amounted to SEK 9.6m (8.0) and to SEK 30.1m (21.3) year to date 2017. The increase year to date is explained by commercial build-up and recorded non-cash costs for the company's employee long term incentive program (LTIP 2016) amounting to SEK 2.9m.

Research and development expenses

Research and developments expenses amounted to SEK 31.2m (19.5) for the third quarter 2017 and to SEK 101.3m (57.8) year to date 2017 and include recorded non-cash costs for the company's long term incentive programs (LTIP 2016) amounting to SEK 3.6m. The increase year to date was mainly due to intensified CMC development and continued build-up of the clinical and regulatory organization.

Financial result

Operating result for the third quarter 2017 amounted to SEK -37.4m (-27.0) and SEK -127.2m (-77.6) year to date 2017.

Net profit/loss for the third quarter 2017 amounted to SEK -37.5m (-26.9) and to SEK -127.7m (-77.6) year to date 2017.

Cash flow and investments

Cash flow from operating activities amounted to SEK -38.4m (-27.8) for the third quarter 2017 and to SEK -121.0m (-67.4) year to date 2017. Cash and cash equivalents including short term investments amounted to SEK 130.9m on September 30 2017, as compared with SEK 170.0m at the end of second quarter 2017.

Investments for the third quarter 2017 amounted to SEK 0.7m (2.0) and to SEK 1.7m (4.8) year to date 2017.

Shareholders' equity

On September 30, 2017 equity amounted to SEK 167.9m compared with SEK 138.8m at the end of the corresponding period 2016.

Parent company

The parent company's net revenue for the third quarter 2017 amounted to SEK 0.7m (0.9) and to SEK 2.4m (2.0) year to date 2017. Profit/loss for the parent company amounted to SEK -37.5m (-23.0) for the third quarter and to SEK -127.5m (-74.9) year to date 2017. On September 30, 2017, cash and cash equivalents including short term investments amounted to SEK 128.6m compared with SEK 167.7m at the end of second quarter 2017.

The parent company's equity amounted to SEK 157.9m as per September 30, 2017, as compared with SEK 137.3m at the end of the corresponding period 2016.

The Group consists of the parent company Hansa Medical AB and the subsidiaries Cartela R&D AB and Immago Biosystems Ltd, in which no business is currently conducted.

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Cash and cash equivalents including short term investments	130,871	103,948	130,871	103,948	253,578

Other information

Employees and organization

The number of employees at the end of the third quarter 2017 was 34, compared to 23 at the end of corresponding period 2016.

Share warrant program

On September 2, 2015, Hansa Medical's Annual General Meeting adopted a share warrant program for the company's employees. 355,000 warrants have been acquired by the company's employees during 2015 and 2016. Each warrant entitles the holder to subscribe for one new share in Hansa Medical. Subscription for shares in accordance with the terms of the warrants may take place during the period from June 15, 2018 to June 15, 2019. The warrants were sold to the company's employees on market terms at a price established on the basis of an estimated market value of the warrants using the Black & Scholes model calculated by an independent valuation institute.

The increase in the company's share capital upon full exercise of the share warrants will amount to SEK 355,000, and corresponds to a dilution of 1.1 percent of the total number of shares and the total number of votes in the company. The option program is subsidized by the company, and the employees, except the CEO, have been given a one-time bonus as part of the stock option purchase. The options are linked to continued employment with the company only in the sense that, if the employment would be terminated, the stock option owner shall offer the warrants to the company and repay the resulting subsidy. The subsidy will affect the company's results proportionately during the option period in accordance with the same principles as in IFRS 2.

Long-term incentive program (LTIP 2016)

The Hansa Medical's Extraordinary General Meeting November 21, 2016 resolved to adopt a long-term incentive program (LTIP 2016) in the form of a performance based share program for all employees of the Hansa Medical Group, meaning that not more than 30 individuals within the group may participate. The rationale for LTIP 2016 is to create conditions for motivating and retaining competent employees of the Hansa Medical group and for the alignment of the targets of the employees with those of the shareholders and the company, as well as to increase the motivation of meeting and exceeding the company's financial targets. A maximum of 305,000 rights may be allotted to participants under LTIP 2016 and 289,750 rights have been totally allocated at September 30, 2017. Participants will, provided that certain conditions are fulfilled, be granted the opportunity to obtain ordinary shares free of charge, i.e. so-called "Performance shares" after the vesting period. The rights allocated on September 30, 2017, are divided into two vesting periods, the first of which ends November 28, 2019 and the second May 18, 2020.

The general meeting further resolved, in order to implement LTIP 2016 cost effectively, to authorize the Board to decide on a directed share issue of a maximum of 401,000 Class C shares to a participating bank, of which a maximum of 96,000 Class C shares to be issued to cover any social costs arising from the program and to authorize the Board to resolve to repurchase all issued C-shares. The directed share issue of the 401,000 Class C-shares and the repurchase were executed in May 2017. After the conversion of C shares to ordinary shares, these shall partly be transferred to participants in LTIP 2016 and partly divested in the market for cash flow purposes to secure certain payments related to LTIP 2016, mainly social security costs. Not more than 305,000 ordinary shares can be transferred to participants under LTIP 2016 and 96,000 common shares can be used to cover any social security contributions due to the LTIP 2016, which means a dilution of 1.2 per cent of the ordinary shares and votes in the company.

LTIP 2016 will be reported in accordance with IFRS 2 which means that rights should be expensed as a personnel cost over the vesting period. The cost of LTIP 2016, calculated in accordance with IFRS 2, including social security contributions is expected to amount to approximately SEK 28.6 m, of which SEK 6.5 m is included in the results for the parent company and the group year to date 2017. The program is not expected to have any net effect on cash flow provided it is secured fully in the manner described above.

Committee for the 2018 Annual General Meeting

Hansa Medical AB's Nomination Committee for the AGM 2018 will consist of Erika Kjellberg Eriksson representing Nexttobe AB, Max Mitteregger representing Gladiator AB and Sven Sandberg representing Thomas Olausson. It also includes the chairman of the board Ulf Wiinberg as convener.

Financial calendar

Year-end report 2017	14 February 2018
Annual report 2017	11 April 2018
Interim report for January–March 2018	25 April 2018
Annual General Meeting	29 May 2018
Interim report for January–June 2018	19 July 2018
Interim report for January–September 2018	1 November 2018

Shareholder information

The Hansa Medical share is listed on Nasdaq OMX Stockholm, under the ticker HMED and in the following indexes:

- OMX Nordic Mid Cap
- OMX Nordic Health Care index
- OMX Stockholm Benchmark Index
- OMX Stockholm Health Care
- OMX Stockholm Pharmaceuticals & Biotechnology
- MSCI Global Small Cap
- NASDAQ Biotechnology Index

Brief facts, the HMED share

Listing	Nasdaq OMX Stockholm
Number of shares	35,455,860
	(35 054 860 A-shares and 401 000 C-shares)
Market capitalization September 30, 2017	SEK 7,537 m
Ticker	HMED
ISIN	SE0002148817

10 largest shareholders, September 30, 2017

Name	Number of shares	Share (%)
Nexttobe AB	9,443,761	26.9
AFA Försäkring	1,686,959	4.8
Försäkringsbolaget, Avanza Pension	1,351,328	3.9
Gladiator	1,348,849	3.8
Olausson, Thomas	1,049,001	3.0
Handelsbanken fonder	1,024,966	2.9
Tredje AP-Fonden	723,684	2.1
BWG Invest	600,370	1.7
Catella Fondförvaltning	588,083	1.7
Sven Sandberg	527,500	1.5
Other	16,710,359	47.7
In total	**35,054,860**	**100.0**

According to the shareholder register maintained by Euroclear Sweden AB, as of September 30, 2017, Hansa Medical had 11,469 shareholders. On September 30 2016, Hansa Medical had 4,923 shareholders. Information regarding shareholders and shareholdings is updated each quarter on the company's website, www.hansamedical.com.

Legal disclaimer

This financial report includes statements that are forward looking, and actual future results may differ materially from those stated. In addition to the factors discussed, among other factors that may affect results are development within research programs, including development in preclinical and clinical trials, the impact of competing research programs, the effect of economic conditions, the effectiveness of the company's intellectual property rights and preclusions of potential second party's intellectual property rights, technological development, exchange rate and interest rate fluctuations and political risks.

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Registration number

556734-5359

Condensed financial statements

Consolidated statement of comprehensive income

	Q3		January– September		Year
KSEK	2017	2016	2017	2016	2016
Net revenue	678	907	2,429	2,036	2,579
Direct cost of net revenue	-54	-55	-168	-163	-217
Gross profit	**624**	**852**	**2,261**	**1,873**	**2,362**
Other operating income	2,778	–	2,047	–	–
Sales, general and administration expense	-9,617	-7,972	-30,103	-21,272	-29,703
Research and development expenses	-31,219	-19,460	-101,292	-57,837	-82,850
Other operating expenses	–	-374	-75	-337	-944
Operating profit/loss	**-37,434**	**-26,954**	**-127,162**	**-77,573**	**-111,135**
Financial income/expenses	-103	28	-539	–	-17
Profit/loss for the period before tax	**-37,537**	**-26,926**	**-127,701**	**-77,573**	**-111,152**
Tax	10	–	29	–	23
Net profit/loss for the period	**-37,527**	**-26,926**	**-127,672**	**-77,573**	**-111,129**
Attributable to					
Parent company shareholders	-37,527	-26,926	-127,672	-77,573	-111,129
Earnings per share					
Before dilution (SEK)	-1,07	-0,83	-3,64	-2,39	-3,39
After dilution (SEK)	-1,07	-0,83	-3,64	-2,39	-3,39
Other comprehensive income					
Items that have been, or may be reclassified to profit or loss for the period					
Translation differences	-31	-32	-66	-32	-26
Changes in fair value on available-for-sale financial assets	5,439	5,496	8,289	4,181	4,690
Other comprehensive income for the period	**5,408**	**5,464**	**8,223**	**4,149**	**4,664**
Total net comprehensive income	**-32,119**	**-21,462**	**-119,449**	**-73,424**	**-106,465**

Consolidated balance sheet

	September 30		December 31
KSEK	2017	2016	2016
ASSETS			
Non-current assets			
Intangible fixed assets	34,221	37,287	36,554
Tangible fixed assets	3,701	2,097	2,570
Financial fixed assets	22,849	14,052	14,566
Total non-current assets	**60,771**	**53,436**	**53,690**
Current assets			
Current receivables, non-interest bearing	3,275	1,390	3,404
Short-term investments	104,975	49,983	39,990
Cash and cash equivalents	25,896	53,965	213,588
Total current assets	**134,146**	**105,338**	**256,982**
TOTAL ASSETS	**194,917**	**158,774**	**310,672**
EQUITY AND LIABILITIES			
Shareholders' equity	**167,890**	**138,806**	**283,693**
Long term liabilities			
Deferred tax liabilities	537	603	581
Other provisions	3,030	–	114
Long term liabilities, interest bearing	574	547	552
Total long term liabilities	**4,141**	**1,150**	**1,247**
Current liabilities			
Current liabilities, interest bearing	18	44	44
Current liabilities, non-interest bearing	4,379	1,852	8,390
Accrued expenses and deferred income	18,489	16,922	17,298
Total current liabilities	**22,886**	**18,818**	**25,732**
TOTAL EQUITY AND LIABILITIES	**194,917**	**158,774**	**310,672**

Consolidated changes in equity

	January– September		Year
KSEK	2017	2016	2016
Opening shareholders' equity	**283,693**	**211,526**	**211,526**
Result for the period	-127,672	-77,573	-111,129
Other comprehensive income for the period	8,223	4,149	4,664
Net comprehensive income	**-119,449**	**-73,424**	**-106,465**
Transactions with the group's owner			
New share issue [1]	401	–	185,000
Expenses attributable to new share issue	-110	–	-7,504
Repurchase own shares [1]	-401	–	–
Issued warrants	161	704	772
Long term incentive program	3,595	–	364
Total transactions with the group's owner	**3,646**	**704**	**178,632**
Closing shareholders' equity	**167,890**	**138,806**	**283,693**

1) Values for 2017 refer to directed share issue and repurchase of 401,000 class C shares for financing of the company's long term incentive program (LTIP 2016).

Consolidated cash flow statement

	Q3		January– September		Year
KSEK	2017	2016	2017	2016	2016
Operating activities					
Operating profit/loss	-37,434	-26,954	-127,162	-77,573	-111,135
Adjustment for items not included in cash flow [1]	3,364	907	9,467	2,769	4,269
Interest received and paid, net	-139	-27	-581	-55	-78
Income taxes received and paid, net	-148	553	-217	144	–
Cash flow from operations before change in working capital	**-34,357**	**-25,521**	**-118,493**	**-74,715**	**-106,944**
Change in working capital	-4,070	-2,254	-2,470	7,337	12,381
Cash flow from operating activities	**-38,427**	**-27,775**	**-120,963**	**-67,378**	**-94,563**
Investing activities					
Acquisition of business, net cash effect	–	-1,924	–	-1,924	-1,924
Investments in intangible fixed assets	–	–	–	–	-57
Investments in tangible fixed assets	-698	-82	-1 677	-298	-927
Investment of financial assets	–	–	–	-2,588	-2,588
Short term investments	-34,989	-64,978	-205,909	-164,927	-194,918
Divestment short term investments	35,000	115,000	141,000	115,000	155,000
Cash flow from investing activities	**-687**	**48,016**	**-66,586**	**-54,737**	**-45,414**
Financing activities					
New share issue [2]	–	–	401	–	185,000
Issue expenses	–	–	-110	–	-7,504
Repurchase own shares [2]	–	–	-401	–	–
Issued warrants	–	3	–	429	429
Repayment of leasing liabilities	-11	-10	-33	-32	-43
Cash flow from financing activities	**-11**	**-7**	**-143**	**397**	**177,882**
Net change in cash	**-39,125**	**20,234**	**-187,692**	**-121,718**	**37,905**
Cash and cash equivalents, beginning of period	65,021	33,731	213,588	175,683	175,683
Cash and cash equivalents, end of period	**25,896**	**53,965**	**25,896**	**53,965**	**213,588**

1) Values for 2017 pertain mainly to costs of share based incentiveprograms including social contributions.

2) Values for 2017 refer to directed share issue and repurchase of 401,000 class C shares for financing of the company's long term incentive program (LTIP 2016).

Consolidated key ratios and other information

	Q3		January– September		Year
KSEK, unless otherwise stated	2017	2016	2017	2016	2016
Profit numbers					
Net revenue	678	907	2,429	2,036	2,579
Operating profit/loss	-37,434	-26,954	-127,162	-77,573	-111,135
Net profit/loss	-37,527	-26,926	-127,672	-77,573	-111,129
Per share data					
Earnings/loss per share before and after dilution (SEK)	-1,07	-0,83	-3,64	-2,39	-3,39
Shareholders' equity per share (SEK)	4,79	4,28	4,79	4,28	8,09
Other information					
Equity ratio (%)	86	87	86	87	91
Cash and cash equivalents including short term investments	130,871	103,948	130,871	103,948	253,578
Number of outstanding shares at the end of the period	35,054,860	32,412,003	35,054,860	32,412,003	35,054,860
Weighted average number of shares before and after dilution	35,054,860	32,485,477	35,054,860	32,485,477	32,773,304

Parent company – Statement of comprehensive income

	Q3		January– September		Year
KSEK	2017	2016	2017	2016	2016
Net revenue	678	907	2,429	2,036	2,579
Direct cost of net revenue	-54	-55	-168	-163	-217
Gross profit	**624**	**852**	**2,261**	**1,873**	**2,362**
Other operating income	2,778	–	2,047	–	–
Sales, general and administration expenses	-9,629	-7,970	-30,119	-21,262	-29,690
Research and development expenses	-31,154	-19,460	-101,105	-57,837	-82,735
Other operating expenses	–	-374	-75	-337	-944
Operating profit/loss	**-37,381**	**-26,952**	**-126,991**	**-77,563**	**-111,007**
Result from other securities and receivables which are fixed assets	–	3,943	–	2,628	2,628
Result from short term financial receivables	42	–	69	–	–
Other financial expenses	-145	28	-607	3	-14
Profit/loss for the period (before and after taxes)	**-37,484**	**-22,981**	**-127,529**	**-74,932**	**-108,393**
Other comprehensive income for the period	**–**	**–**	**–**	**–**	**–**
Total net comprehensive income	**-37,484**	**-22,981**	**-127,529**	**-74,932**	**-108,393**

Parent company – Balance sheet

	September 30		December 31
KSEK	2017	2016	2016
ASSETS			
Non-current assets			
Intangible fixed assets	31,410	34,216	33,513
Tangible fixed assets	3,701	2,067	2,554
Financial fixed assets	17,317	17,317	17,317
Total non-current assets	**52,428**	**53,600**	**53,384**
Current assets			
Current receivables, non-interest bearing	3,433	1,389	3,504
Short-term investments	104,974	49,983	39,995
Cash and cash equivalents	23,623	51,706	211,329
Total current assets	**132,030**	**103,078**	**254,828**
TOTAL ASSETS	**184,458**	**156,678**	**308,212**
EQUITY AND LIABILITIES			
Shareholders' equity	**157,903**	**137,319**	**281,786**
Long term liabilities			
Other provisions	3,030	–	114
Long term liabilities, non-interest bearing	574	532	548
Total long term liabilities	**3,604**	532	**662**
Current liabilities			
Liabilities to group companies	98	98	98
Current liabilities, non-interest bearing	4,364	1,807	8,368
Accrued expenses and deferred income	18,489	16,922	17,298
Total current liabilities	**22,951**	**18,827**	**25,764**
TOTAL EQUITY AND LIABILITIES	**184,458**	**156,678**	**308,212**

Parent company – Changes in equity

	January– September		Year
KSEK	2017	2016	2016
Opening shareholders' equity	**281,786**	**211,547**	**211,547**
Result for the period	-127,529	-74,932	-108,393
New share issue [1]	401	–	185,000
Expenses attributable to new share issue	-110	–	-7,504
Repurchase own shares [1]	-401	–	–
Issued warrants	161	704	772
Long term incentive program	3,595	–	364
Total transactions with the group's owner	**3,646**	**704**	**178,632**
Closing shareholders' equity	**157,903**	**137,319**	**281,786**

1) Values for 2017 refer to directed share issue and repurchase of 401,000 class C shares for financing of the company's long term incentive program (LTIP 2016).

Financial notes

Note 1 Basis of Preparation and Accounting policies

This consolidated interim report has been prepared in accordance with IAS 34 Interim Financial Reporting and applicable rules in the Swedish Annual Accounts Act. The interim report for the parent Company has been prepared in accordance with the Swedish Annual Accounts Act chapter 9, Interim Financial Reporting. A full description of the accounting principles applied in this interim report can be found in the Annual Report 2016. The Annual report 2016 was published on April 26, 2017 and is available on www.hansamedical.com. Disclosures in accordance with IAS 32.16A are as applicable in the notes or on the pages before the consolidated income statement.

Note 2 Fair value of financial instruments

The reported value is assessed as being a fair approximation of the fair value for all of the Group's financial instruments. The financial instruments reported at fair value in the balance sheet are comprised partly of the Group's holding of shares in Genovis, which are listed on Nasdaq First North and partly of holdings of short-term commercial papers. The fair value of the shares as per the balance sheet date September 30, 2017 was SEK 22,849k, SEK 14,052k on September 30, 2016 and SEK 14,566k on December 31, 2016. The fair value of the commercial papers as per the balance sheet date September 30, 2017 was SEK 104,975k, SEK 49,983k on September 30, 2016 and SEK 39,990k on December 31, 2016. The fair value of the financial instruments is calculated on the basis of the closing price. The valuation of the holdings is, thereby, in accordance with Level 1 in the valuation hierarchy.

Reference list

1. Winstedt el al., “Complete Removal of Extracellular IgG Antibodies in a Randomized Dose Escalation Phase I Study with the Bacterial Enzyme IdeS – A Novel Therapeutic Opportunity”, PLOS ONE 2015, 10(7)

2. Jordan et al., “IgG Endopeptidase in Highly Sensitized Patients Undergoing Transplantation”, N Engl J Med 2017;377:442-53.

3. Kluth et al., “Anti-Glomerular Basement Membrane Disease”, J Am Soc Nephrol. 1999 Nov;10(11):2446-53

4. Puttarajappa et al., “Antibody-Mediated Rejection in Kidney Transplantation: A Review”, J. Transplant.Volume 2012 (2012), Article ID 193724

5. Koo et al., “Current progress in ABO-incompatible kidney transplantation “, Kidney Res Clin Pract 34 (2015) 170–179

6. McGrogan et al., “The Epidemiology of Guillain-Barré Syndrome Worldwide“, Neuroepidemiology;2009, 32(2):150-63

7. Wang et al. “IgG-degrading enzyme of Streptococcus pyogenes (IdeS) prevents disease progression and facilitates improvement in a rabbit model of Guillain-Barré syndrome”, Exp Neurol. 2017 May;291:134-140

8. Järnum et al., “Enzymatic inactivation of endogenous IgG by IdeS enhances therapeutic antibody efficacy”, Molecular Cancer Therapeutics, 2017, May 22

9. Linder et al., “Heparin-binding protein improves prediction of severe sepsis in the emergency department”, Critical Care, 2013; 17(Suppl 4): P3

10. Mayr et al., “Epidemiology of severe sepsis”, Virulence 5:1, 4-11, January 1, 2014

Glossary

ABMR
Antibody mediated transplant rejection.

Antibody
One type of proteins produced by the body's immune system with the ability to recognize foreign substances, bacteria or viruses. Antibodies are also called immunoglobulins.

Anti-GBM disease (Goodpasture disease)
Anti-GBM antibody disease is a disorder in which circulating antibodies directed against an antigen intrinsic to the glomerular basement membrane (GBM) in the kidney, thereby resulting in acute or rapidly progressive glomerulonephritis.

Autoimmune disease
Diseases that occur when the body's immune system reacts against the body's own structures.

Biopharmaceutical
A pharmaceutical drug that is manufactured using biotechnology.

Biotechnology
The use of live cells or components of cells, to produce or modify products used in health care, food, and agriculture.

Clinical studies
Investigation of a new drug or treatment using healthy subjects or patients with the intention to study the efficacy and safety of a not-yet-approved treatment approach.

Clinical Phase I
The first time that a drug under development is administered to humans. Phase I studies are often conducted with a small number of healthy volunteers to assess the safety and dosing of a not yet approved form of treatment.

Clinical Phase II
Refers to the first time that a drug under development is administered to patients for the study of safety, dosage and efficacy of a not yet approved treatment regimen.

Clinical Phase III
Trials that involve many patients and often continue for a longer time; they are intended to identify the drug's effects and side effects during ordinary but still carefully controlled conditions.

EMA
The European Medicines Agency (EMA) is a European Union agency for the evaluation of medicinal products.

EndoS
A bacterial endoglycosidase of *Streptococcus pyogenes*. An enzyme with the unique ability to modify a specific carbohydrate chain of immunoglobulins.

Enzyme
A protein that accelerates or starts a chemical reaction without itself being consumed.

FDA
US Food and Drug Administration.

Guillain–Barré syndrome
GBS, Guillain–Barré syndrome, is an acute autoimmune disease in which the peripheral nervous system is attacked by the immune system and IgG antibodies.

HBP
Heparin Binding Protein is a naturally occurring protein that is produced by certain immune cells, i.e. neutrophilic granulocytes, to direct immune cells from the bloodstream into the tissues.

HLA
Human Leukocyte Antigen is a protein complex found on the surface of all cells in a human. The immune system uses HLA to distinguish between endogenous and foreign.

IdeS
IdeS, immunoglobulin G-degrading enzyme of *Streptococcus pyogenes*, a bacterial enzyme with strict specificity for IgG antibodies. The enzyme has a unique ability to cleave and thereby inactivate human IgG antibodies.

IgG
IgG, Immunoglobulin G, is the predominant type of antibody in serum.

In vitro
Term within biomedical science to indicate that experiments or observations are made, for example in test tubes, i.e. in an artificial environment and not in a living organism.

In vivo
Term within biomedical science to indicate that experiments or observations are made on living organisms.

IVD
IVD, *In vitro* diagnostics, are tests that can detect diseases, conditions, or infections, usually from blood samples or urine samples. Some tests are used in laboratory or other health professional settings and other tests are for consumers to use at home.

Milestones
Payments a company receives in accordance with a cooperation agreement after the company reaches a pre-set target, such as "proof-of-concept".

Pivotal trial
A clinical trial intended to provide efficacy and safety data for NDA approval at e.g. FDA or EMA. In some cases, Phase II studies can be used as pivotal studies if the drug is intended to treat life-threatening or severely debilitating conditions.

PRA
Panel Reactive Antibody (PRA) is an immunological laboratory test routinely performed on the blood of people awaiting organ transplantation. The PRA score is expressed as a percentage between 0 percent and 99 percent. It represents the proportion of the population to which the person being tested will react via pre-existing antibodies.

Preclinical development
Testing and documentation of a pharmaceutical candidate's properties (e.g. safety and feasibility) before initiation of clinical trials.

Sepsis
Diagnosed or suspected infection in combination with the patient being in a systemic inflammatory state (SIRS). Clinical symptoms of systemic inflammation may be a combination of fever, increased heart rate and increased respiratory rate.

Severe sepsis
Sepsis is progressing into severe sepsis when the patient may suffer circulatory effects and reduced functions of vital organs such as the brain, heart, lungs, kidneys or liver.

Streptococcus pyogenes
A Gram-positive bacterium that primarily can be found in the human upper respiratory tract. Some strains can cause throat or skin infections.

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