Hansa Medical

Interim report January – March 2018

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IdeS (INN: imlifidase) continues to demonstrate its unprecedented ability to enable transplantation for highly sensitized patients

January-March 2018 in brief

- Søren Tulstrup appointed new President and CEO of Hansa Medical, effective March 20, 2018. He has broad and extensive experience as senior executive in the global biopharma industry. Hansa Medical's acting CEO Ulf Wiinberg reverts to his former role as Chairman of Hansa Medical and Birgit Stattin Norinder reverts to her former role as board member.
- Completed enrollment in Hansa Medical's international multicenter Phase II study Highdes with lead candidate IdeS. The primary objective of the study – to turn a positive crossmatch test into a negative and thereby enable kidney transplantation – was accomplished in all 18 treated patients. All patients will be monitored for six months.
- Intermediate clinical results from seven of the 18 patients in the Highdes study were published in an abstract ahead of the *138th Annual Meeting of the American Surgical Association (ASA)* in Phoenix, Arizona, end of April, 2018. No serious adverse events were reported in the intermediate results and all seven patients had functioning kidneys at a median follow up of 171 days (5.5 months).
- Finalized enrollment in US investigator-initiated Phase II study with IdeS in highly sensitized patients. IdeS effectively reduced levels of donor specific antibodies (DSAs) in all 17 treated patients and turned the crossmatch tests from positive to negative, thereby enabling transplantation for all patients. All patients will be followed for six months to monitor safety, kidney function and DSA levels.
- The FDA granted orphan drug designation to IdeS for the treatment of Guillain-Barré syndrome. The FDA Orphan Drug Act (ODA) grants special status to a drug or biological product to treat a rare disease that affects fewer than 200,000 people in the US. Orphan drug designation qualifies the sponsor of the drug for various development incentives of the ODA, including tax credits, protocol assistance and up to seven years of orphan drug exclusivity.
- Clinical results from Hansa Medical's first Phase II study (ClinicalTrials.gov Identifier: NCT02224820) IdeS were published by the *American Journal of Transplantation (AJT)*, the monthly peer reviewed medical journal published by the *American Society of Transplant Surgeons* and the *American Society of Transplantation*. The publication describes the design and results from Hansa Medical's initial clinical study in sensitized patients, during which the first transplantation through IdeS-based desensitization was performed. Stable kidney function has been maintained in this very first patient for more than three years.

Financial summary – First quarter

	Q1		Year
KSEK, unless otherwise stated	2018	2017	2017
Net revenue	588	1,058	3,442
Operating profit/loss	-46,622	-44,827	-176,083
Net profit/loss	-46,498	-44,994	-176,660
Earnings per share before and after dilution (SEK)	-1.23	-1.27	-4.97
Shareholders' equity	591,805	240,065	630,661
Cash flow from operating activities	-44,094	-43,739	-150,105
Cash and cash equivalents including short term invesments	575,049	209,351	616,061

CEO statement

I am excited and honored to join Hansa Medical. The company has created an exciting proprietary drug development platform based on IgG-modulating enzymes for transplant related indications and acute autoimmune diseases.

The team at Hansa Medical has successfully designed and managed a series of clinical studies with its lead compound IdeS, demonstrating its ability to enable lifesaving kidney transplantation in highly sensitized patients, an indication area where there is significant unmet medical need. With a growing body of clinical evidence, opportunities to broaden the use of IdeS to a multitude of indications and next-generation drug candidates in development, Hansa is well positioned to become a fast growing biopharmaceutical company.

At the beginning of the year, enrollment was finalized in the two ongoing Phase II studies with IdeS in highly sensitized kidney transplant patients. A total of 18 patients were enrolled in the international multicenter study Highdes, and 17 patients were enrolled in the US investigator-initiated study at Cedars-Sinai Medical Center led by principal investigator, Professor Stanley Jordan. Treatment with IdeS enabled kidney transplantation for all 35 patients in the two studies by turning positive cross-match tests for donor specific antibodies into negative cross-match tests. The unique and novel mechanism of action of IdeS in depleting IgG antibodies enabled kidney transplantation for the patients in these two studies where previous attempts at desensitization had failed. We have managed to transplant patients that have been on dialysis for more than 20 years. All treated patients will be monitored for six months to collect follow-up data with respect to safety, kidney function and frequency of antibody mediated rejection (AMR). We expect to have the six month follow up data from all 35 patients by end of third quarter this year.

Meanwhile, we are preparing for meetings with both the US Food and Drug Administration (FDA) and European Medicines Agency (EMA) to discuss a potential route towards filing of a BLA (Biologics License Application) in the US and/or filing of an MAA (Market Authorization Application) in Europe at end of 2018 or early 2019. In addition to the compelling data demonstrating the efficacy and safety of IdeS in enabling kidney transplantation, important items for these discussions will be the six-month follow-up data, validation of the IdeS manufacturing process, and the significant medical need for these highly sensitized patients who today have very limited chances, if any, to be transplanted.

In parallel with our progress in kidney transplantation, we are equally determined to pursue the therapeutic potential of IdeS in other indications. We believe that the fast onset and efficacy of IdeS has the potential to significantly contribute to the critical care in several transplant-related indications and acute autoimmune diseases.

A Phase II study is ongoing in anti-GBM antibody disease, a rare and acute autoimmune kidney disease, where approximately two thirds of patients lose their kidney function, resulting in the need of chronic dialysis. As of end of March, 2018, seven patients had been included in the investigator-initiated Phase II study in severe anti-GBM. Limited follow-up data is currently available from five of these seven patients who have all responded favorably. IdeS appears to be well tolerated. The study aims to enroll approximately 15 patients at clinics across Europe.

In February, the FDA granted orphan drug designation to IdeS for the treatment of Guillain-Barré syndrome (GBS), a rare acute autoimmune neurological disease. The ability of IdeS to fast and effectively cleave IgG antibodies has significant treatment potential in GBS, and we are planning a Phase II study with IdeS in this acute neurological disease.

Through my career, I have gained extensive experience in building organizations and teams in both Europe and the United States in various pharmaceutical companies, including fast growing biopharma companies – a scenario that I think Hansa Medical is also facing now since we are getting close to a potential launch. We will continue to strengthen our organization both in Europe and the US, naturally within R&D but we will also put a lot of emphasis on growing our commercial and medical affairs infrastructure to provide further insight into currently published data from clinical studies with IdeS and prepare for a successful launch.

Hansa Medical has continued to make strong progress in delivering on its strategy and has successfully achieved several important clinical and regulatory milestones according to plan. The foundations are in place to achieve our vision of becoming a world-leading IgG-modulating company providing important, life-saving products to patients across a range of conditions where IgG plays a key role in disease progression or forms a barrier for patients to receive appropriate treatment. I look forward to updating you on our continued progress.

Søren Tulstrup
President and CEO of Hansa Medical

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 next generation 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 potentially cancer. Hansa Medical is based in Lund, Sweden, and its shares are listed on Nasdaq Stockholm (ticker: HMED). www.hansamedical.com

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.

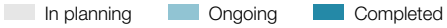
NiceR is a program developing novel IgG inactivating drug candidates for repeat dosing, which may translate to wider usage in relapsing autoimmune diseases and oncology.

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[1]	Indication	Research/ Preclinical	Phase I[2]	Phase I/II	Phase II	Pivotal	Registration
THERAPEUTICS							
IdeS	Kidney transplantation in highly sensitized patients[3]						
	Anti-GBM antibody disease						
	Antibody mediated kidney transplant rejection (AMR)						
	Guillain-Barré syndrome (GBS)						
NiceR	Recurring treatment in autoimmune disease, transplantation and oncology						
EnzE	Cancer immunotherapy						
DIAGNOSTICS							
HBP-assay (IVD)[4]	Prediction of severe sepsis						



[1] The EndoS project has been deprioritized and is put on hold.

[2] 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).

[3] Two separate Phase II studies with IdeS in highly sensitized patients are currently ongoing.

[4] 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 two finalized Phase II studies in sensitized patients awaiting kidney transplantation[2, 3]. 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. Patient recruitment to these two Phase II studies was completed in early January 2018, and the patients will be monitored for six months with respect to safety, kidney function and DSA levels. Results from these two studies are expected by end of the third quarter of 2018.

An investigator-initiated Phase II study with IdeS in the rare and acute autoimmune kidney disease anti-GBM antibody disease is ongoing in collaboration with several European nephrology clinics. Additional Phase II studies with IdeS are being planned within acute AMR and treatment of the acute autoimmune neurological disease Guillain-Barré syndrome (GBS).

Ongoing clinical studies with IdeS

IdeS – Pre-treatment of patients with donor-specific antibodies

Latest developments

In January 2018, patient enrolment was completed in two ongoing open label single arm Phase II clinical studies with IdeS in highly sensitized patients; the Hansa Medical-sponsored multicenter study named Highdes and an investigator-initiated study at Cedars-Sinai Medical Center in Los Angeles, led by Professor Stanley Jordan.

The ongoing Highdes study (ClinicalTrials.gov Identifier: NCT02790437) has enrolled and transplanted a total of 18 patients at NYU Langone Medical Center in New York, Cedars-Sinai Medical Center in Los Angeles, The Johns Hopkins Hospital in Baltimore, Necker Hospital in Paris and Uppsala University Hospital in Uppsala, Sweden. The primary objective of the study is to evaluate the efficacy of IdeS in patients who are on the waiting list for kidney transplant and have previously undergone desensitization unsuc-

cessfully or in whom effective desensitization with currently available methods will be highly unlikely. At study entry, the patients had an available deceased or live donor with a positive crossmatch test. The study assesses efficacy and safety of IdeS in removing DSAs and thereby converting a positive crossmatch test to negative. All treated and transplanted patients will be followed for six months. The primary objective of the study – to turn a positive cross match test into a negative and thereby enable kidney transplantation – has been accomplished in all 18 treated patients.

Intermediate clinical results from seven of the 18 patients in the Highdes-study were presented at the *138th Annual Meeting of the American Surgical Association (ASA)* in Phoenix, Arizona, in late April 2018. An abstract from the presentation summarizes that all seven patients were highly sensitized, with PRA levels 99-100%, (PRA=Panel Reactive Antibody) and positive crossmatches prior to IdeS treatment and thus prohibited for transplantation. IdeS treatment resulted in negative crossmatch tests for all patients, who thereafter could be successfully transplanted. Three of the seven patients experienced episodes of antibody mediated rejection (AMR) which responded to standard of care. Three of the seven patients had delayed graft function which ultimately resolved. No serious adverse events were associated with IdeS, and all seven patients had functioning kidneys at a median follow up of 171 days (5.5 months). All seven patients were enrolled at NYU Langone Medical Center in New York and the abstract summarizing the presentation is available at the ASA website through the following link: http://www.americansurgical.org/meeting/abstracts/2018/10.cgi

The ongoing US investigator initiated Phase II study has enrolled and transplanted a total of 17 patients at Cedars-Sinai Medical Center with Professor Stanley Jordan as principal investigator. (ClinicalTrials.gov Identifier: NCT02426684). The included patients had donorspecific antibodies (DSAs) and a positive cross-match test prior to IdeS treatment. Attempts to desensitize these patients using currently available methods had been made prior to inclusion in the IdeS-study. IdeS effectively reduced the level of DSAs in all patients and turned the cross-match tests from positive to negative, thereby enabling transplantation for all 17 patients. All patients will be followed for six months to monitor safety, kidney function and DSA-levels.

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[4] and less than one third of the patients survive with a preserved kidney function after six months follow-up[5].

In June 2017, an open label investigator-initiated Phase II study in severe anti-GBM antibody disease was initiated with Hansa Medical lead candidate IdeS. The study (ClinicalTrials.gov Identifier NCT03157037) is coordinated by Professor Mårten Segelmark at Linköping University Hospital, Linköping, Sweden, who is also the principal investigator/sponsor. Approximately 15 patients will be recruited to the study at up to 15 clinics in Europe. The primary objective of the study is to evaluate the safety and tolerability of IdeS in patients with severe anti-GBM antibody disease in addition to standard-of-care. The efficacy of IdeS will be assessed by evaluating renal function at six months after IdeS treatment.

Latest developments

To date, seven patients have been included in the study. Limited follow-up data is currently available from five of these seven patients who have all responded favorably and IdeS appears to be well tolerated. 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 ten patients with anti-GBM disease have been treated with IdeS as of the end of March 2018.

Finalized and ongoing clinical studies with IdeS

Type of study	Clinical trials.gov identifier	Subjects	Status	Results	Publication
Phase I in healthy subjects	NCT01802697	29	Completed	IdeS is efficacious and well tolerated with a favorable safety profile.	*PLOS ONE* (2015) [1]
Phase II in sensitized patients	NCT02224820	8	Completed	IdeS treatment resulted in HLA levels acceptable for transplantation in all patients.	*American Journal of Transplantation* (2018) [2]
Phase II in sensitized patients	NCT02475551	10	Completed	IdeS enabled kidney transplantation for all patients with a favourable safety profile.	*The New England Journal of Medicine* (2017) [3]
Phase II in highly sensitized patients	NCT02426684	17	Fully enrolled. Final results by Q3 2018	IdeS effectively reduced the level of DSAs in all patients and has enabled transplantation for all patients. All patients will be followed for six months.	*The New England Journal of Medicine* (2017) [3]
Multicenter Phase II in highly sensitized patients (Highdes)	NCT02790437	18	Fully enrolled. Final results by Q3 2018	The primary objective of the study – to turn a positive crossmatch test into a negative and thereby enable kidney transplantation – accomplished in all treated patients. All patients will be followed for six months.	
Phase II in Anti-GBM disease (GOOD-IDES)	NCT03157037	Approx. 15	Enrolling		

Manufacturing of IdeS

During 2017, Hansa Medical made significant investments in process development. The IdeS manufacturing process has been transferred to two manufacturers suitable for making products for commercialization. The manufacturing processes has been optimized and the product for commercialization is a lyophilized product. A lyophilized version of IdeS brings the advantages of easy off-the-shelf use and effective global distribution.

The first GMP batch for further clinical studies was produced in late 2017. Full process characterization and validation for commercial supply will be completed during 2018.

Regulatory strategy for IdeS in desensitization

The Highdes study has enrolled patients with a positive crossmatch test against their available live or deceased donor. These patients have either failed on previous attempts of desensitization or are highly likely to fail desensitization with currently available methods due to their immunological state.

In May 2017, EMA granted IdeS access to its Priority Medicines (PRIME) scheme for desensitization of highly sensitized kidney patients. Through PRIME, EMA offers early and proactive scientific advice meeting support. A product that benefits from PRIME can be expected to be eligible for accelerated assessment of the Marketing Authorization Application (MAA) once submitted. In the US there are also expedited programs in place for products that address an unmet medical need in the treatment of a serious condition. Hansa Medical is planning to request a formal meeting with the FDA to discuss the potential for expedited development and review of the IdeS Biologics License Application (BLA). Hansa Medical is planning to meet with both the FDA and EMA as soon as six months follow up data from the ongoing Highdes study is available.

Planned clinical studies with IdeS in additional indications

Treatment of kidney transplant antibody-mediated rejection (AMR)

There is no effective therapy for the treatment of AMR. In heart, lung and kidney transplants, AMR occurs in up to 10–20 percent[6] of patients and remains a significant unmet medical need associated with loss of graft function. IdeS is highly effective in inactivating IgG and has the potential to halt progression of AMR and be an effective treatment in severe AMR. It is anticipated that IdeS with its ability to instantly remove DSAs damaging the kidney, can make a significant difference in the treatment of these patients.

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 people annually[7]. Patients are treated with either IVIG or plasmapheresis; however, there remains a significant unmet medical need. In February 2018, IdeS received orphan drug designation from the FDA for the treatment of GBS.

Preclinical development projects

NiceR – *Novel Immunoglobulin Cleaving Enzymes for Repeat dosing*

Hansa Medical is developing completely new IgG-degrading enzymes based on experience from IdeS and similar molecules. The aim of the development is to create novel IgG-inactivating drugs that can be used for repeated dosing in autoimmune conditions, oncology and transplantation where patients benefit from more than one dose of an IgG-modulating enzyme. Several novel immunoglobulin cysteine endopeptidases have been developed and patented. The development program is currently in lead optimization phase with the ambition to select a lead candidate.

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.

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 Abbott 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–March 2018

Net revenue

Net revenue for the first quarter 2018 amounted to SEK 0.6 m (1.1) and is comprised of royalty income from Axis-Shield Diagnostics and re-invoiced expenses.

Other operating income and expenses

Other operating income for the first quarter 2018 amounted to SEK 0.2 m (0.2) and is comprised of a grant from Vinnova. Other operating expense amounted to SEK 0.4 m for the first quarter 2018 and is comprised of net currency differences.

Sales, general and administration expenses

Sales, general and administration expenses for the first quarter 2018 amounted to SEK 15.5 m (9.8). The expenses reflect the continued build-up of the organization to prepare for commercial launch and include recorded non-cash costs for the company's employee long term incentive program (LTIP 2016) amounting to SEK 4.9 m.

Research and development expenses

Research and developments expenses amounted to SEK 31.6 m (36.2) for the first quarter 2018 and include recorded non-cash costs for the company's long-term incentive programs (LTIP 2016) amounting to SEK 0.4 m. Compared with the previous year, expenses are lower due to significant investment in CMC development in 2017.

Financial result

Operating result for the first quarter 2018 amounted to SEK -46.6 m (-44.8). Profit/loss for the first quarter 2018 amounted to SEK -46.5 m (-45.0).

Cash flow and investments

Cash flow from operating activities amounted to SEK -44.1 m (-43.7) for the first quarter 2018. Cash and cash equivalents including short term investments amounted to SEK 575.0 m on March 31, 2018, as compared with SEK 616.1 m at the end of 2017. Investments for the first quarter 2018 amounted to SEK 0.3 m (0.5).

Shareholders' equity

On March 31, 2018, equity amounted to SEK 591.8 m compared with SEK 240.1 m at the end of the corresponding period 2017.

Parent company

The Parent company´s net revenue for the first quarter 2018 amounted to SEK 0.7 m (1.1). Profit/loss for the Parent company amounted to SEK -46.8 m (-44.9) for the first quarter 2018. On March 31, 2018, cash and cash equivalents including short-term investments amounted to SEK 572.8 m compared with SEK 613.8 m at the end of 2017.

The Parent company's equity amounted to SEK 582.7 m as per March 31, 2018, as compared with SEK 237.9 m at the end of the corresponding period 2017.

The Group consists of the Parent company Hansa Medical AB and the subsidiaries Cartela R&D AB and Immago Biosystems Ltd. Immago Biosystems Ltd is owner of patent rights to the Enze concept.

Financial summary for the group – First quarter

	Q1		Year
KSEK, unless otherwise stated	2018	2017	2017
Net revenue	588	1,058	3,442
Operating profit/loss	-46,622	-44,827	-176,083
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Earnings per share before and after dilution (SEK)	-1.23	-1.27	-4.97
Shareholders' equity	591,805	240,065	630,661
Cash flow operating activities	-44,094	-43,739	-150,105
Cash and cash equivalents including short term investments	575,049	209,351	616,061

Shareholder information

The Hansa Medical share is listed on Nasdaq OMX Stockholm, under the ticker HMED and included in several indexes including the OMX Nordic Mid Cap, OMX Nordic Health Care, MSCI Global Small Cap and NASDAQ Biotechnology Index.

Brief facts, the HMED share

Listing	Nasdaq OMX Stockholm
Number of shares	38,208,386 (37,878,125 A-shares and 330,261 C-shares)
Market capitalization March 31, 2018	SEK 8,923 m
Ticker	HMED
ISIN	SE0002148817

15 largest shareholders, March 31, 2018

Name	Number of shares	Share (%)
Nexttobe AB	9,443,761	24.9
Thomas Olausson (private and via company)	1,548,569	4.1
Oppenheimer	1,415,560	3.7
Handelsbanken Fonder	1,333,566	3.5
Avanza Pension	1,314,043	3.5
Gladiator	915,000	2.4
AFA Försäkring	841,639	2.2
Norron Fonder	778,201	2.1
Polar Capital	610,190	1.6
BWG Invest Sàrl	600,370	1.6
Tredje AP-fonden	561,465	1.5
Catella Fonder	513,639	1.4
Sven Sandberg	512,000	1.4
C WorldWide Asset Management	457,291	1.2
Invesco	416,536	1.1
Other	16,616,295	43.8
In total	**37,878,125**	**100.0**

Source: Monitor by Modular Finance AB. Compiled and processed data from various sources, including Euroclear, Morningstar and the Swedish Financial Supervisory Authority (Finansinspektionen).

According to the shareholder register maintained by Euroclear Sweden AB, as of March 31, 2018, Hansa Medical had 13,828 shareholders. On March 31 2017, Hansa Medical had 6,941 shareholders. Information regarding shareholders and shareholdings is updated each quarter on the company's website, www.hansamedical.com.

Other information

Employees and organization

The number of employees at the end of the first quarter 2018 amounted to 35, compared with 30 at the end of the corresponding period 2017.

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 0.9 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 former 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. At March 31, 2018, 289,750 rights have been allocated in total, of which 55,000 rights allocated to the former CEO have been excluded from the program due to his passing, so remaining allocated rights at March 31, 2018 are 234,750. 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 March 31, 2018, 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. 70,739 of the Class C-shares were converted to ordinary shares in January 2018 and then vested, transferred and used to cover social security contributions in February 2018. Not more than 251,173 ordinary shares can be transferred to participants under LTIP 2016 and 79,088 common shares can be used to cover any social security contributions due to the LTIP 2016 going forward, which means a dilution of 0.9 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 24.9 m, of which SEK 5.3 m is included in the results for the parent company and the group for the first quarter 2018. The program is not expected to have any net effect on cash flow provided it is secured fully in the manner described above.

Annual general meeting 2018

The annual general meeting of Hansa Medical AB (publ) will take place on May 29 2018 in the auditorium at the company's offices on Scheelevägen 22 in Lund. Notice to attend the annual general meeting has been published on Hansa Medical's website at www.hansamedical.com.

Financial calendar

Annual General Meeting	May 29, 2018
Interim report for January–June 2018	July 19, 2018
Interim report for January–September 2018	November 1, 2018

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 third party's intellectual property rights, technological development, exchange rate and interest rate fluctuations and political risks.

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Condensed financial statements

Consolidated statement of comprehensive income

	Q1		Year
KSEK	2018	2017	2017
Net revenue	588	1 058	3 442
Direct cost of net revenue	-50	-61	-221
Gross profit	**538**	**997**	**3 221**
Other operating income	214	213	1,479
Sales, general and administration expenses	-15,470	-9,811	-43,723
Research and development expenses	-31,537	-36,226	-137,060
Other operating expenses	-367	–	–
Operating profit/loss	**-46,622**	**-44,827**	**-176,083**
Financial income/expenses	114	-177	-616
Profit/loss before tax	**-46,508**	**-45,004**	**-176,699**
Tax	10	10	39
Net profit/loss for the period	**-46,498**	**-44,994**	**-176,660**
Attributable to			
Parent company shareholders	-46,498	-44,994	-176,660
Earnings per share			
Before dilution (SEK)	-1.23	-1.27	-4.97
After dilution (SEK)	-1.23	-1.27	-4.97
Other comprehensive income			
Items that have been, or may be reclassified to profit or loss for the period translation differences	123	-10	-22
Changes in fair value on available-for-sale financial assets	3,549	298	3,535
Other comprehensive income for the period	**3,672**	**288**	**3,513**
Total net comprehensive income	**-42,826**	**-44,706**	**-173,147**

Consolidated balance sheet

	March 31		December 31
KSEK	2018	2017	2017
ASSETS			
Non-current assets			
Intangible fixed assets	33,769	35,782	33,749
Tangible fixed assets	4,032	2,919	3,976
Financial fixed assets	22,049	14,852	18,508
Total non-current assets	**59,850**	**53,553**	**56,233**
Current assets			
Current receivables, non-interest bearing	12,534	3,246	8,121
Short-term investments	474,957	90,995	34,983
Cash and cash equivalents	100,092	118,356	581,078
Total current assets	**587,583**	**212,597**	**624,182**
TOTAL ASSETS	**647,433**	**266,150**	**680,415**
EQUITY AND LIABILITIES			
Shareholders' equity	**591,805**	**240,065**	**630,661**
Long term liabilities			
Deferred tax liabilities	560	569	538
Other provisions	5,384	432	5,017
Long term liabilities, interest bearing	652	559	601
Total long term liabilities	**6,596**	**1,560**	**6,156**
Current liabilities			
Current liabilities, interest bearing	–	38	–
Current liabilities, non-interest bearing	15,204	7,844	11,056
Accrued expenses and deferred income	33,828	16,643	32,542
Total current liabilities	**49,032**	**24,525**	**43,598**
TOTAL EQUITY AND LIABILITIES	**647,433**	**266,150**	**680,415**

Consolidated changes in equity

	Q1		Year
KSEK	2018	2017	2017
Opening shareholders' equity	**630,661**	**283,693**	**283,693**
Result for the period	-46,498	-44,994	-176,660
Other comprehensive income for the period	3,672	288	3,513
Net comprehensive income	**-42,826**	**-44,706**	**-173,147**
Transactions with the group's owner			
New share issue [1]	–	–	545,401
Expenses attributable to new share issue	-1,070	–	-30,049
Repurchase/Sales own shares [1]	4,473	–	-401
Issued warrants	29	67	190
Long term incentive program	538	1,011	4,974
Total transactions with the group's owner	**3,970**	**1,078**	**520,115**
Closing shareholders' equity	**591,805**	**240,065**	**630,661**

[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) and directed share issue in Q4 2017 of 2,752,526 ordinary shares. In Q1 2018 70,739 of the C-shares where converted to ordinary shares, partly transferred and partly divested in the market.

Consolidated cash flow statement

	Q1		Year
KSEK	2018	2017	2017
Operating activities			
Operating profit/loss	-46,622	-44,827	-176,083
Adjustment for items not included in cash flow [1]	1,713	2,306	13,827
Interest received and paid, net	-207	-178	-638
Cash flow from operations before change in working capital	**-45,116**	**-42,699**	**-162,894**
Change in working capital	1,022	-1,040	12,789
Cash flow from operating activities	**-44,094**	**-43,739**	**-150,105**
Investing activities			
Investments in intangible fixed assets	-25	–	-214
Investments in tangible fixed assets	-275	-512	-2,195
Short term investments	-449,995	-80,981	-240,898
Divestment short term investments	10,000	30,000	246,000
Cash flow from investing activities	**-440,295**	**-51,493**	**2,693**
Financing activities			
New share issue [2]	–	–	545,401
Issue expenses	-1,070	–	-30,050
Repurchase/Sales own shares [2]	4,473	–	-401
Repayment of leasing liabilities	–	–	-48
Cash flow from financing activities	**3,403**	**–**	**514,902**
Net change in cash	**-480,986**	**-95,232**	**367,490**
Cash and cash equivalents, beginning of year	581,078	213,588	213,588
Cash and cash equivalents, end of period	**100,092**	**118,356**	**581,078**

[1] Values for 2017 pertain mainly to costs of share based incentive program (LTIP 2016) including social contributions.
[2] Values for 2017 refer to directed share issue, repurchase of 401,000 class C shares for financing of the company's long term incentive program (LTIP 2016) and directed share issue in Q4 2017 of 2,752,526 ordinary shares. In Q1 2018 70,739 of the C-shares where converted to ordinary shares, partly transferred and partly divested in the market.

Consolidated key ratios and other information

	Q1		Year
KSEK, unless other stated	2018	2017	2017
Profit numbers			
Net revenue	588	1,058	3,442
Operating profit/loss	-42,622	-44,827	-176,083
Net profit/loss	-46,498	-44,994	-176,660
Per share data			
Earnings/loss per share before and after dilution (SEK)	-1.23	-1.27	-4.97
Shareholders' equity per share (SEK)	15.65	6.85	16.68
Other information			
Equity ratio (%)	91	90	93
Cash and cash equivalents including short term invesments	575,049	209,351	616,061
Number of outstanding shares at the end of the period	37,878,125	35,054,860	37,807,386
Weighted average number of shares before and after dilution	37,854,545	35,306,636	35,519,029

Parent company – Statement of comprehensive income

	Q1		Year
KSEK	2018	2017	2017
Net revenue	685	1,058	3,739
Direct cost of net revenue	-50	-61	-221
Gross profit	**635**	**997**	**3,518**
Other operating income	214	213	1,479
Sales, general and administration expenses	-15,463	-9,775	-43,740
Research and development expenses	-31,575	-36,181	-137,015
Other operating expenses	-367	–	–
Operating profit/loss	**-46,556**	**-44,746**	**-175,758**
Result from other securities and receivables which are fixed assets	3	–	97
Other financial expenses	-252	-176	-712
Profit/loss for the period (before and after taxes)	**-46,805**	**-44,922**	**-176,373**
Other comprehensive income for the period	**–**	**–**	**–**
Total net comprehensive income	**-46,805**	**-44,922**	**-176,373**

Parent company – Balance sheet

	March 31		December 31
KSEK	2018	2017	2017
ASSETS			
Non-current assets			
Intangible fixed assets	30,570	32,810	30,709
Tangible fixed assets	4,032	2,916	3,976
Financial fixed assets	17,317	17,317	17,317
Total non-current assets	**51,919**	**53,043**	**52,002**
Current assets			
Current receivables non-interest bearing	13,113	3,386	8,588
Short-term investments	474,997	90,988	34,992
Cash and cash equivalents	97,811	116,097	578,795
Total current assets	**585,921**	**210,471**	**622,375**
TOTAL ASSETS	**637,840**	**263,514**	**674,377**
EQUITY AND LIABILITIES			
Shareholders' equity	**582,693**	**237,942**	**625,528**
Long-term liabilities			
Other provisions	5,384	432	5,017
Long term liabilities, non-interest bearing	652	559	601
Total long-term liabilities	**6,036**	**991**	**5,618**
Current liabilities			
Liabilities to group companies	98	98	98
Current liabilities, non-interest bearing	15,204	7,840	10,606
Accrued expenses and deferred income	33,809	16,643	32,527
Total current liabilities	**49,111**	**24,581**	**43,231**
TOTAL EQUITY AND LIABILITIES	**637,840**	**263,514**	**674,377**

Parent company – Changes in equity

	Q1		Year
KSEK	2018	2017	2017
Opening shareholders' equity	**625,528**	**281,786**	**281,786**
Result for the period	-46,805	-44,922	-176,373
New share issue [1]	–	–	545,401
Expenses attributable to new share issue	-1,070	–	-30,049
Repurchase/Sales own shares [1]	4,473	–	-401
Issued warrants	29	67	190
Long term incentive program	538	1,011	4,974
Total transactions with the group's owner	**3,970**	**1,078**	**520,115**
Closing shareholders' equity	**582,693**	**237,942**	**625,528**

[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) and directed share issue in Q4 2017 of 2,752,526 ordinary shares. In Q1 2018 70,739 of the C-shares where converted to ordinary shares, partly transferred and partly divested in the market.

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 2017. The Annual report 2017 was published on April 11, 2018 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.

Effects of IFRS 15 Revenue from contracts with customers

IFRS 15 came into effect as of January 1, 2018. The Group's revenue from contracts with customers currently consists mainly of royalty revenue from the agreement with Axis-Shield Diagnostics (ASD). The transition to IFRS 15 has not affected how Hansa Medical recognises revenue from the agreement with ASD.

Effects of IFRS 9 Financial instruments

IFRS 9 came into effect as of January 1, 2018 and replaces IAS 39 Financial Instruments: Recognition and Measurement as the standard on recognition and measurement of financial instruments in IFRS. Compared with IAS 39, IFRS 9 primarily brings changes regarding classification and measurement of financial assets and financial liabilities, impairment of financial assets and hedge accounting. IFRS 9 has affected how the Group accounts for investments in interest rate funds. Under IAS 39 the funds have been measured at fair value through other comprehensive income. However, the funds do not meet the criteria in IFRS 9 for changes in fair values to be recognised in other comprehensive income. Instead, under IFRS 9 the changes in the fair values of the funds has been reported in profit or loss. Therefore, accumulated changes in fair values of the funds of SEK -403 k has been transferred from the "Fair value reserve" to "Retained earnings" in the opening balance as per January 1, 2018.

The Group also has investments in commercial papers, which under IAS 39 has been measured at fair value through other comprehensive income. Under IFRS 9, investments in commercial papers has instead been measured at amortised cost. The accumulated change in the fair values of the commercial papers of SEK -9 k has been removed from the "Fair value reserve" and booked against the carrying amount of the commercial papers in the balance sheet. The commercial papers has therefore been reported at a carrying amount of SEK 34,992 k in the opening balance for the Group as per January 1, 2018.

The transition to IFRS 9 has not had any other material effects for the Group.

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 except investments in short term commercial papers, which have been measured at amortised cost. The financial instruments reported at fair value in the balance sheet are comprised partly of holdings of interest rate funds consisting of investments in interest-bearing securities and other interest-rate instruments of high-rating and partly of the Group's holding of shares in Genovis, which are listed on Nasdaq First North. The fair value of the interest funds as per the balance sheet date March 31, 2018 was SEK 429,960 k and SEK 429,597 k as per December 31, 2017. The fair value of the shares as per the balance sheet date March 31, 2018 was SEK 22,049 k and SEK 18,507 k as per December 31, 2017. 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

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

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

5. Hellmark et al., Journal of Autoimmunity 48-49 (2014) 108e112. “Diagnosis and classification of Goodpasture’s disease (anti-GBM)”

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

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

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”,

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

Glossary

AMR
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. The human immune system uses different classes of antibodies so called isotypes known as IgA, IgD, IgE, IgG, and IgM. The different isotypes have slightly different structures and they play different roles in the immune system. Immunoglobulin G, IgG, is the most common type in the blood and tissue and provides the majority of antibody-based immunity against invading pathogens. IgA is mainly found in mucosal areas and prevents colonization by pathogens. IgD mainly functions as receptor on B-cells that have not yet been activated. IgE binds to allergens and is involved in allergy. IgM is mainly found in the blood and is part of the first response against an infection.

Anti-GBM disease (Goodpasture syndrome)
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.

B-cells
B-cells, also known as B-lymphocytes, are a type of white blood cell of the lymphocyte subtype. They are an important part of the adaptive immune system and secrete antibodies.

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.

CD20
B-lymphocyte antigen CD20 is a protein expressed on the surface of B-cells. Its function is to enable optimal B-cell immune response.

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 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 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.

DSA
Donor specific antibodies. Donor specific antibodies are antibodies in a transplant patient which bind to HLA and/or non-HLA molecules on the endothelium of a transplanted organ, or a potential donor organ. The presence of pre-formed and de novo (newly formed) DSA, specific to donor/recipient mismatches are major risk factors for antibody-mediated rejection.

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.

Guillian-Barré syndrome
GBS, Guillian-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 while leaving other Ig-isotypes intact.

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

imlifidase
imlifidase is the generic name, International Nonproprietary Name (INN), for IdeS.

INN
International Nonproprietary Name (INN) is a generic and non-proprietary name to facilitate the identification of a pharmaceutical substances or active pharmaceutical ingredient. Each INN is a unique name that is globally recognized and is public property. The INN system has been coordinated by the World Health Organization (WHO) since 1953.

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% and 99%. 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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