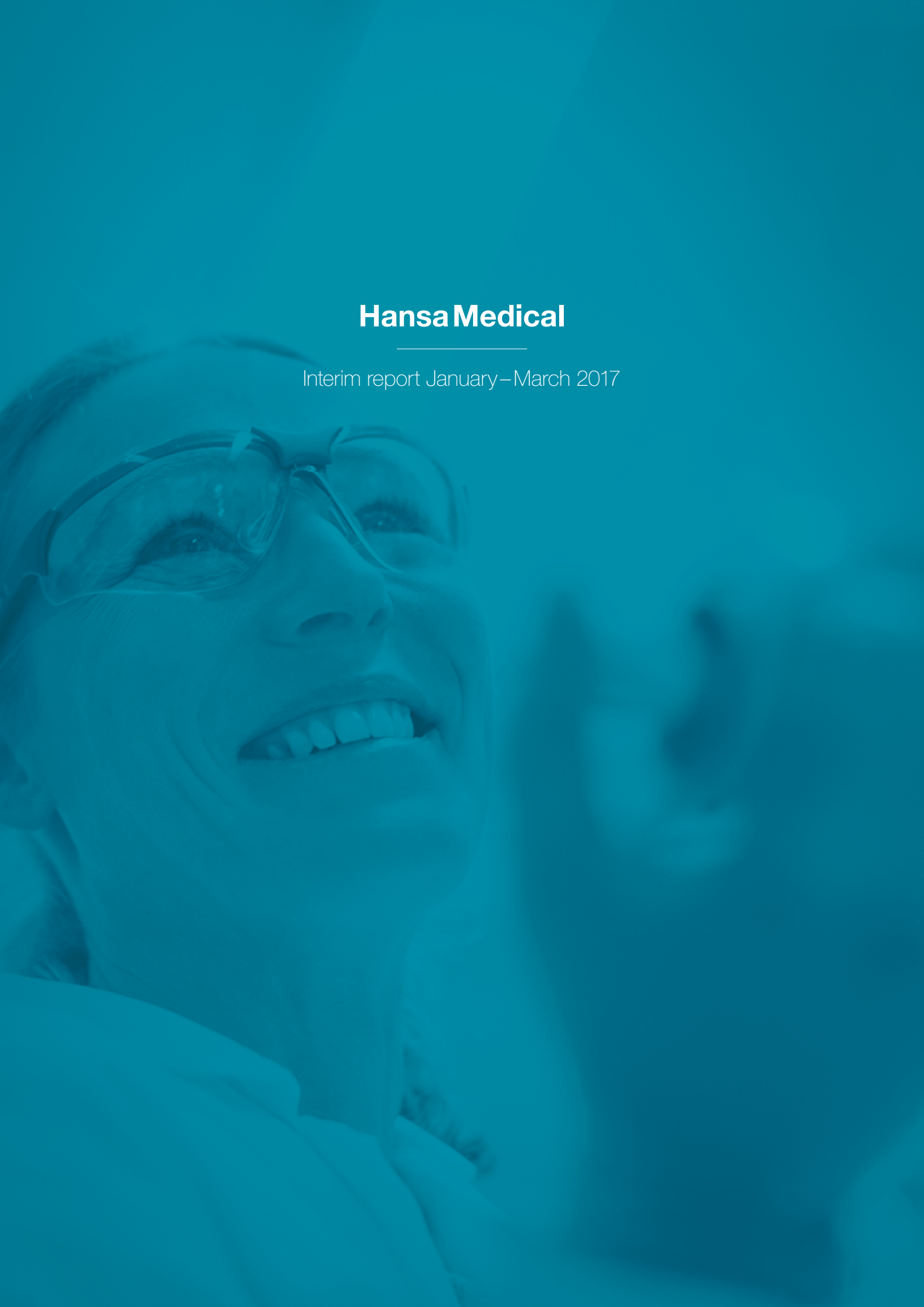
Hansa Medical

Interim report January – March 2017



New clinical data further support the efficacy and safety profile of IdeS

January-March 2017 in brief

- Positive top-line results from the US clinical study with Hansa Medical's lead candidate IdeS demonstrated that treatment with IdeS completely eliminates donor specific antibodies (DSAs), enabling transplantation of all 15 reported HLA incompatible patients. The clinical results will be presented at the American Transplant Congress (ATC) in Chicago, Illinois, on 30 April, 2017.
- A Phase II study with IdeS in the rare autoimmune kidney disease anti-GBM antibody disease (anti-GBM) has been initiated. The study is investigator initiated at several European nephrology clinics.
- Novel published preclinical data demonstrated that treatment with IdeS could be a novel therapeutic strategy for the treatment of Guillain-Barré syndrome (GBS).
- Hansa Medical appointed Dr. Sam Agus as new Chief Medical Officer. Dr. Agus has extensive experience in medical strategy, multidisciplinary team leadership and medical marketing. His experience will form a central part in the company's next phase and the commercialization strategy for IdeS.

"Hansa Medical has reached several important clinical and regulatory milestones. And although we set our objectives high, we have managed to meet them according to plan. But what is most important – and trigger us to increase our efforts even further – is the fact that to date, more than 30 patients have been treated with IdeS and subsequently transplanted in the US and Europe."

Göran Arvidson
President and CEO of Hansa Medical

Financial summary – First quarter

	Q1		Year
KSEK, unless otherwise stated	2017	2016	2016
Net revenue	1,058	587	2,579
Operating profit/loss	-44,827	-19,946	-111,135
Net profit/loss	-45,004	-19,976	-111,152
Earnings per share before and after dilution (SEK)	-1.28	-0.61	-3.39
Shareholders' equity	240,065	190,922	283,693
Cash flow from operating activities	-43,739	-17,560	-94,563
Cash and cash equivalents including short term invesments	209,351	158,080	253,578

CEO statement

During the first quarter of 2017, we have remained focused on our strategy and continued to create value and to strengthen our platform, as we reached several important milestones and accomplished many important objectives.

We continued the development of our novel and innovative immunomodulatory enzymes. Through the ground-breaking work with our lead candidate IdeS, enabling transplantation in sensitized patients, we have seen a lot of interest for our research in the scientific and medical communities. Results from the recent studies with IdeS have been presented by the principal investigators at several renowned scientific and medical meetings, with more to come this year.

In March, we announced top-line clinical results from the ongoing investigator initiated US study with IdeS that will be presented in an oral session at the American Transplant Congress (ATC) in Chicago on 30 April. These results demonstrated that treatment with IdeS eliminates donor specific antibodies (DSAs) and enables transplantation of HLA incompatible patients.

The IdeS treatment resulted in total IgG and HLA antibody elimination. 14 of 15 patients were successfully transplanted without discernible adverse events. Antibody mediated rejection episodes occurred in four patients and all four responded to anti-rejection treatment. One graft loss occurred due to non-HLA IgM and IgA antibodies. A comparison of the levels of donor specific antibodies before IdeS treatment and one month after IdeS treatment shows a significant reduction.

These results support our belief that IdeS has the potential to become the first therapy to enable highly HLA sensitized kidney disease patients to be transplanted. HLA sensitization impacts approximately 30 percent of patients with kidney disease and is a significant barrier to kidney transplantation.

In parallel with our ground-breaking work in organ transplantation, we are equally determined to pursue the therapeutic potential of IdeS in several 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.

In February, we presented novel pre-clinical *in vivo* data that demonstrate the treatment potential of IdeS in the acute autoimmune disease Guillain-Barré syndrome (GBS), by reducing the degeneration of peripheral nerves. The data was presented in an article which was published in the scientific journal Experimental Neurology. The data covered by this publication demonstrate that our IdeS treatment could be a promising therapeutic strategy for the treatment of GBS.

Over the last 12 months, we have also continued to build a strong, committed team at Hansa Medical, in order to prepare ourselves for the next exciting phase of the company's growth. In March, we announced the recruitment of Dr. Sam Agus as Chief Medical Officer. He is a board-certified neurologist and has extensive experience in medical marketing as well as clinical trial design and product launches.

Dr. Agus' key focus will be on the company's lead project IdeS, and we are very pleased to have him joining our team in this truly exciting phase for Hansa Medical. His experience from building and leading strong teams will be key in this next phase.

To summarize, Hansa Medical has reached several important clinical and regulatory milestones. And although we set our objectives high, we have managed to meet them according to plan. But what is most important – and trigger us to increase our efforts even further – is the fact that to date, more than 30 patients have been treated with IdeS and subsequently transplanted in the US and Europe. We strongly believe that this drug has shown significant potential to become a novel treatment option to enable patients to receive the lifesaving transplantation they desperately need.

Göran Arvidson
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 project 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 a wide range of acute autoimmune indications. The company also has a strong pipeline of preclinical assets that may provide a second wave of potential drugs. Under the project name NiceR, novel immunoglobulin cleaving enzymes are developed for repeat dosing translating the Hansa Medical technology into relapsing autoimmune diseases and oncology. Hansa Medical is based in Lund, Sweden, its shares (ticker: HMED) are listed on Nasdaq Stockholm.

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 human diseases.

NiceR. In parallel with the development IdeS, Hansa Medical is also developing novel IgG inactivating drug candidates for repeat dosing under the project name NiceR, which may translate to wider usage in relapsing autoimmune diseases and oncology.

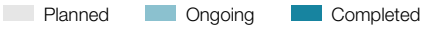
EndoS is an IgG-modulating enzyme that has proven efficacious in a range of autoimmune models. Preclinical research and development aiming at enabling clinical trials with EndoS in autoimmune diseases is ongoing.

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 infectious disease symptoms. 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.
[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 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 autoimmune diseases.

IdeS has been evaluated in a Phase I study[1] in healthy subjects and in two completed Phase II studies in sensitized patients awaiting kidney transplantation. The results in these studies demonstrate that IdeS is highly effective in reducing anti-HLA antibodies to levels acceptable for transplantation with a favorable safety profile.

The efficacy and safety of IdeS is currently being investigated in two ongoing Phase II studies in sensitized kidney transplantation patients. Additional Phase II studies within kidney transplantation are being planned 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 autoimmune kidney disease anti-GBM antibody disease has been initiated in collaboration with several European nephrology clinics. In addition, a Phase II study with IdeS in the rare autoimmune disease Guillain-Barré syndrome (GBS) is being planned.

Ongoing clinical studies with IdeS

IdeS – Desensitization prior to kidney transplantation

Latest developments

In December 2016, a Swedish Phase II study evaluating the safety, tolerability, efficacy and pharmacokinetics of intravenous ascending doses of IdeS in kidney transplantation was successfully completed, and the primary and secondary objectives were met. In the study, 10 sensitized kidney patients were given IdeS, which enabled all of them to subsequently have a kidney transplantation. The results of the study have been submitted for peer review in a scientific journal.

In March 2017, top-line results based on 15 patients in an ongoing US clinical study with IdeS were reported demonstrating that treatment with IdeS completely eliminates donor-specific IgG antibodies (DSAs) and enabled transplantation for all the treated patients. The clinical results will be presented at the American Transplant Con-

gress in Chicago, Illinois, on 30 April, 2017. Principal investigator Professor Stanley Jordan is aiming at recruiting 20 patients in total to this ongoing study by mid 2017. All patients are then followed for 6 months post IdeS treatment and kidney transplantation.

The ongoing Hansa Medical-sponsored multicenter study named Highdes, initiated in October 2016, is enrolling patients according to plan. The primary objective of the study is to assess the efficacy of IdeS in creating a negative crossmatch test in refractory HLA sensitized patients with antibodies to the donor. Removing donor-specific antibodies will enable transplantation in patients who would otherwise not qualify for transplantation. The study will also evaluate safety, kidney function and immunogenicity during the 6-month follow-up period. The aim is to complete enrolment of approximately 20 patients during 2017.

IdeS – Treatment of anti-GBM antibody disease

Anti-GBM antibody disease is a disorder in which antibodies directed against the basement membrane of the kidney and lung cause acute and rapidly progressive glomerulonephritis and lung haemorrhage. Anti-GMB antibody disease is a rare disease affecting one in a million annually [2].

Latest developments

An investigator initiated Phase II study with IdeS in anti-GBM has been initiated with patients to be enrolled at several European nephrology clinics.

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: All IdeS treated patients possible to transplant. Manageable safety profile with favorable risk benefit profile.
Phase II in kidney transplantation	Uppsala University Hospital, Sweden Karolinska University Hospital, Sweden	10 sensitized patients, with transplantation.	● Completed 2016. Conclusion: Primary and secondary objectives achieved.
Phase II in kidney transplantation (Investigator initiated)	Cedars Sinai Medical Center, Los Angeles, USA	20 sensitized patients, with transplantation.	● Ongoing. Aim to complete recruitment mid 2017. Top line results demonstrate that IdeS completely eliminates donor specific IgG antibodies (DSAs) and enabled transplantation for all the treated patients.
Highdes – Phase II in kidney transplantation	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. Aim to complete recruitment 2017.
Phase II in anti-GBM (Investigator initiated)	Europe. Several sites.	15 patients with anti-GBM antibody disease.	● Initiated

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.

Regulatory strategy for IdeS in desensitization
The Highdes study will recruit patients who have either failed on previous attempts of desensitization or are likely to fail desensitization with currently available methods. Hansa Medical aims to obtain market authorization in the US and Europe for IdeS for this category of patients as soon as possible. The company anticipates that the Highdes study, together with the completed and ongoing studies, will provide data to support a Biologics License Application (BLA) in the US and a Marketing Authorization Application (MAA) in the EU.

Planned clinical studies with IdeS in additional indications

Treatment of kidney transplant antibody-mediated rejection (ABMR)
Approximately 10 percent[3] 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. In the more severe cases of ABMR, these experimental protocols are generally not sufficient to rescue the kidney since the magnitude of the antibody response exceeds the capacity of the treatment, e.g. plasmapheresis, to clear the antibodies.

Blood-group incompatible (ABOi) kidney transplantation
ABOi transplantations have increased worldwide in order to shorten the long waiting times for transplantation[4]. If not adequately removed, the presence of preformed antibodies compared to donor blood group antigens is likely to result in severe ABMR and early graft loss.

Acute 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[5]. In February 2017, preclinical data demonstrating the treatment potential of IdeS in GBS was published[6]. The data demonstrate that inactivation of IgG by IdeS treatment significantly promoted the recovery and reduced the degeneration of peripheral nerves in a model of GBS. The data covered by this publication demonstrate that treatment with the IdeS could be a promising therapeutic strategy for the treatment of GBS. Potentially it could offer faster time to recovery, shorter stay in ICU/hospital and reduced risk of residual neurological deficits. Hansa Medical is planning a Phase II study in GBS.

Preclinical development projects

NiceR – Novel immunoglobulin cleaving enzymes for repeat dosing
Hansa Medical develops completely novel IgG-degrading enzymes. The aim of project NiceR is to create novel IgG-inactivating biopharmaceuticals that can be used for repeated dosing in autoimmune conditions where patients would benefit from more than one dose of an IgG-modulating enzyme.

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 effective 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 be a novel therapy for autoimmune diseases.

EnzE – Enzyme-based antibody Enhancement
Many antibody-based cancer therapies rely on activation of the immune system via antibody-dependent cell-mediated cytotoxicity (ADCC). The antibodies bind to antigens on cancer cells and once attached, the antibodies attract immune cells to destroy the cancer cells. For instance, the anti-CD20 antibody, which is used for treatment of lymphoma and leukemia, binds to CD20 on cancer cells and activates cytotoxic immune cells to kill the cancer cells. The immune cells are activated through binding of the Fc-part of the antibody to Fc-gamma receptors on the cell surface of the immune cells. The Fc-gamma receptors are involved in the therapeutic effector functions of many different antibodies and often needed to have sufficent effect. However, due to the abundancy of normal IgG in blood, the Fc-gamma receptors are occupied by IgG and the therapeutic antibodies have to compete for binding to the Fc-gamma receptors. Hence, pre-treatment with IdeS, or EndoS, has the potential to potentiate presently available antibody-based cancer therapies. Results from in vitro testing of the concept have been published by Baruah et al[7].

Out-licensed royalty generating programs

HBP – Prediction of severe sepsis
HBP-assay (measurement of Heparin Binding Protein) is a novel diagnostic method developed and patented by Hansa Medical to help predict severe sepsis in patients with infectious disease symptoms at emergency departments[8]. 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[9].

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

Financial review January–March 2017

Financial result

Net revenue for the first quarter 2017 amounted to SEK 1.1 m (0.6) and is comprised of royalty income from Axis-Shield Diagnostics and re-invoiced expenses.

Operating result for the first quarter 2017 amounted to SEK -44.8 m (-19.9). The expenses consist primarily of the activities around CMC development, clinical studies, regulatory work for the market applications and commercial build-up.

Profit/loss for the first quarter 2017 amounted to SEK -45.0 m (-20.0).

Cash flow and investments

Cash flow from operating activities amounted to SEK – 43.7 m (-17.6) for the first quarter 2017. Cash and cash equivalents including short-term investments amounted to SEK 209.4 m on March 31 2017, as compared with SEK 253.6 m at the end of 2016. Investments for the first quarter 2017 amounted to SEK 0.5 m.

Shareholders' equity

On March 31, 2017, equity amounted to SEK 240.1 m compared with SEK 190.9 m at the end of the corresponding period 2016.

Parent company

The parent company's net revenue for the first quarter 2017 amounted to SEK 1.1 m (0.6). Profit/loss for the parent company amounted to SEK -44.9 m (-20.7) for the first quarter. On March 31, 2017, cash and cash equivalents including short-term investments amounted to SEK 207.1 m compared with SEK 251.3 m at the end of 2016.

The parent company's equity amounted to SEK 237.9 m as per March 31, 2017, as compared with SEK 190.9 m 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.

Financial summary for the group – First quarter

	Q1		Year
KSEK, unless otherwise stated	2017	2016	2016
Net revenue	1,058	587	2,579
Operating profit/loss	-44,827	-19,946	-111,135
Net profit/loss	-44,994	-19,976	-111,129
Earnings per share before and after dilution (SEK)	-1.28	-0.61	-3.39
Shareholders' equity	240,065	190,922	283,693
Cash flow operating activities	-43,739	-17,560	-94,563
Cash and cash equivalents including short term investments	209,351	158,080	253,578

Other information

Employees and organization

The number of employees at the end of the first quarter 2017 was 30, compared to 20 at the end of corresponding period 2016.

Share warrant program

On June 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 234,750 rights have been totally allocated at March 31, 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 November 28, 2019.

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 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. 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 IFRS 2, including social security contributions is expected to amount to approximately SEK 16.9 m, of which SEK 1.3 m is included in the results for the parent company and the group for the first quarter 2017. 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 2017

The annual general meeting of Hansa Medical AB (publ) will take place on 23 May 2017 in the auditorium at the company's offices on Scheelevägen 22 in Lund. Notice to attend the annual general meeting is available on Hansa Medical's website at www.hansamedical.com.

Financial calendar

Annual General Meeting	May 23, 2017
Interim report for January-June 2017	July 20, 2017
Interim report for January-September 2017	November 14, 2017

Shareholder information

The Hansa Medical share is listed on Nasdaq OMX Stockholm, under the ticker HMED and included in both the OMX Nordic Mid Cap and Health Care sector index.

Brief facts, the HMED share

Listing	Nasdaq OMX Stockholm
Number of shares	35,054,860
Market capitalization March 31, 2017	SEK 4,697 m
Ticker	HMED
ISIN	SE0002148817

10 largest shareholders, March 31, 2017

Name	Number of shares	Share (%)
Nexttobe AB	9,443,761	26.9
Gladiator	2,262,798	6.5
Afa Försäkring	1,333,000	3.8
Olausson, Thomas	1,253,474	3.6
Försäkringsaktiebolaget, Avanza Pension	1,166,097	3.3
Farstorps Gård AB	1,084,070	3.1
Handelsbanken Fonder	1,013,156	2.9
Tredje AP-Fonden	805,144	2.3
Catella Fondförvaltning	638,088	1.8
BWG Invest	600,370	1.7
Other	15,454,902	44.1
In total	**35,054,860**	**100.0**

According to the shareholder register maintained by Euroclear Sweden AB, as of March 31 2017, Hansa Medical had 6,941 shareholders. On March 31 2016, Hansa Medical had 3,517 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 third 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

	Q1		Year
KSEK	2017	2016	2016
Net revenue	1,058	587	2,579
Direct cost of net revenue	-61	-54	-217
Gross profit	**997**	**533**	**2,362**
Other operating income	213	–	–
Sales, general and administration expenses	-9,811	-4,974	-29,703
Research and development expenses	-36,226	-15,403	-82,850
Other operating expenses	–	-102	-944
Operating profit/loss	**-44,827**	**-19,946**	**-111,135**
Financial income/expenses	-177	-30	-17
Profit/loss before tax	**-45,004**	**-19,976**	**-111,152**
Tax	10	–	23
Net profit/loss for the period	**-44,994**	**-19,976**	**-111,129**
Attributable to			
Parent company shareholders	-44,994	-19,976	-111,129
Earnings per share			
Before dilution (SEK)	-1.28	-0.61	-3.39
After dilution (SEK)	-1.28	-0.61	-3.39
Other comprehensive income			
Items that have been, or may be reclassified to profit or loss for the period translation differences	-10	–	-26
Changes in fair value on available-for-sale financial assets	298	-728	4,690
Other comprehensive income for the period	**288**	**-728**	**4,664**
Total net comprehensive income	**-44,706**	**-20,704**	**-106,465**

Consolidated balance sheet

	March 31		December 31
KSEK	2017	2016	2016
ASSETS			
Non-current assets			
Intangible fixed assets	35,782	35,623	36,554
Tangible fixed assets	2,919	2,077	2,570
Financial fixed assets	14,852	6,555	14,566
Total non-current assets	**53,553**	**44,255**	**53,690**
Current assets			
Current receivables, non-interest bearing	3,246	1,670	3,404
Short-term investments	90,995	99,935	39,990
Cash and cash equivalents	118,356	58,145	213,588
Total current assets	**212,597**	**159,750**	**256,982**
TOTAL ASSETS	**266,150**	**204,005**	**310,672**
EQUITY AND LIABILITIES			
Shareholders' equity	**240,065**	**190,922**	**283,693**
Long term liabilities			
Deferred tax liabilities	569	–	581
Other provisions	432	–	114
Long term liabilities, interest bearing	559	38	552
Total long term liabilities	**1,560**	**38**	**1,247**
Current liabilities			
Current liabilities, interest bearing	38	42	44
Current liabilities, non-interest bearing	7,844	2,312	8,390
Accrued expenses and deferred income	16,643	10,691	17,298
Total current liabilities	**24,525**	**13,045**	**25,732**
TOTAL EQUITY AND LIABILITIES	**266,150**	**204,005**	**310,672**

Consolidated changes in equity

	Q1		Year
KSEK	2017	2016	2016
Opening shareholders' equity	**283,693**	**211,526**	**211,526**
Result for the period	-44,994	-19,976	-111,129
Other comprehensive income for the period	288	-728	4,664
Net comprehensive income	**-44,706**	**-20,704**	**-106,465**
Transactions with the group's owner			
New share issue	–	–	185,000
Expenses attributable to new share issue	–	–	-7,504
Issued warrants	67	100	772
Long term incentive program	1,011	–	364
Total transactions with the group's owner	**1,078**	**100**	**178,632**
Closing shareholders' equity	**240,065**	**190,922**	**283,693**

Consolidated cash flow statement

	Q1		Year
KSEK	2017	2016	2016
Operating activities			
Operating profit/loss	-44,827	-19,946	-111,135
Adjustment for items not included in cash flow	2,306	941	4,269
Interest received and paid, net	-178	-30	-78
Income taxes paid	-120	80	–
Cash flow from operations before change in working capital	**-42,819**	**-18,955**	**-106,944**
Change in working capital	-920	1,395	12,381
Cash flow from operating activities	**-43,739**	**-17,560**	**-94,563**
Investing activities			
Acquisition of business, net cash effect	–	–	-1,924
Investments in intangible fixed assets	–	–	-57
Investments in tangible fixed assets	-512	-18	-927
Investment of financial assets	–	–	-2,588
Short term investments	-80,981	–	-194,918
Divestment short term investments	30,000	-99,949	155,000
Cash flow from investing activities	**-51,493**	**-99,967**	**-45,414**
Financing activities			
New share issue	–	–	185,000
Issue expenses	–	–	-7,504
Issued warrants	–	–	429
Repayment of leasing liabilities	–	-11	-43
Cash flow from financing activities	–	**-11**	**177,882**
Net change in cash	**-95,232**	**-117,538**	**37,905**
Cash and cash equivalents, beginning of year	213,588	175,683	175,683
Cash and cash equivalents, end of period	**118,356**	**58,145**	**213,588**

Consolidated key ratios and other information

	Q1		Year
KSEK, unless other stated	2017	2016	2016
Profit numbers			
Net revenue	1,058	587	2,579
Operating profit/loss	-44,827	-19,946	-111,135
Net profit/loss	-44,994	-19,976	-111,129
Per share data			
Earnings/loss per share before and after dilution (SEK)	-1.28	-0.61	-3.39
Shareholders' equity per share (SEK)	6.85	5.89	8.09
Other information			
Equity ratio (%)	92	94	91
Cash and cash equivalents including short term invesments	209,351	158,080	253,578
Number of outstanding shares at the end of the period	35,054,860	32,412,003	35,054,860
Weighted average number of shares before and after dilution	35,054,860	32,485,477	32,773,304

Parent company – Statement of comprehensive income

	Q1		Year
KSEK	2017	2016	2016
Net revenue	1,058	587	2,579
Direct cost of net revenue	-61	-54	-217
Gross profit	**997**	**533**	**2,362**
Other operating income	213	–	–
Sales, general and administration expenses	-9,775	-4,970	-29,690
Research and development expenses	-36,181	-15,403	-82,735
Other operating expenses	–	-102	-944
Operating profit/loss	**-44,746**	**-19,942**	**-111,007**
Result from other securities and receivables which are fixed assets	–	-728	2,628
Result from short term financial receivables	–	-14	–
Other financial expenses	-176	-15	-14
Profit/loss for the period (before and after taxes)	**-44,922**	**-20,699**	**-108,393**
Other comprehensive income for the period	**–**	**–**	**–**
Total net comprehensive income	**-44,922**	**-20,699**	**-108,393**

Parent company – Balance sheet

KSEK	March 31 2017	March 31 2016	December 31 2016
ASSETS			
Non-current assets			
Intangible fixed assets	32,810	35,623	33,513
Tangible fixed assets	2,916	2,019	2,554
Financial fixed assets	17,317	8,488	17,317
Total non-current assets	**53,043**	**46,130**	**53,384**
Current assets			
Current receivables non-interest bearing	3,386	1,669	3,504
Short-term investments	90,988	99,935	39,995
Cash and cash equivalents	116,097	56,314	211,329
Total current assets	**210,471**	**157,918**	**254,828**
TOTAL ASSETS	**263,514**	**204,048**	**308,212**
EQUITY AND LIABILITIES			
Shareholders' equity	**237,942**	**190,948**	**281,786**
Long-term liabilities			
Other provisions	432	–	114
Long term liabilities, non-interest bearing	559	–	548
Total long-term liabilities	**991**	**–**	662
Current liabilities			
Liabilities to group companies	98	98	98
Current liabilities, non-interest bearing	7,840	2,311	8,368
Accrued expenses and deferred income	16,643	10,691	17,298
Total current liabilities	**24,581**	**13,100**	**25,764**
TOTAL EQUITY AND LIABILITIES	**263,514**	**204,048**	**308,212**

Parent company – Changes in equity

	Q1		Year
KSEK	2017	2016	2016
Opening shareholders' equity	**281,786**	**211,547**	**211,547**
Result for the period	-44,922	-20,699	-108,393
New share issue	–	–	185,000
Expenses attributable to new share issue	–	–	-7,504
Issued warrants	67	100	772
Long term incentive program	1,011	–	364
Total transactions with the group's owner	**1,078**	**100**	**178,632**
Closing shareholders' equity	**237,942**	**190,948**	**281,786**

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 description of the accounting principles applied in this interim report can be found in the Annual Report 2016. The Annual report 2016 has been 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 March 31, 2017 was SEK 14,852 k and SEK 14,566 k as per December 31, 2016. The fair value of the commercial papers as per the balance sheet date March 31, 2017 was SEK 90,981 k and SEK 39,990 k as per 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.

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

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

9. 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 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.

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.

Thrombotic Thombocytopenic Purpura
TTP, Thrombotic Thombocytopenic Purpura, is a rare thrombotic disorder. In the majority of patients, TTP is a result of autoantibody-mediated inhibition of an enzyme (ADAMTS13) that is vital in controlling clotting.

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