

## HSCI Announces Full Year 2016 Consolidated Results under IFRS

**Moscow – 28 April, 2017.** PJSC “HSCI” – The Human Stem Cells Institute (“HSCI”, MOEX: [ISKJ](#)), one of Russia’s leading biotech companies, today announced its audited consolidated results for the full year 2016 in accordance with the International Financial Reporting Standards (IFRS).

In 2016, the HSCI Group of Companies (hereinafter – “the Company”, or “HSCI Group”, or “HSCI”) demonstrated the following main consolidated financial results:

RUB thousands	2016	2015	% change, y-o-y
<b>Revenue</b>	<b>390,356</b>	<b>310,821</b>	<b>25.6%</b>
<b>Operating expenses, incl.</b>	<b>(534,027)</b>	<b>(406,338)</b>	<b>31.4%</b>
Depreciation & amortization	(23,992)	(26,195)	-8.4%
<b>OIBDA<sup>1</sup></b>	<b>(119,679)</b>	<b>(69,322)</b>	<b>72.6%</b>
<i>OIBDA margin, %</i>	<i>n/a</i>	<i>n/a</i>	<i>n/a</i>
<b>Operating income/ (loss)</b>	<b>(143,671)</b>	<b>(95,517)</b>	<b>50.4%</b>
<i>Operating margin, %</i>	<i>n/a</i>	<i>n/a</i>	<i>n/a</i>
<b>Net profit/ (loss)</b>	<b>(130,968)</b>	<b>(62,525)</b>	<b>109.5%</b>
<i>Net margin, %</i>	<i>n/a</i>	<i>n/a</i>	<i>n/a</i>
<b>Total comprehensive income/ (loss)</b>	<b>(130,968)</b>	<b>(62,525)</b>	<b>109.5%</b>

### IP development and intangible assets growth

Being a company involved in R&D and commercialization of innovative biomedical products, HSCI been always paying significant attention to the development of intellectual property and the creation of intangible assets.

This IP, among other things, is used to invest into joint ventures and for licensing.

HSCI Group is actively implementing its patent development policy: as of now, 37 patents (24 - Russia, 13 - abroad) have been received and 35 applications for patents (3 - Russia, 32 - abroad) have been filed. Over the past 3 years, the number of patents granted to the companies of HSCI Group has increased 4-fold.

### Consolidated revenue and revenues generated by key products and services

*The Company’s consolidated revenue for FY2016 amounted to RUB 390.356 million, a year-on-year increase of 25.6% – mainly as a result of a significant increase in revenues from Genetico<sup>®</sup> services (genetic testing and counselling, reproductive cell bank /donation, personal storage/).*

The largest portion of the consolidated revenue – 52.0% – was generated by HSCI PJSC as well as its subsidiaries, IMCB LLC and Cryonix JSC, from cord blood stem cell isolation, cryopreservation and personal storage service.

The second largest revenue generator was Genetico<sup>®</sup> services (genetic testing and counselling, Reprobank<sup>®</sup>) with the share in the consolidated revenue of 36.4%.

SPRS-therapy service provision accounted for 9.4%, the sales of Neovasculgen<sup>®</sup> – for 1.8%, other revenues – for 0.4% of the consolidated revenue in the reporting year.

*The total (summarized) revenue generated by SPRS-therapy<sup>®</sup>, Neovasculgen<sup>®</sup> and Genetico<sup>®</sup> increased by 91.0% year on year - from RUB 97.179 million in 2015 to RUB 185.624 million in 2016, with their share in the Company’s consolidated revenue increasing from 31.3% in 2015 to 47.6% in 2016.*

<sup>1</sup> OIBDA is a non-U.S. GAAP and non-IFRS financial measure, which the Company calculates as total revenues less operating expenses excluding depreciation and amortization. We believe that OIBDA provides useful information to investors because it is an indicator of the strength and performance of our business operations, including our ability to finance investments and to incur and service debt. OIBDA should not be considered in isolation as an alternative to net income, operating income or any other measure of performance under U.S. GAAP or IFRS.

***Neovasculgen® – the first-in-class gene-therapy drug for treatment of Peripheral Arterial Disease (PAD), including Critical Limb Ischemia (CLI)***

In 2016 revenues from the sales of [Neovasculgen®](#) amounted to RUB 7.011 million (1.8% of the Company's consolidated revenue), compared to RUB 1.454 million for 2015 (+382.2%).

To explain the amount of revenues for 2015 and 2016, and the difference with the revenues for 2013 and 2014, it's important to mention that in 2015-2016 the distributors offloaded the stock of Neovasculgen® previously supplied by HSCI – in line with a wholesale RUB 200 million contract. The batches of the drug were supplied by HSCI under this contract in 2013 and 2014 (see the corresponding press-releases), and the distributor sold them out in the Russian market up to October 2016.

In order to facilitate patients' access to Neovasculgen®, the Company is actively interacting with the professional medical community and regulatory authorities from the drug's launch in the Russian market in 2012. One of the first sound results of this work was the inclusion of Neovasculgen® in the List of vital and essential drugs (VED), which enables a significant increase in hospital purchases.

The Government directive on the inclusion of Neovasculgen® into the VED list starting 2016 (# 2724-p.) was published on December 26, 2015 and in mid-March 2016, following the obligatory rule and procedure for all drugs included into the VED list, the cap price limit for manufacturer's wholesales was set for Neovasculgen® in the amount of RUB 120,000 (VAT excluded). The course of treatment for a patient costed RUB 260,000 (the treatment course comprises 2 sequential injections (i.e. 2 vials) with an interval of 14 days).

But in 2017, setting its first goal to accelerate the widespread introduction of Neovasculgen® into medical practice and to increase its accessibility for patients (also striving to promote the fastest import substitution of less effective foreign drugs of the previous generation), the Company reduced the price of Neovasculgen® 2.5 times. So currently the treatment course for a patient costs less than RUB 99,000.

HSCI's Board of Directors adopted this decision being also guided by actual possibilities of the state budget of the Russian Federation in the field of health care, on which the prospects and volumes of state public medicine subsidy programs (state drug reimbursement) depend.

Therefore, having made this step, the Company expects to expand the use of Neovasculgen® in medical practice and, consequently, increase its sales volumes – primarily in the commercial segment (deliveries to pharmacies by the Company), and, subsequently, in the hospital segment (upon the placement of Neovasculgen® as the VED list drug in hospital's procurement plans budgeted by the State).

As of today, dozens of healthcare centers (hospitals) across the Russian Federation have positive track of Neovasculgen® clinical administration. The Company continues to work on further promotion of the drug within medical community as well as on increasing vascular surgeons' and angiologists' awareness of this new therapy approach (therapeutic angiogenesis). The data on therapeutic effect following a treatment course of Neovasculgen® according to 3-5-year observation have been reported at the professional conferences and also published (3 years – aggregated data, 5 years – from 1 clinical site, aggregated data will come soon).

In January 2017 the results of an international postmarketing surveillance study of Neovasculgen's safety and efficacy were published in American Journal of Cardiovascular Drugs (*doi:10.1007/s40256-016-0210-3*: "[Results of an International Postmarketing Surveillance Study of pl-VEGF165 Safety and Efficacy in 210 Patients with Peripheral Arterial Disease](#)"). It total, 210 patients with stage II-III chronic limb ischemia (according to the Fontaine-Pokrovsky classification) in 33 healthcare facilities in Russia and the Ukraine were enrolled in the study which makes it one of the largest among the clinical trials of gene therapy drugs. For details, see our [press-release](#).

In addition to the drug promotion in the Russian market, HSCI is working on the *development of Neovasculgen® in the foreign markets*.

For the development of the drug candidate based on IP connected with the Russian drug Neovasculgen® in the United States, the agreements with the US partners have been signed in 2016 (see our press-releases: [Human Stem Cells Institute Licenses Its Innovative Ischemia Drug to ArtGen, Inc. for Development in the United States and Canada](#), [Human Stem Cells Institute Becomes a Stockholder in Artgen, Inc.](#)). In the course of 3 years from the project start, the contract manufacturing is planned to be set up on the U.S. grounds and pre-clinical studies and the Phase I clinical trials are expected to be completed. For the purposes of developing the drug in the US, HSCI with partners plan to attract the necessary investments.

As Neovasculgen's action mechanism – therapeutic angiogenesis – introduces a new approach to the treatment of ischemia (the use of an evolutionarily programmed process of blood vessel creation and growth), HSCI plans to implement new clinical trial protocols in order to expand the range of indications for applying Neovasculgen®. To start with, HSCI aims to work in the therapy of Diabetic Foot Syndrome and IHD (Ischemic Heart Disease). In October 2016 HSCI received a permission to start clinical trials for Diabetic Foot Syndrome in Russia (CT will start in summer 2017 right from Phase II). while in September 2016 HSCI's subsidiary "NextGen" Co. Ltd. received a patent for gene-therapy method of Diabetic Foot Syndrome treatment.

In addition, the R&D is in progress for the creation of gene-activated bone grafts based on Neovasculgen<sup>®</sup>. In March 2017 clinical trials of Nucleostim-VEGF started. Nucleostim-VEGF (gene construction /active substance of Neovasculgen<sup>®</sup> as transgene/ + scaffold) is a gene-activated bone substitute indicated for bone grafting procedures in oral and maxillofacial surgery, especially for alveolar ridge augmentation.

We develop a pipeline of gene-activated bone substitutes containing Neovasculgen<sup>®</sup> to cover a bone reconstruction in any clinical cases.

Widening the drug's use in the practical healthcare, sales increase in the domestic market and bringing Neovasculgen<sup>®</sup> to the new markets outside of Russia (for which new powerful GMP-manufacturing is to be set up) – these are areas the Company plans to invest in – its own and attracted funds during the nearest 2 years.

Peripheral Arterial Disease (PAD) is a serious, incapacitating disease, which is exceeded in frequency (amongst cardiovascular diseases) only by ischemic heart disease (IHD) and brain stroke. Over 202 million people are diagnosed with PAD worldwide. In the Russian Federation the number of patients with critical form of the disease (CLI, Critical Limb Ischemia) annually amounts up to 145,000, of which 35,000 - 40,000 undergo amputations, while around 25% of patients die. A part of patients diagnosed with CLI is inoperable, and for them Neovasculgen<sup>®</sup> could be the only treatment, allowing the opportunity to evade amputation as well as to significantly improve the quality of life.

According to the drug's clinical trial data and results of its use in practical healthcare, Neovasculgen<sup>®</sup> increases the functioning capillaries number in ischemic tissues, improves the blood supply, reduces the rate of amputation in patients with lower limb ischemia, especially in those who are inoperable for an occlusive PAD.

Containing the gene of the Vascular Endothelial Growth Factor (VEGF) embedded in a plasmid vector (carrier), Neovasculgen<sup>®</sup> stimulates the growth of collateral blood vessels (angiogenesis) and, as a result, promotes a long-term therapeutic effect and improves patients' quality of life, first of all manifested in a substantial increase of Pain Free Walking Distance. In addition, the drug has a significant healthcare economic efficiency (cost-saving effect).

Compared to standard therapies, Neovasculgen<sup>®</sup> has a long-term effect (up to 5 years – compared to 6-8 months for standard therapies) and can be effectively applied at PAD, including CLI (Stages 2a-3 of low limb ischemia according to Fontaine-Pokrovsky).

### ***Cord blood stem cell isolation, cryopreservation and personal storage service – bio-insurance (Gemabank<sup>®</sup>)***

In 2016 consolidated revenues from this service provided by Gemabank<sup>®</sup> amounted to RUB 203.040 million (52.0% of the Company's consolidated revenue), staying flat compared to 2015 (-0.4%).

The steady Gemabank's revenue is attributable to a sustainable growth in revenues from the long-term storage of cord blood stem cells - as a result of increase in the number of samples in Gemabank<sup>®</sup>. As of today, the total number of personal cord blood stem cell samples held in storage at Gemabank<sup>®</sup> has exceeded 26 thousand.

Despite the increase in activity and the number of competitors, Gemabank<sup>®</sup> retains its position as a leading player in the Russian market, traditionally outpaced the peers as for geographical coverage and the number of samples in storage.

Gemabank<sup>®</sup> is aimed at implementing a competitive marketing strategy that meets both the requirements of the current market situation and the state of consumer demand. In order to involve new consumer groups, apply a differentiated pricing policy, ensure the synergy of the business lines of the HSCI Group, in 2016 – early 2017 Gemabank<sup>®</sup> expanded the range of services and launched attractive package offers with flexible pricing.

On November 1st, 2016, Gemabank<sup>®</sup> launched a new unique service called "Bio-insurance with cryostorage of DNA," which, along with cord blood banking, includes the preservation of a DNA sample isolated from a drop of newborn's umbilical cord blood - for future use for genetic testing.

This stored DNA can be immediately used for neonatal screening for inherited disorders – treatable genetic conditions. From January 1, 2017, Gemabank<sup>®</sup>, as part of the package proposal, provides a service of the genetic screening of a newborn for a wide range of the most common hereditary diseases and their carrier status: in order to prevent the development of complications and even clinical symptoms of the disease if early identified, or for family prophylactic treatment of the most widespread inherited disorders (if carrier status is detected). Neonatal screening is carried out based on Gemascreen panel, which was developed by specialists of GENETICO LLC, a subsidiary of HSCI PJSC (see the section on Genetico<sup>®</sup> services below).

Starting from 2016, Gemabank<sup>®</sup> provides the service of cryopreservation and storage of mesenchymal stem cells isolated from umbilical cord – a valuable biomaterial with the potential for therapeutic application in the field of regenerative medicine.

**NB:** From October 1, 2015 the Company started rendering Gemabank<sup>®</sup> services through IMCB LLC (HSCI's 100%-subsidiary) – with the aim to increase effectiveness as well as to use state tax allowance for medical companies.

IMCB (International Medical Center for Biomaterials Processing and Cryostorage) was set up in October, 2014 and in July 2015 obtained the license for hematopoietic cord blood stem cell isolation, transportation and storage services.

In Q4 2015 IMCB started providing this complex service of personal cord blood stem cell banking which used to be provided by HSCI itself, and recorded the revenue from new clients.

In the course of 2017 the whole client base from Gemabank's first days up to Q4 2015 is planned to be handed over from HSCI to IMCB. Therefore, IMCB total revenue will include both revenues from isolation & cryopreservation of cord blood SCs and revenues from the storage of cord blood SCs samples in Gemabank® (annual charges from new and old clients).

IMCB's net income, starting 2016, is allocated to the parent company in the form of dividends to contribute to HSCI's net profit under RAS (unconsolidated) which may be distributed through dividend payment to the HSCI's shareholders.

***SPRS-therapy® – a set of personalized diagnostic and treatment procedures for repairing skin damage due to aging or other structural changes.***

Revenue from [SPRS-therapy®](#), including the long-term storage of autologous skin fibroblasts, in 2016 amounted to RUB 36.688 million (9.4% of the Company's consolidated revenue) – a year-on-year increase of 19.3%.

In the reporting year, the revenue growth rates were slowed down by a decrease of primary appeals because of unstable economic position of potential clients (the service belongs to the premium segment of esthetic medicine market and primary demand is suffer from economic recession in the country). However, we should note a stable growth of secondary appeals: right now more than 80% of patients return for the second and/or additional skin treatments in other areas besides the face. This fact shows us patients' satisfaction by the result. From financial point of view, it should be noted that an additional or repeated service is cheaper for the client as for such service we use the patient's skin fibroblast culture from his/her personal cryobank.

Therefore, the increase in number of requests for services within the spectrum of SPRS-therapy® (both initial and follow-up applications) is securing revenue stability/growth.

The SPRS-therapy® complex service was authorized by the Russian healthcare regulator in 2009-2010 and introduced to the Russian market starting in January 2011.

An innovative medical technology, SPRS-therapy® entails the use of autologous skin fibroblasts to correct the effects of aging and skin damage. The service includes diagnostics of the condition of the patient's skin; a therapy course using the cell product with the patient's own fibroblasts; and long-term storage of the patient's skin fibroblast culture in a cryogenic bank.

The service is primarily offered through the leading dermatology and cosmetics clinics of Moscow, with the growing number of clinics in Russia's regions and CIS (in 18 cities). Overall, more than 70 clinics are providing the service as of now. The total number of patients who have used the service since its introduction to the market is over 700 people.

SPRS-therapy® marketing strategy includes continued work in professional aesthetic medicine community (attracting new clinics, conducting trainings and seminars for doctors, lecturing postdoc students at field-specific medical universities) as well as the promotion of SPRS-therapy® services (including SPRS-bank service for young clients as the type of bio-insurance) directly to consumers (among other things, via Social Media).

Also, the Company maintains the protection of the IP related to SPRS-therapy®. The Company thwarts violation of exclusive rights to the intellectual property, including trademarks, in court.

In addition to the Russian market, the Company is making efforts to promote SPRS-therapy® and the Service of personalized skin diagnosis ("Skin Passport") internationally.

Alongside, work on obtaining global patent protection for the unique diagnostic component of SPRS-therapy know-how, i.e. personalized skin diagnosis ("Skin Passport"), is underway. By now, the patents have been already received in the US (2014), Europe (2017) and Japan (2016).

The Company's plans include expanding the use of technology to treat various serious skin diseases and burns.

In addition, the technology of restoring periodontium soft and hard tissues by application of autologous gingival fibroblasts and biocomposite osteoplastic material is under development (SPRB+SPRG-therapy – a set of personalized diagnostics and treatment procedures).

In 2016 the innovative SPRG-therapy service was launched as stand-alone.

SPRG-therapy (Service for Personal Regeneration of Gum) is a cell-based technology designed to correct and restore periodontal soft tissues by applying autologous gingival fibroblasts. The marketing authorization was received in Russia in December 2010.

## **Genetico<sup>®</sup> services (genetic testing and counseling as well as Reprobank<sup>®</sup> services by Genetico<sup>®</sup> center & lab)**

[Genetico<sup>®</sup>](#) is HSCI's socially significant project for the development of personalized medicine in the field of early detection, prediction and prophylactic treatment of genetic disorders, including reproductive system diseases (via HSCI's own Medical genetics center & lab providing a wide range of [genetic testing and counseling services](#)). In addition, the project entails the development of [Reprobank<sup>®</sup>](#) – reproductive cell personal storage and donation.

The project is implemented by HSCI in partnership with RVC BioFund (a Russian state investment fund), and with a support from IDF (the Russian State Industrial Development Fund).

In 2016 revenues from Genetico<sup>®</sup> services amounted to RUB 141.925 million (36.4% of the Company's consolidated revenue) – a 2.2 times increase over FY 2015 (or +118.5%).

The services that accounted for the biggest share of revenues in the reporting year were preimplantation genetic diagnosis and screening (PGD/PGS) and non-invasive prenatal testing (NIPT).

Reprobank<sup>®</sup> was the third main revenue generator in 2016. HSCI's reproductive cell and tissue bank offers services of sperm and oocytes donation as well as their personal storage as a form a bio-insurance. Reprobank<sup>®</sup> is Russia's largest reproductive cell bank operating independently of IVF clinics.

Genetico<sup>®</sup> services were introduced in the Russian market starting 2013, and their range is continually expanding with a substantial annual revenue growth. Genetico<sup>®</sup> center & molecular diagnostic lab is striving for leadership in the Russian market of reproductive genetics offering a wide range of services relating to different human reproduction stages starting from pregnancy planning and up to a newborn health.

The services are provided by [GENETICO LLC](#) – a subsidiary of HSCI, in which RVC BioFund obtains a 20.01% stake as of now.

The genetic testing labs and Reprobank<sup>®</sup> facilities are located in HSCI's new laboratory and production complex opened in 2013 in Moscow. As of today, Genetico<sup>®</sup> Molecular Genetics Laboratory consists of a Microarray Lab (incl. NIPT Lab), NGS Lab and Genotyping Lab to provide a wide variety of medical genetics services based on different testing methods and techniques (including NGS, DNA microarrays; microfluidic PCR, CMA, CGH, Karyotyping, etc.):

[PGD/PGS](#) – preimplantation genetic diagnosis / screening of early-stage embryos for monogenic inherited diseases / chromosomal abnormalities during an IVF cycle, which allows specialists to determine which embryos can be recommended for transplantation into the uterus. HSCI's PGD laboratory, created in cooperation with the pioneer and world leader in this field – the US Reproductive Genetics Institute, as of today holds #1 place in Russia by the number of patients. The laboratory uses a broad arsenal of methods and technologies which meet the strictest requirements for the fullness, informative value and reliability of the analysis as applicable to any situation in which preimplantation genetic diagnosis is required: when there is a risk of giving birth to a child with a serious inherited disease, in the case of high risk of chromosome abnormality which could lead to the death of an embryo or birth of a child with a pathology (such as Down syndrome), when it is vital to ensure that the future child will be a suitable donor of hematopoietic stem cells for the treatment of an older brother or sister suffering from an inherited disease (the selection of an embryo which is free of the disease-inducing mutation and also a compatible match (HLA-matched) for the sick sibling). *HSCI is the first in Russia to have implemented the technology combining PGD, IVF, and transplantation of hematopoietic cord blood stem cells – see: [Bone Marrow Transplantation advance online publication 27 March 2017; doi: 10.1038/bmt.2017.46](#) (First experience of hematopoietic stem cell transplantation treatment of Shwachman–Diamond syndrome using unaffected HLA-matched sibling donor produced through preimplantation HLA typing).*

[NIPT](#) (Prenetix<sup>®</sup> / Harmony<sup>™</sup> Prenatal Test) – non-invasive prenatal testing of fetal chromosome aberrations using maternal venous blood (can be performed as early as 10 weeks in pregnancy to assess the risk of having a child with Down syndrome and other severe genetic conditions).

Starting from Q4 2013, HSCI offers in Russia a service of non-invasive prenatal testing followed by a genetic consultation on the results under Prenetix<sup>®</sup> brand name. Prenetix<sup>®</sup> service is based on the analysis elaborated in the USA – Ariosa Diagnostics' Harmony<sup>™</sup> Prenatal Test that delivers a high level of accuracy on the back of a proprietary cell-free DNA technology (AcfS) including precise measurement of fetal fraction found in maternal blood and individualized results scoring. Initially it was a send-out test. In 2017 HSCI's Genetico<sup>®</sup> laboratory makes technology transfer and becomes the first in Russia and the CIS equipped by Roche (who acquired Ariosa Diagnostics Inc. in 2015) to produce the Harmony<sup>™</sup> Prenatal Test locally. *The project is supported by IDF – for details – see below.*

[Genetic panels and tests](#) for specific cases, classes and types of socially significant diseases and genetically determined pathologies, including in the reproductive health area:

For the newborns - neonatal screening (for early identification to prevent the development of clinical symptoms / complications as well as for prophylactic treatment of the most widespread inherited disorders).

For patients with infertility.

For women with recurrent miscarriages and pregnancy complications.

For couples in pregnancy planning - preconception screening to minimize the risks of giving birth to a child with a monogenic disease (in case the carrier status is identified among expectant parents, development of the pathology in offspring can be prevented with the help of IVF with PGD).

**Oncogenetics** – identification of genetic predisposition to breast cancer and/or ovarian cancer; NGS-based extended diagnostic panel for familial oncological diseases.

Pharmacogenetics – for the selection of better therapy while treating cardiovascular diseases and chemo therapy in case of cancers when the therapeutic effect depends on the genetics of tumor.

NGS-based genome sequencing and interpretation, including Whole Exome Sequencing for the diagnosis of complicated inherited disease cases, Clinical Exome Sequencing, a range of extended diagnostic panels for specific disease categories and cases.

The Company's plans include further promotion of Genetico<sup>®</sup> services among both medical and patient communities, geographic expansion of sales and the increase in the number of partnerships with health centers in Russia. In addition, the Company plans to launch its services in the field of medical, including reproductive, genetics on the markets outside of Russia.

To scale the business of providing Genetico<sup>®</sup> services, first of all – through technology transfer and localization of production of DNA-tests/diagnostic panels in Russia, the Company has attracted a long-term loan from IDF (Russian State Industry Development Fund) – in the amount of RUB 300 million for 5 years, with an interest rate of 5% per annum with a grace period for the payment of principal debt (starting the 4<sup>th</sup> year): see - [HSCI GENETICO Center received RUB 300 mln from IDF](#).

Under this project, on the basis of Genetico<sup>®</sup> Center, HSCI will organize production of genetic tests on the base of DNA arrays (microfluidic) and next-generation sequencing (NGS) for non-invasive prenatal testing of fetal chromosome abnormalities and early detection and prevention of inherited diseases, including identification of genetic predisposition to hereditary cancers as well as selection of targeted therapy.

In Q2 2017 Genetico<sup>®</sup> Center set up new laboratories (NIPT lab and NGS lab) to become one of the best European centers of genetic diagnostics furnished with state of the art equipment and unique technologies. This will enable Russia to export genetic testing services in neighboring countries and Europe. With high quality of DNA tests, Genetico<sup>®</sup> will reduce the costs for imported components of the tests to make them more affordable for customers and proper for inclusion in the CHI state program.

The Company also cooperates with regulatory, medical and patient communities to develop and implement new standards and programs aimed at the development of cutting-edge technologies in genetic diagnostics and their widespread introduction into practical healthcare (including within the framework of the National Technology Initiative, initiated by the President of the Russian Federation).

### **Operating expenses, OIBDA, Operating profit/ (loss)**

**Consolidated operating** expenses in 2016 increased by 31.4% year on year to RUB 534.027 million.

The increase in operating costs is derived from the investment stage of some projects and the necessity to increase the expenses associated with capturing and maintaining the leading positions in the current and promising prospective markets (we would like to take an advantage from these fast-growing markets – to capture a majority market share and then capitalize on the market growth, for our leadership to serve a base for the Company sustainable development in the long-term).

These are costs for production of services as well as sales costs (first of all, “Suppliers and reagents”, “Services of contractors”, “Wages, salaries, other benefits and payroll taxes” – staff costs surged mainly due to the creation / expansion of in-house sales and marketing teams as well as strong management teams for each company of HSCI Group as part and parcel of ongoing corporate restructuring /separating business units by segment so as to increase operating efficiency and facilitate proper valuation and PE investment/).

In order to ensure the increase in revenues generated by Genetico<sup>®</sup> services and SPRS-therapy service on the back of growing number of customers, we increased expenses for consumables, reagents and services of third-party contractors. Behind the surge in these costs there was mainly the surge of price for outsourced genetic tests and consumables purchased abroad (due to the increase in the number of outsourced tests as well as depreciation and current fluctuation of the Russian ruble).

For example, in the reporting year we saw an increase in demand for our non-invasive prenatal testing service. It was a send-out test - based on the analysis elaborated in the USA (*Ariosa Diagnostics' Harmony<sup>TM</sup> Prenatal Test*). To cut costs and reduce prices for the client, the Company decided to have technology transfer and manufacturing localization for import substitution (see above “Genetico<sup>®</sup> services” chapter – a long-term loan from IDF). In Q2 2017 HSCI's Genetico<sup>®</sup> laboratory makes technology transfer and becomes the first in Russia and the CIS equipped by Roche (who acquired Ariosa Diagnostics Inc. in 2015) to produce the Harmony<sup>TM</sup> Prenatal Test locally.

The increase in costs for Consulting and legal services was driven by preparation and taking of steps towards implementation of the Company's strategic goals in different fields (including promotion of the Company's services outside of Russia, the project of development of the drug candidate based on IP linked to the Russian drug Neovasculgen<sup>®</sup> in the United States and Canada, restructuring of international SynBio project).

As there was no such revenue increase to compensate rather high operating expenses necessary as of now to promote a range of promising products and services, for 2016 the Company demonstrated negative operating profitability and margins (*see Appendix I below*).

Operating expenses before depreciation and amortization amounted to RUB 510.035 million, resulting in a negative OIBDA of RUB -119.679 million.

The Company's operating loss amounted to RUB 143.671 million in the reporting year.

### **Net other gain/ loss, Profit / (loss) before income tax**

In 2016, the Company's consolidated net other loss (share of loss of associates + net interest expense + net other non-operating income + net foreign exchange loss) amounted to RUB 6.043 million – compared to consolidated net other gain of RUB 35.208 million in 2015 (*see Appendix I below*).

The size of consolidated net other loss in 2016 and the difference with 2015 were largely determined by:

- A RUB 4.519 million loss from the sale of purchased securities (quoted shares) and a revaluation loss of RUB 12.064 million – due to the reduction in the number of these financial instruments held for trading, along with the current stock market trends (compared to RUB 42.422 million revaluation gain in 2015).
- A RUB 23.165 million net interest loss – due to the interest expense increase caused by borrowed funds (compared to net interest loss of RUB 4.622 million for 1H 2015).
- A net foreign exchange loss in the amount of RUB 2.455 million against a net foreign exchange gain in the amount of RUB 0.902 million in 2015.

As a result of both operating and non-operating loss, in the reporting year the Company recognized loss before income tax in the amount of RUB 149.714 million.

### **Profit / (loss) for the year (net profit / (loss))**

Due to the reasons mentioned above, in 2016 the Company demonstrated a consolidated net loss totaling RUB 130.968 million.

### **Consolidation**

The consolidated financial statements for the full year 2016 include the operating results of HSCI PJSC and its subsidiaries – IMCB LLC, GENETICO LLC, NextGen LLC, Vitacel LLC, Cryonix JSC, Cell Technologies Laboratory LLC, NVG-cardio LLC, “Angiogenesis” LLC and also HSCI's share in the loss of its associated company IceGen LLC (*see Notes 2, 3, 9, 10 to HSCI's audited consolidated financial statements as of and for the Full Year of 2016 under IFRS*).

### **APPENDICES:**

1. Audited consolidated statements of profit and loss and comprehensive income for the years ended December 31, 2016, and December 31, 2015 – in RUB thousands (extended).
2. Condensed audited consolidated statements of financial position as of December 31, 2016 and December 31, 2015 – in RUB thousands

*HSCI's audited consolidated financial statements prepared in accordance with IFRS as of and for year ended December 31, 2016 can be viewed on the Company's corporate website under “For Investors” (Financial Reports -> IFRS):*

<http://eng.hsci.ru/investoram-i-aktsioneram/financial-reports/financial-reports-in-accordance-with-international-financial-reporting-standards-ifrs>

## Appendix I

Audited consolidated statements of profit and loss and comprehensive income for the years ended December 31, 2016, and December 31, 2015 – in RUB thousands (extended).

'000 RUB	2016	2015	% change, y-o-y
<b>Revenue from products and services:</b>			
Isolation, cryopreservation and personal storage of cord blood stem cells	203,040.0	203,865.0	-0.4%
Neovasculgen <sup>®</sup>	7,011.0	1,454.0	382.2%
SPRS-therapy <sup>®</sup>	36,688.0	30,762.0	19.3%
Genetico <sup>®</sup> center & lab (genetic testing and counselling, Reprobank <sup>®</sup> )	141,925.0	64,963.0	118.5%
Sale of medical devices, supplies (distribution for Cytori Therapeutics, Inc., USA)	-	5,000.0	n/a
Research and development agreements	811.0	4,444.0	-81.8%
Other revenue	881.0	333.0	164.6%
<b>Total revenue</b>	<b>390,356.0</b>	<b>310,821.0</b>	<b>25.6%</b>
Wages, salaries, other benefits and payroll taxes	(132,656.0)	(79,650.0)	66.5%
Rental fee	(34,667.0)	(27,977.0)	23.9%
Supplies and reagents	(60,309.0)	(47,407.0)	27.2%
Services of third-party organizations (contractors)	(54,482.0)	(41,156.0)	32.4%
Consulting and legal services	(77,331.0)	(38,282.0)	102.0%
Advertising costs	(52,559.0)	(63,333.0)	-17.0%
R&D costs	(36,908.0)	(28,854.0)	27.9%
Transportation, Travel and Representation expenses	(19,177.0)	(15,953.0)	20.2%
Bad debt recovery/ (expense)	(10,799.0)	(7,741.0)	39.5%
Telecommunications services, software and maintenance	(9,390.0)	(8,967.0)	4.7%
Tax expenses	(1,613.0)	(3,944.0)	-59.1%
Maintenance of cryogenic equipment	(2,268.0)	(2,717.0)	-16.5%
Other operating expenses	(17,876.0)	(14,162.0)	26.2%
<b>Operating expenses before depreciation &amp; amortization</b>	<b>(510,035.0)</b>	<b>(380,143.0)</b>	<b>34.2%</b>
<b>OIBDA</b>	<b>(119,679.0)</b>	<b>(69,322.0)</b>	<b>72.6%</b>
<b>OIBDA margin, %</b>	<b>n/a</b>	<b>n/a</b>	<b>n/a</b>
Depreciation & amortization	(23,992.0)	(26,195.0)	-8.4%
<b>Total operating expenses</b>	<b>(534,027.0)</b>	<b>(406,338.0)</b>	<b>31.4%</b>
<b>Operating profit / (loss)</b>	<b>(143,671.0)</b>	<b>(95,517.0)</b>	<b>50.4%</b>
<b>Operating margin, %</b>	<b>n/a</b>	<b>n/a</b>	<b>n/a</b>
<b>Gain / (loss) from associates</b>	<b>(460.0)</b>	<b>(474.0)</b>	<b>-3.0%</b>
<b>Other income/ (loss) - net, incl.</b>	<b>(5,583.0)</b>	<b>35,682.0</b>	<b>n/a</b>
Net interest expense (interest income + interest expense)	(23,165.0)	(4,622.0)	401.2%
Other non-operating income / (loss) - net, incl.	20,037.0	39,402.0	-49.1%
Gain / (loss) from revaluation of financial instruments held for trading (purchased quoted securities)	(12,064.0)	42,422.0	n/a
Foreign exchange gain / (loss), net	(2,455.0)	902.0	n/a
<b>Profit / (loss) before income tax</b>	<b>(149,714.0)</b>	<b>(60,309.0)</b>	<b>148.2%</b>
Income tax	18,746.0	(2,216.0)	n/a
<b>Profit/ (loss) for the year (net profit/ (loss))</b>	<b>(130,968.0)</b>	<b>(62,525.0)</b>	<b>109.5%</b>
<b>Net margin, %</b>	<b>n/a</b>	<b>n/a</b>	<b>n/a</b>
<b>Other comprehensive income, net of tax</b>	<b>-</b>	<b>-</b>	<b>n/a</b>
<b>Total comprehensive income / (loss) for the year, net of tax</b>	<b>(130,968.0)</b>	<b>(62,525.0)</b>	<b>109.5%</b>

## Appendix II

Condensed audited consolidated statements of financial position as of December 31, 2016 and December 31, 2015 – in RUB thousands

<b>RUB thousands</b>	<b>Dec. 31, 2016</b>	<b>Dec. 31, 2015</b>	<b>% change, y-o-y</b>
<b>ASSETS</b>			
<b>Non-current Assets, incl.:</b>	<b>477,268</b>	<b>471,228</b>	<b>1.3%</b>
Property, plant and equipment	153,142	96,553	58.6%
Intangible assets	59,151	47,659	24.1%
Investments in associates	245,318	313,952	-21.9%
<b>Current Assets, incl.:</b>	<b>561,923</b>	<b>361,306</b>	<b>55.5%</b>
Accounts receivable	119,728	89,273	34.1%
Other current financial assets, incl.	92,518	159,195	-41.9%
Financial assets at fair value through profit or loss (held for trading)	80,956	144,771	-44.1%
Cash and cash equivalents	285,545	50,761	462.5%
<b>Total Assets</b>	<b>1,039,191</b>	<b>832,534</b>	<b>24.8%</b>
<b>EQUITY AND LIABILITIES</b>			
<b>Shareholders' equity:</b>	<b>238,631</b>	<b>359,401</b>	<b>-33.6%</b>
Equity attributable to equity holders of the parent, incl.	153,815	287,624	-46.5%
Retained earnings	71,807	183,116	-60.8%
Dividends declared for payment	(22,500)	-	n/a
Non-controlling interests	84,816	71,777	18.2%
<b>Non-currents liabilities, incl.:</b>	<b>323,111</b>	<b>54,372</b>	<b>494.3%</b>
Long-term loans and borrowings	307,400	-	n/a
Deferred tax liabilities	15,711	29,747	-47.2%
<b>Current liabilities, incl.:</b>	<b>477,449</b>	<b>418,761</b>	<b>14.0%</b>
Short-term loans and borrowings	38,851*	90,048**	-56.9%
Advances received	346,708	299,027	15.9%
Accounts payable (trade and other)	87,610	19,299	354.0%
Deferred income	-	7,990	n/a
<b>Total Liabilities</b>	<b>800,560</b>	<b>473,133</b>	<b>69.2%</b>
<b>Total Equity and Liabilities</b>	<b>1,039,191</b>	<b>832,534</b>	<b>24.8%</b>
<b>Net debt***</b>	<b>-20,250</b>	<b>-80,859</b>	<b>-75.0%</b>

\* Including short-term portion of long-term loans to be repaid within less than one year period – in the amount of RUB 15,283 thousand.

\*\* Including short-term portion of long-term loans to be repaid within less than one year period – in the amount of RUB 14,905 thousand.

\*\*\* Net debt is calculated as the sum of long-term and short-term loans and borrowings minus cash and cash equivalents and financial assets at fair value through profit or loss (held for trading) – quoted securities.

**Human Stem Cells Institute PJSC (HSCI, [www.eng.hsci.ru](http://www.eng.hsci.ru))** is a Russian public biotech company founded in 2003.

HSCI engages in drug discovery, R&D and marketing of innovative proprietary products and services in the field of regenerative medicine, bio-insurance, medical genetics including reproductive genetics, gene therapy and biopharmaceutics.

The Company aims to foster a new culture of medical care – developing new health care opportunities in such areas as personalized and preventive medicine.

HSCI owns the largest family cord blood stem cell bank in Russia and the CIS – [Gemabank<sup>®</sup>](#), as well as the reproductive cell and tissue bank [Reprobank<sup>®</sup>](#) (personal storage and donation).

The Company launched [Neovascugen<sup>®</sup>](#), the first-in-class gene therapy drug for the treatment of Peripheral Arterial Disease, including Critical Limb Ischemia, and also introduced the innovative cell technology [SPRS-therapy<sup>®</sup>](#), which entails the use of autologous dermal fibroblasts to repair skin damage due to aging and other structural changes.

HSCI is implementing a socially significant [Genetico<sup>®</sup>](#) project for the development of its own Medical genetics center & lab to provide a wide range of [genetic testing and counseling services](#) with the aim of early identification, prediction and prophylactic treatment of genetic disorders, including reproductive system diseases (e.g. [PGS/PGD](#), [NIPT](#), [Oncogenetics](#), Bioinformatics, genetic panels for specific disease categories and cases).

The Company actively promotes its products and services on the Russian market and intends to open new markets throughout the world.

HSCI is listed on the Innovation & Investment Market (iIM) of the Moscow Exchange (ticker: [ISKJ](#)). The Company conducted its IPO in December 2009, becoming the first Russian biotech company to go public.

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*Certain statements in this press-release are forward-looking statements within the meaning of the U.S. federal securities laws and are intended to be covered by the safe harbors created thereby.*

*Those forward-looking statements include, but are not limited to:*

- *management's assessment of the Company's future results, including revenue, net profit(loss), profit(loss) per share, dividends, investments, capital structure, margins and other operating and financial results;*
- *forecasts of the present value of future cash flows and related factors;*
- *the Company's plans, goals and tasks relating, among other things, to its products and services development;*
- *the Company's expectations with respect to improving its corporate governance practices;*
- *the Company's market position – as anticipated;*
- *economic outlook and industry trends;*
- *the Company's expectations as to the sector regulation and assessment of impact of regulatory initiatives on the Company's activity;*
- *assumptions and prerequisites under the statements.*

*Such forward-looking statements are subject to risks, uncertainties and other factors, which could cause actual results to differ materially from those expressed or implied by these forward-looking statements.*

*These risks include the risk of changes in political, economic and social conditions in Russia as well as changes in global economic environment, the risks relating to changes in industry regulation and the Russian legislation, the risk of changes in the Company's operations and business prospects, the competition and other risks.*

*For a more detailed discussion of these and other factors, see the Company's Annual Report and other public filings.*

*Many of these factors are beyond the Company's ability to control or predict. Given these and other uncertainties, readers are cautioned not to place undue reliance on any of the forward-looking statements contained herein or otherwise. The Company does not undertake any obligation to release publicly any revisions to these forward-looking statements (which are made as of the date hereof) to reflect events or circumstances after the date hereof or to reflect the occurrence of unanticipated events, except as may be required under applicable laws.*

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