HSCI Reports Full Year 2013 Results under RAS

Moscow – 2 April 2014 OJSC HSCI – The Human Stem Cells Institute ("HSCI", MOEX: ISKJ), one of Russia's leading biotech companies, today announced its audited unconsolidated results for 2013 in accordance with the Russian Accounting Standards (RAS):

- *HSCI's revenue for the full year 2013 amounted to RUB 402.0 million, increasing by 42% year on year; new products (Neovasculgen®, SPRS-therapy, genetic diagnostics and consulting) accounted for 46.6% of total revenue.*
- *Gross profit rose by 66% year on year to RUB 194.9 million for a gross profit margin of 48.5%; operating profit amounted to RUB 61.5 million compared to an operating loss of RUB 0.4 million in the previous year.*[1]
- *OIBDA*[2] *amounted to RUB 78.5 million compared to RUB 6.9 million in 2012; OIBDA margin for 2013 amounted to 19.5% .*
- *Net profit in 2013 amounted to RUB 11.5 million compared to a net loss of RUB 31.6 million in the previous year.*

General Director of HSCI Artur Isaev commented:

"Last year the Company increased revenues by 40% and achieved all key objectives for the development of our projects in the market. The year was one of active work on the launch of sale and marketing of new products and services of HSCI.

An important event in 2013 was the opening of HSCI's unique new laboratory and production complex for the creation of products and provision of services in regenerative medicine and medical genetics. We have completed the licensing process and the Molecular Genetics laboratory has begun function, allowing us to launch the entire spectrum of services for medical genetics diagnostics and consultations, including Ethnogene and PGD. We received a license for pharmaceutical production. Reprobank – a reproductive cell and tissue bank – has also opened at our new laboratory and production complex. All these services are offered to the public through a network of advanced medical genetics centers which are being opened by the company across Russia under the *Genetico* brand. As of today Genetico centers have been established and licensed in 4 cities in Russia and the opening of 2 more is expected in the nearest future. It should be noted that revenues from these specific services are reflected in the Company's consolidated revenue, as they are provided by RGMC HSCI LLC, a subsidiary of HSCI. Consequently, the first sales results will be presented in the Company's consolidated annual financial statements according to IFRS, which will be published no later than April 30 of this year.

Revenue from the sale via distributors of the innovative drug Neovasculgen®, which was launched on the Russian market in late-2012, have significantly changed the structure of HSCI's total revenue. However, it is important to note that we have not yet succeeded in getting the drug included on the state drug subsidy programs, which is hindering the development of resale and accessibility to this drug for all patients in need. The absence of Neovasculgen® in the official list of Vital and Essential Drugs, which has not been updated in Russia for the past three years according to the governmental decision, makes it impossible for state medical facilities to place batch orders for the drug. We continue to work on the inclusion of the drug in the list which is being formulated for 2015 and we have reason to believe that the situation will change. We have also made the decision to take the drug to other markets which are substantially larger than the Russian market. Work on registration of Neovasculgen® in the United States and China is expected to begin this year.

Moreover, substantial work has been done to attract investment to finance further development of the *Genetico* project, and our partner will be RVC BioFund, a state investment fund."

---

[1] Here and below comparative results for 2012 are presented with restatements made according to the recommendations of the auditors – E&Y (Ernst & Young). We also note that in the process of preparing 2013 financial statements, the Company introduced a number of corrections in order to accurately reflect the condition of its business, with these corrections concerning interim reporting periods during 2013.

[2] 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.

HSCI's revenue and income by project

HSCI's revenue in 2013 increased by 41.9% in comparison to the previous year and reached RUB 401.975 million.

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

Revenues from the sale of HSCI's own innovative drug Neovasculgen® through distributors in Russia and Ukraine in 2013 amounted to RUB 166.680 million (41.5% of the Company's total revenue). Since the launch of the drug in the Russian market at the end of the third quarter of 2012, revenues have totaled RUB 176.130 million (approximately 3,500 packages).

Neovasculgen® received marketing authorization on December 7, 2011 (registration decision RU № LP-000671). After industrial production of the first batches of Neovasculgen was launched and certified (in late-September 2012), the drug went on sale in Russia in the form of a ready-to-use drug (lyophilisate to prepare an injection solution; the treatment course comprising 2 sequential injections /i.e. 2 vials/) offered through distributors.

In March 2013 HSCI signed a sales agreement with Sotex Pharm Firm, which is part of Protek Group and has extensive experience in bringing medicines to market. The agreement covers three commercial years.

Throughout 2013 significant outreach efforts were made to engage the professional community of cardiovascular surgeons and angiologists as well as state healthcare bodies to promote Neovasculgen® and for the comprehensive development of its market in Russia. In June 2013 Neovasculgen® was included in the National Recommendations for treating patients with Peripheral Arterial Disease, the new version of which was approved at the international conference of vascular surgeons in Novosibirsk.

Due to the fact that this drug is innovative and expensive, the dynamics of sales to end-customers is highly dependent on its inclusion in state medicine financing programs. Thus one of the Company's key objectives is the inclusion of Neovasculgen® in federal and regional public drug subsidy programs. An import step in this direction would be the inclusion of Neovasculgen® in the list of Vital and Essential Drugs. However, changes the list were not approved by the Government for either 2013 or 2014 (a government directive from December 19, 2013 stipulated that the list would not be changed for 2014, thus leaving in place for a third year in a row the list confirmed for 2012). In 2014 the Company will submit another application for the inclusion of Neovasculgen® in the Vital and Essential Drugs list for 2015.

In addition to the Russian market, HSCI intends to make Neovasculgen® available on other markets as well.

In February 2013 marketing authorization for Neovasculgen® was received in Ukraine: the first deliveries of the drug to Ukraine were made in the second quarter of 2013 with corresponding revenues reflected in the reporting period.

In 2014 efforts will be undertaken to launch the process of receiving marketing authorization for Neovasculgen® in the United States and China.

HSCI has prepared a business plan to introduce Neovasculgen® to the US market, analyzed the potential of the market (which is substantially larger than the Russian market), selected potential partners for addressing regulatory issues and contract production as well as preclinical studies and clinical trials, and made calculations of the financing required. According to preliminary estimations, the required volume of investments for carrying out preclinical studies and clinical (Phase I and II) trials in the United States would be approximately US$20 million. The Company intends to attract the required funds from both Russian and international investors. One of possible options is an SPO on the Moscow Exchange and/or a private placement with an institutional investor(s). Other options are also being considered for attracting financing for the development of the drug in the United States.

A business plan for bringing Neovasculgen® to the Chinese market is also in the works.

The action mechanism of Neovasculgen® – therapeutic angiogenesis – introduces a new approach to the treatment of ischemia: the use of an evolutionarily programmed process of blood vessel creation and growth. For this reason HSCI aims to implement new pre-clinical studies and clinical trial protocols in order to expand the range of indications for applying Neovasculgen® (other nosologies in addition to PAD, including cardiovascular diseases, i.e. IHD).

Isolation, cryopreservation and storage of umbilical cord blood stem cells *– bio-insurance (Gemabank®)*

In 2013 revenue from this service amounted to RUB 201.223 million (50.0% of the Company's total revenue). Revenue from this service was down 11.7% from 2012.

During the reporting period HSCI' s revenues from the storage of cord blood stem cells rose (+24,8% – RUB 56.402 million compared to RUB 45.187 million in 2012) while revenues from the isolation and cryopreservation of cord blood stem cells declined (-20,7% – RUB 144.821 million compared to RUB 182.638 million in 2012). The number of contracts signed for cord blood stem cell banking declined by 25.3% year on year and totaled 2,776. Thus the total number of personal cord blood stem cell samples held in storage at Gemabank® at the end of 2013 increased to 19,700.

One of the reasons for the decline in sales was the impact of consumers' reaction to a negative article on cord blood stem cell banking published in a well-known Russian magazine in the end of January 2013. The article contained false information which discredits this medical field on the whole and tarnishes the reputation of stem cell banks, including Gemabank®. In response to this HSCI has engaged in an informational and public awareness campaign and also filed a lawsuit against Mediaholding Expert (owners of the Russky Reporter magazine) with the demand that the magazine publish HSCI's response to the article in Russkiy Reporter No.3 (281) from 24 January 2013 "Money for Babies' Blood". In October 2013 the Arbitration Court of the City of Moscow ruled in favor of HSCI. The decision came into force on 26 November 2013, however, the court rulling has yet to be fulfilled and HSCI's response has not been published in Russky Reporter till today.

Research and assessment of the cord blood stem cell banking market in Russia conducted by the Company has shown that in 2013 Gemabank® retained its leading positions. However, it should be noted that competitors have become more active and new players have emerged, particularly on the market for Moscow and the Moscow region. Another important feature is that the Russian market for personalized cord blood stem cell banking, according to the research, has potential for growth: over the past three years the country has seen rising birth rates and rising consumer demand while the market for cord blood stem cell banking has remained virtually unchanged from the level reached in 2011.

On the whole, it should be noted that in 2012-2013 the relative decline in consumer demand for cord blood stem cell banking has been observed not only in Russia but in other countries as well, now the market stabilizes and becomes more consolidated. HSCI believe that in the second half of 2014, despite possible crisis downtrends in consumer demand, the growth dynamic will return.

Ukraine's largest cord blood bank Hemafund, in which HSCI holds a 50% stake, as of the end of 2013 held more than 7,100 cord blood stem cell samples in storage.

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

Revenue from SPRS-therapy, including the long-tern storage of autologous skin fibroblasts, in 2013 totaled RUB 19.938 million (5.0% of the Company's total revenue). Revenue from the service was up 18.9% from 2012.

This service was authorized by the Russian healthcare regulator 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.

This service is primarily offered through the leading dermatology and cosmetics clinics of Moscow (more than 20); however, in 2012 cooperation in providing this service began to extend to clinics in Russia's regions (covering 5 cities by the end of 2013).

The total number of patients that had used this service as of the end of 2013 was 356 people. A third of patients have returned for second and/or additional skin treatments in other areas besides the face. The number of requests for services within the spectrum SPRS-therapy (both initial and follow-up applications) in 2013 increased by 35% from 2012.

In parallel with continued work with doctors and clinics specializing in aesthetic medicine, the marketing strategy continues to also include a focus on the promotion of SPRS-therapy services directly to consumers.

In September 2012, Vitacel LLC (a fully owned subsidiary of HSCI) applied for an international patent (PCT) to protect its IP for the related "Diagnostic method for connective tissue and its application", which is necessary to receive global patent protection for SPRS-therapy and, in particular, personalized skin diagnostics (Skin Passport®). This PCT application was published on April 11, 2013, which provides temporary legal protection of the technology in countries which allow for patent applications in English. In July 2013 the international patent application moved to the national and regional phases, and in September the corresponding Eurasian Patent Application (covering the CIS) was published and in October the United States patent application was published.

In February 2014, the US Patent Office completed its expert review and issued Vitacel a patent for its "Method of determining tissue regenerative ability of the skin", which provides the opportunity to protect the SPRS-therapy know-how in the United States and, consequently, provides an opportunity for the development of this innovative technology on the US market.

In late-March 2014 national patent applications were submitted to the European Patent Office as well as to the Patent Office of Brazil.

Genetic diagnostics and consultation services at Genetico medical genetics centers – *HSCI's socially significant project aimed at promoting the widespread use in Russia of medical genetics diagnostics and consultation for the identification and prophylactic treatment of monogenic inherited diseases and multifactorial disorders.*

Revenues from the provision of Gemascreen service for newborns reflected in HSCI revenues amounted to RUB 0.834 million in 2013 (0.2% of the Company's revenues). At the same time it should be noted that starting in the second quarter of 2013 the provision of Gemascreen service was transferred to RGMC HSCI LLC, a fully owned subsidiary of HSCI. Therefore, in total, revenues from this service in 2013 amounted for RUB 1.7 million (under RAS). Starting in the fourth quarter of 2013 the provision of Gemascreen service has been halted due to the launch of a broader service using HSCI's proprietary DNA array (see below).

The revenues received from the provision of Ethnogene service as well as PGD (Preimplantation Genetic Diagnosis) are reflected in the results of RGMC HSCI and are thus considered part of the Company's consolidated revenues. Consolidated revenues from all types of genetic diagnostics and consulting services were presented for the first time in HSCI's interim IFRS statements for the first half of 2013 (published on August 29, 2013). The figures for the annual revenues from these services will be presented in the consolidated financial results of HSCI for 2013 under IFRS (to be published no later than 30 April 2014).

In 2011 HSCI developed a project to create its own a Russia-wide network of advanced medical genetics centers to provide genetic diagnostics and consulting services with a physician-geneticist.

The main aim of the project is to identify and forecast risks for clinically healthy individuals and their progeny, i.e. to foster and promote among the Russian public a new attitude towards one's own health and the health of future generations. Genetic diagnostics and consulting services are intended to foster a preventative approach to healthcare, whereby every person has the opportunity to in a timely manner discover their genetic features and take the necessary measures (including with the help of new medical technologies) to maintain good health and the health of one's children as well as to prevent the coincidental birth in the family of children with serious inherited pathologies.

In January 2012 the Company began to implement the first test phase of the project, launching the Russia-wide Gemascreen for Newborns program. This service included DNA screening and consulting services on the six most widespread inherited disorders in Russia and congenital features. DNA screening was mainly carried out using cord blood of the newborn. Through follow-up consultations with a genetic doctor the parents received information on prophylactic treatment of complications and prevention of the development of clinical symptoms of a disease (if discovered) or advice on approaches to planning the health of the child's progeny (in the case that carrier status is identified).

In parallel during 2012 substantial progress was also made on the creation of a proprietary DNA array which makes it possible to test for a large number of inherited diseases (monogenic) and predisposition to widespread multifactorial disorders. One of the key ideas behind the creation of this DNA array is its practical application: it reflects the spectrum of inherited diseases characteristic for residents of Russia and the CIS.

In February 2013, HSCI completed the technical validation of the array and in April completed its clinical validation. Genetic screening using this DNA array of HSCI, which has been called Ethnogene, allows to simultaneously test for

the presence or carrier status of more than 60 monogenic inherited diseases and also predisposition to the development of several prevalent multifactorial disorders.

Starting in the second half of April 2013 HSCI began using this array to provide its new Ethnogene service – medical genetics consultations for a broad range of consumers: for children and adults (determination of the genetic features and identification of risks for healthy individuals (including those concerning their future offspring) with the aim of preventing a combination of genetic factors which would allow for the expression of inherited disorders or to prevent the development of complications arising from already existing risks), as well as for couples in pregnancy planning (preconception screening to minimize the risks of giving birth to a sick child).

In November 2013 as a part of efforts to develop the Ethnogene offer for newborns, a new specialized version of this service is being promoted called *Ethnogene Neo*, which replaces Gemascreen service previously offered in Russia. Ethnogene Neo includes genetic screening using the HSCI's DNA array as well as diagnosis of the presence of Gilbert's syndrome and congenital adrenal hyperplasia (via analysis of cord/peripheral blood of the newborn).

In the third quarter of 2013 the Company also began to provide the spectrum of PGD services – preimplantation genetic diagnosis of an embryo for monogenic inherited diseases and chromosome anomalies during IVF cycles. The PGD laboratory, which operates within the HSCI's new laboratory and production complex, was created in cooperation with the pioneer and world leader in this field – the Reproductive Genetics Institute in the United States. 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 (for more information see: http://eng.hsci.ru/products/pgd).

The provision of the entire line of genetic diagnostics and consulting services with a physician-geneticist is being made possible by the launch of a Russia-wide network of advanced medical genetics centers under the Genetico brand. Over the next five years Genetico centers will be opened and operating in 19 major cities throughout Russia. At present Genetico has a presence in 4 cities in the Russian Federation and within several months the network's scope will expand to reach 6 Russian cities.

As a part of efforts to expand the range of medical genetics consulting services offered, in the fourth quarter of 2013 a NIPT service called Prenetix was launched (non-invasive prenatal testing). For more information, see here: http://eng.hsci.ru/products/non-invasive-prenatal-testing.

Operating Expenses, OIBDA, Profits and Losses

HSCI's operating expenses in 2013 amounted to RUB 340.491 million, increasing by 20.0% from the previous year.

Cost of sales increased by 24.9% (up RUB 41.3 million), commercial expenses by 4.5% (up RUB 1.815 million), and general and administrative expenses by 17.5% (up RUB 13.636 million).

The cost of goods sold (COS) grew largely due growth in royalty payments to HSCI's subsidiaries for the use of the know-how of SPRS-therapy (the intellectual property rights for SPRS-technology are held by HSCI's subsidiary Vitacel LLC, which is engaged in the further development of SPRS and other cell technologies) as well as the use of know-how of "The method for producing the drug Neovasculgen®", the rights to which belong to HSCI's subsidiary NextGen LLC, which in part is focused on R&D in the area of gene therapy.

The cost of goods sold was also increased by amortization as the clean room premises of the new laboratory and production complex were commissioned.

General and administrative expenses increased largely as a result of higher staff costs due to the formation toward the beginning of the year of highly professional teams for the mid-term perspective as well as higher rent expenses resulting from the expansion of office space.

Nonetheless, as revenue growth exceeded by twofold growth in operating expenses (revenue grew by 42% (i.e. by RUB 118.6 million) while operating expenses grew by 20% (i.e. RUB 56.8 million)), the Company demonstrated higher profitability and margins – *see Key Financial Results table below*.

Consequently, **OIBDA** amounted to RUB 78.459 million, **OIBDA margin** – 19.5%, while **operating profit** totaled RUB 61.484 million.

The Company's non-operating losses in 2013 amounted to RUB 39.287 million (up 7.6% from RUB 36.519 million in the previous year).

The reasons for this substantial non-operating loss in the reporting period were the following.

Due to the use of long-term and short-term borrowings for investment in development, in 2013 **net interest expense** (the difference between interest income and interest expenses) amounted to RUB 13,960 million compared to a net interest expense of RUB 3.262 million in the previous year, when the long-term loan agreements were initially signed.

Other losses (the difference between other expenses and other income in the Financial results statements) in the reporting period amounted to RUB 25.327 million, down 23.8% from the previous year. Other losses in the reporting period can largely be attributed to reserves set aside to cover the impairment of financial investments, including the impairment loss of HSCI's 50% stake in Hemafund in Ukraine in the amount of RUB 23.0 million.

However, the substantial negative results from non-operating activities during the reporting period was compensated by the volume of operating profit, resulting in a **profit before taxes** of RUB 22.197 million and a **net profit** for HSCI in 2013 of RUB 11.452 million (compared to a net loss of RUB 31.562 million in 2012).

Key Financial Results:

Profit and Loss Statement, '000 RUB	**2013**	**2012 (as restated)**	***% change, y-o-y***
Revenue	**401,975**	**283,343**	***41.9%***
Cost of goods sold (COS)	(207,115)	(165,812)	*24.9%*
Gross profit	**194,860**	**117,531**	***65.8%***
Gross margin	*48.5%*	*41.5%*	*n/a*
SG&A	(133,376)	(117,925)	*13.1%*
Total operating expenses, incl.	**(340,491)**	***(283,737)***	***20.0%***
Depreciation & amortization	16,975	7,278	*133.2%*
OIBDA	**78,459**	**6,884**	***by a factor of 11.4***
OIBDA margin	*19.5%*	*2.4%*	*n/a*
Operating profit / (loss)	**61,484**	**(394)**	***n/a***
Operating margin	*15.3%*	*n/a*	*n/a*
Other gains & losses, incl.	**(39,287)**	**(36,519)**	***7.6%***
Interest income/(loss), net	(13,960)	(3,262)	*328.0%*
Other	(25,327)	(33,257)	*-23.8%*
Profit / (loss) before tax	**22,197**	**(36,913)**	***n/a***
Profit tax	(3,349)	-	*n/a*
Deferred tax liabilities	(2,955)	(2,252)	*31.2%*
Deferred tax assets	(4,441)	7,603	*n/a*
Net profit / (loss)	**11,452**	**(31,562)**	***n/a***
Net margin	*2.8%*	*n/a*	*n/a*

Human Stem Cells Institute OJSC (HSCI, www.eng.hsci.ru) is a Russian public biotech company founded in 2003.

HSCI engages in R&D as well as commercialization and marketing of innovative proprietary products and services in the field of regenerative medicine, medical genetics, bio-insurance, gene therapy, 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 – Gemabank®, as well as the reproductive cell and tissue bank Reprobank® (personal storage, donation).

The Company launched Neovasculgen®, the first-in-class gene-therapy drug for treating Peripheral Arterial Disease, including Critical Limb Ischemia, and also introduced the innovative cell technology SPRS-therapy, 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 project to create its own Russia-wide network of *Genetico* medical genetics centers to provide genetic diagnostics and consulting services for monogenic inherited diseases as well as multifactorial disorders (Ethnogene, PGD, Prenetix and other services).

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

HSCI is a co-investor in SynBio – a long-term multilateral project to create new unique medicines (first-in-class and BioBetters) for the Russian and international markets. The SynBio project, supported by an investment from RUSNANO, unites top Russian and international companies engaged in biotech/biopharm R&D.

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.

***

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.

For additional information, please contact:

Human Stem Cells Institute

Svetlana Samoylova
Director for Investor Relations (IRO)
Telephone: +7 (963) 679 3508
e-mail: ssamoylova@hsci.ru

Elena Romanova
Press Secretary
Telephone: +7 (916) 809 5559
e-mail: rea@gemabank.ru