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**STUDIES ON THE TRANSFORMATION OF THE
RUSSIAN PHARMACEUTICAL INDUSTRY
TO A MARKET ORIENTED SYSTEM**

TF/GLO/92/010

THE RUSSIAN FEDERATION AND THE CITY OF ST. PETERSBURG

Terminal report*

VOLUME 1

Prepared for the Government of the Russian Federation
and the City of St. Petersburg
by the United Nations Industrial Development Organization,
acting as executing agency for the United Nations Development Programme

Based on the work of ICN Pharmaceutical Inc.

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* This document has not been edited.

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ACKNOWLEDGMENTS

In May 1992, Anatoli Sobchak, Mayor of the City of St. Petersburg, Russia, submitted a request to United Nations Industrial Development Organization (UNIDO) that a study of the current state of pharmaceutical production and distribution in that city be conducted. Due in large measure to the encouragement of Jack L. Gosnell of the Consul General of the U.S., resident in St. Petersburg, UNIDO engaged a western pharmaceutical firm as a partner in this project, ICN Pharmaceuticals, Inc. of Costa Mesa, California. The Russian Ministry of Health requested UNIDO to expand the scope of the project to include the entire Russian pharmaceutical industry sector. In April 1993 the UNIDO/ICN study team completed the project report in draft form. In June 1993, the preliminary findings and recommendations of the UNIDO/ICN study team were presented at a briefing for Member States at UNIDO headquarters, Vienna, Austria, co-chaired by Mr. Charles W. Warner, Deputy Director General, UNIDO and Mr. Milan Panic, Chairman, ICN Pharmaceuticals, Inc.

Detailed industry sector analysis require a broad range of expertise in a myriad of subjects. Assembling such a team of experts is as unique a challenge as an intended study, and equally important. UNIDO and ICN take particular pride in the team of international experts assemble for their study of the Russian pharmaceutical industry sector. The UNIDO/ICN study team was unique in both its composition and contribution, bringing together for the first time international pharmaceutical experts, as well as political, economic and regulatory specialists. The contribution of this uniquely qualified team is evident in the following project report, "***STUDIES ON THE TRANSFORMATION OF THE RUSSIAN PHARMACEUTICAL INDUSTRY TO A MARKET ORIENTED SYSTEM***".

This UNIDO report should be considered significant in its content. Not only does the study present a candid assessment of the current state of the Russian pharmaceutical industry (the first of its kind), it also makes a series of recommendations, believed by most participants in the project to be fundamental to the transformation of this former state-controlled industry into a more market-oriented system.

In addition to these recommendations this UNIDO report contains a detailed business strategy developed by ICN for a proposed joint venture with a specific Russian pharmaceutical firm, OKTYABR. The ICN OKTYABR joint venture is the first attempt to implement many of the UNIDO/ICN study team recommendations in an actual commercial project. Although the success or failure of the ICN OKTYABR joint venture will be influenced by a variety of factors, the project will shed some light on the effectiveness of the recommendations in the report and the seriousness of the Russian Federation in market reforms. In short, the ICN OKTYABR joint venture is a benchmark by which to measure Russia's progress in its transition to a more market-oriented economy.

All which follows is the result of the efforts of the UNIDO/ICN study team. UNIDO/ICN take pleasure in acknowledging those organizations and individuals who comprised that team:

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EXECUTIVE SUMMARY

I. FINDINGS

A. The Russian Pharmaceutical Industry USSR (1917 - 1991)

Characteristics:

- State-control via ministry system
- Central planning (e.g. production and distribution)
- State orders
- Integrated system of planning, sourcing, production and distribution
- Financial and material support
- Limited discretion at factory level
- Stability, certainty

Example: Leningrad, Chemical, Pharmaceutical and Industry Association "OKTYABR"

B. "OKTYABR" - State Enterprise

Characteristics:

- Raw and semi-finished materials supplied through state orders
- Integrated system of suppliers and distributors
- Production and distribution directed by Ministry of Health
- Prices and subsidies set by State
- Factory management directed by Ministry of Health

Result:

- Significant levels of quality pharmaceutical products produced and distributed through USSR
- Significant shortages of most basic drugs in Leningrad Region
- Significant subsidies required to maintain high level of quality product

C. Post USSR Period (1992 -)

Characteristics:

- Withdrawal of State control
- Shift of decision-making from central to local, factory-level
- Elimination of State orders, subsidies
- Collapse of integrated system of sourcing, production and distribution
- Conversion of State production capacity to private ownership, e.g. privatization
- Instability, uncertainty

Example: Joint stock company, closed type, "OKTYABR"

D. "OKTYABR" A/O - Private Enterprise

Characteristics:

- Shifting priorities to more profitable production
 - Most drugs are too expensive for apteka to sell to consumer.

- State orders are not sufficient to offset cost of production and rising salaries.
- General Director's objective is to preserve employment, not to produce drugs.
- Spiraling costs for raw and semi-finished materials
- Lack of export markets, licenses
- Loss of suppliers and distributing relationships

Result:

- Fewer pharmaceuticals produced and distributed.
- Gradual conversion of pharmaceutical facility to other forms of production.

Methods and Means of Transitioning "OKTYABR" to a Private, Efficient Producer of Pharmaceuticals

Foreign Investment:

- Finance Transition
 - New GMP facility to permit production of existing drugs and introduction of new approved western drugs;
 - Employee Training Programmes on new machinery in new plant;
 - Management of enterprise as pharmaceutical company, not mixed producer;
 - Establish marketing system throughout Russia and CJS for distribution, including exports.
- Disincentive
 - Cost of raw materials

- VAT, profits taxation, tariffs and duties
- Financing
 - * Unavailable in Russia
 - * Uncertain in West due to political, currency risks

Foreign Partner:

- "Integrated Management"
 - Stability in decision making
 - Certainty, assurance to lenders
 - Incorporates and trains current Russian managers in modern techniques:
 - * Sourcing Production
 - * Distribution, marketing, exporting
 - * Accounting
 - Basis to begin partnership
 - * Trust
 - * Techniques
 - * Market awareness, experience

Example: "Exclusive Corporation Agreement"

- Disincentive
 - * Fear of exploitation
 - * Autonomy of few key managers
 - * Competing priorities

Methods and Means of Transition to Market Economy

Foreign Investment:

- Key to finance transition
 - New plants, equipment
 - Training of employees
 - Market vs. state management

- Development of new markets, e.g. exports
- Disincentives to Investment
 - Tax policy
 - Uncertain laws and regulations, e.g. property ownership, intellectual property
 - Political risk
 - Currency instability

Foreign Partner:

- Key to manage transition
 - Stability in Decision Making
 - Modern Techniques
 - * Production
 - * Distribution
 - * Accounting
 - New Drugs, Distributed Through Existing System
 - Disincentives to Foreign Partners
 - * Fear of exploitation by Russian partner
 - * "Integrated Management" between foreign and Russian entities misunderstood
 - * Aging plant and equipment
 - * Uncertain liabilities, e.g. environmental and operating costs

II. CONCLUSIONS

The Russian pharmaceutical industry, as with other state-controlled production and distribution sectors, has undergone dramatic changes. Previous to the economic reform programme of President Yeltsin, the control and direction of this industry was centrally planned, by the Minister of Health. State orders and accompanying financial support determined all pharmaceutical production and distribution in the USSR, as well as the CMEA countries. It was not unusual for large volumes of pharmaceutical production to be distributed beyond the region wherein the production complex was located, such as the City of St. Petersburg, formerly Leningrad. One such example was the Leningrad Chemical, Pharmaceutical and Industrial Association "OKTYABR."

OKTYABR was a standard state-controlled production association. Its raw and semi-finished materials were supplied through the state orders system; its production was distributed by a similar state-controlled association and its products were made available to the public at state prices in the state-controlled Apotekar. This system of state orders for all inputs and outputs, with companion state-decision making with respect to operating costs, sourcing, pricing, product lists, and distribution was closely monitored by several levels of bureaucracies in the Ministry. The Ministry set the priorities of output, both volume and distribution, often exchanging such output among other Ministries in the USSR for their respective output, i.e. pharmaceuticals for consumer goods, or to other pharmaceutical Ministries throughout the CMEA network in exchange for raw, semi or finished materials. As long as the system was closely monitored, and market sources were not introduced which could effect its more inefficient or over-producing parts, a significant volume of pharmaceutical production and distribution was achieved. The absence of market forces and prioritization

of state orders without regard to local need, however, negated the marginal efficiencies of the system. The result was the inconsistency of significant industry output often characterized by the local shortages.

OKTYABR, for example, produced significant levels of quality pharmaceutical products. Leningrad City, however, experienced significant shortages of even the most basic pharmaceutical products; a serious result among a population with large numbers of elderly and children.

The Gorbachev/Yeltsin economic reforms seriously disrupted the CMEA-control system of pharmaceutical production and distribution. Where previously, all output distribution decisions were made in Moscow in the Ministry of Health, accompanied by the resources essential to such production, these economic reforms began to shift their decision making to the local level while reducing or failing to increase resources necessary to maintain production. As with other industrial sectors, production associations attempted to maintain output levels as a means of avoiding employee layoffs. Hyperinflation and over production soon resulted, effecting the ability of the average citizen to purchase those pharmaceutical products essential to even a minimum standard of health care. Generally, the association, continued to over-produce, and the Ministries no longer monitored output levels and product types. As the Ministry of Health began to fall behind in financial support for the association, the more entrepreneurial general directors of product plants began to produce products unrelated to pharmaceuticals, such as confectionery, or food products.

OKTYABR, for example, shifted some production in 1992 from vitamins to lemonade, chocolate, and olive oil. OKTYABR did not produce as a retailer, but as a supplier to other enterprises or associations. The result was a vicious cycle of increased costs for raw semi-finished materials, diverting production from

primary pharmaceutical products to obtain additional resources to pay salaries and bonuses for workers to avoid layoffs. Salaries, however, could not keep pace with hyperinflation. Short-term production could not produce sufficient amounts of pharmaceuticals and related products. Thus, fewer pharmaceuticals were being produced and distributed and that which was produced was at prices that the average citizen could not pay.

With the transition of decision making from the Ministry to the local level, each component of the production and distribution began to set its own priorities. As state orders were reduced, and in 1992 all but eliminated the incentive to maintain an integrated system of production collapsed, and General Directors at each stage of production began to pursue different pricing, sourcing, product, and distribution strategies more often to maintain full employment than for efficiency.

Finally, despite the prospect of hyperinflation, falling production, over employment, and limited state resources, the mass privatization programme began. Under the law of privatization, each Russian citizen would receive a voucher nominally valued at 10,000 rubles by which he could invest by several means in either his own enterprise or any other enterprise offering shares.

OKTYABR for example, through a vote of its worker collective, decided to enter the process of privatization. By doing so in 1992, the worker's plan of privatization would be based on OKTYABR's overall value set at 1982 levels. In 1993, these value levels would increase by a co-efficient established by the State Committee on Privatization to adjust for hyperinflation. Therefore, an enterprise could privatize itself at a lower price if it filed its plan in 1992.

Contemporaneous to the economic reforms in Russia, was an aggressive promotional effort by the government to attract foreign investment. In principle, foreign investment was viewed as the best means, at least in the early days of the policy, to offset the destabilization of the economic reform programme. Foreign capital could be used to finance the transition from state-control to a market-driven economy. Foreign investment in new plants, equipment, training of employees, distribution and even export could replace, in some industrial sectors, the resource demands on the state, foreign managers/investors could replace the role of the state in decision making. Finally, a foreign investor/manager would have the incentive to inject market discipline at all levels of production and distribution, making the difficult decisions with regard to source, pricing, products, distribution, salaries, and employment levels, relieving the state from making tough political and social decisions. Consequently, a legal framework of Presidential Decrees and Laws of the Supreme Soviet were enacted to encourage, promote and facilitate such investment. Unfortunately, other laws and regulations were enacted which established an equal number of disincentives to such investment, i.e. new forms of taxation, customs duties, and property ownership.

The Russian pharmaceutical industry, therefore, has been under serious stress in the last few years. Structural changes have not stabilized the economic situation; on the contrary, circumstances within the industry are much worse than expected. Unfortunately, the Russian people are those who suffer the consequences of the changing conditions.

International organizations, such as the World Bank, EBRD, United Nations (UNIDO, UNESCO and WHO) have offered resources and assistance to the Russian Federation to stabilize and improve the Russian pharmaceutical sector. A substantial amount of this assistance is in the form of finished pharmaceutical production, e.g. humanitarian aid, which more often than not misses its

intended target, the average Russian, and instead competes with Russian-origin pharmaceutical production in the black and grey markets. A portion of this assistance would be better used to resolve the structural problems of the Russian pharmaceutical industry.

International technical and financial assistance could make a dramatic difference in stabilizing the best elements of the Russian pharmaceutical industry. The system of integrated sourcing, pricing, production, and distribution could be re-established; the Ministry of Health could re-assert its oversight and management. Enterprises, such as OKTYABR, could be encouraged to resume meeting state orders in return for realistic support from the Ministry of Health in the form of operating capital. The most immediate impact of this policy would be to respond more effectively to the health needs of the Russian people.

One does not suggest that the Russian Federation abandon its economic reform programme, as such pertains to the pharmaceutical industry. On the contrary, President Yeltsin's economic reforms have been the difficult process of Transitioning the Russian pharmaceutical industry from sole reliance on state support to market-oriented producers and distributors.

It is the pace of the transition and its near-term impact on the health conditions of the population which should be of concern. In addition, there should be some well-defined, specific design or model of a more market-oriented pharmaceutical industry which the Russian Federation is seeking to achieve from the transition. Unfortunately, it is difficult to identify from the policies and rules of the Russian Federation or Ministry of Health what the design might be. Further, without a specific design or model to follow, each producer and distributor is free to adopt its own form. The new forms of production and distribution do not generally take into consideration the same

policy concerns of priority to either the Ministry of Health or the Russian people. These new forms are the most expedient model to the local producer and distributors; these models are often developed as short-term solutions, a quick fix to address the immediate problem of hyper-inflation, low wages, increased taxation, uncertainty among raw material suppliers, and a concerned labor collective. Often, a General Director responds to these pressures by Transitioning the enterprise away from its primary purpose to a more profitable line of production. Such a transition results in a loss of production of needed pharmaceuticals, an unfortunate result, in that it will be more expensive to re-constitute this production than to maintain it in its present form.

Foreign investment has been suggested by many as the catalyst which will facilitate the transition of the Russian pharmaceutical industry. Foreign investors seek a realistic pace of economic transition, economic focus and a well-defined design or model promoted by the Ministry of Health. Also, foreign producers of pharmaceuticals are generally reluctant to invest large amounts of capital in the industry and are in large measure to the uncertainty of Russia's economic political reform programme, but also, due to the emerging independence of individual producers and distributors. Unlike other terms of manufacture, pharmaceutical production and distribution is subject to some level of state regulation, e.g. Ministry of Health, Food and Drug Administration (USA).

The quality and availability of pharmaceuticals are public policy issues in most countries not just economic. Russia is at risk of losing its basic production and distribution system, with the related political and economic consequences, if it continues to permit the diversification and dissolution of its suppliers, plants, and distributors. The Ministry of Health must re-assert its oversight so as to stabilize conditions of the plant level, to stem the shift in production away from basic drug production.

Otherwise, the sole interest by foreign investors will be in the network of product distributors for the purpose of supplying foreign production as Russian production. Such a result would be a disincentive to produce pharmaceuticals in Russia, further stressing an already over-stressed industry.

The Ministry of Health and regional authorities should review carefully any foreign investment proposal to determine if the project will actually result, in the near-term, in direct improvement, technical and financial, of an existing Russian producer of pharmaceuticals. If the proposal merely substitutes foreign for local production and if the Russian partner merely distributes and has no prospect of new improved means of local production, then the project fails to achieve the overall goal. The Ministry should promote only those projects which will result, at some point in the relationship, in an improved modern means of production employing local workers while preserving, if possible, the current Russian producer. This form of investment benefits all the partners, will also serve the goals of the Ministry of Health, enhancing the production and distribution of pharmaceuticals in Russia. If the foreign investor could be assured that the government would promote the investment through realistic investment incentives which could further contribute to stabilizing the needs of pharmaceutical production and distribution, the risk of a foreign firm entering the Russian market becomes more manageable. Finally, if the foreign manager has the support of the state in making the hard choices any market-driven enterprise must make, such as maximizing profit, reducing cost, developing new products, methods and means of production, then the goal of the Russian government, and in particular the Ministry of Health, to modernize Russian pharmaceutical production and distribution is possible.

Each of these goals must be evaluated in the context of an actual, active producing enterprise, such as OKTYABR. The problems and solutions arising from such projects will frame a

design or model of a production and distribution system unique to the challenges and needs of Russia. Also, from this experience at the local level, the Ministry of Health can project the feasibility of such a model as a design for the entire industry.

The UNIDO team has evaluated the conditions of Russian pharmaceutical industry as it currently exists. The team of international and Russian experts have reviewed the regulatory, ethnical and financial conditions of the industry. The UNIDO team has attempted to compare and contrast conditions, policies and problems in Russia with pharmaceutical operations in Spain, Yugoslavia, and the United States. The team has attempted to concentrate its analysis at two levels: national and local. OKTYABR has served as a focal point of study at the local, enterprise level. The UNIDO team offers its recommendations on the same basis.

III. RECOMMENDATIONS

A. Stabilize the Russian Pharmaceutical Sector

1. The Russian Federation should take into consideration the human resource costs and instability arising from Russia's inability to produce and distribute pharmaceuticals and related products at minimal levels to meet the basic health needs of the population.
2. The Russian Federation needs to recognize the serious strain on the Russian pharmaceutical sector imposed by the current economic reform programme.
3. The Russian Federation needs to develop and adopt policies particularly targeting the Russian pharmaceutical sector the purpose of which would be to stabilize that industry sector by exempting it where appropriate, from elements of the economic reform programme which have caused its deterioration. Technical advice and assistance from international organizations and experts should be focused (e.g. World Bank, EBRD, UNIDO) to assist in the development of these policies.
4. The Russian Federation needs to develop on an emergency basis a near-term programme to improve the production and distribution of pharmaceuticals in Russia which has as its long-term goal a gradual transition of the Russian pharmaceutical sector into a market-oriented industry, taking into consideration the impact of such a transition on the public health.

B. Determine the most efficient form of production and distribution of pharmaceuticals and related products for Russia through model projects.

1. The Russian Federation should encourage the Ministry of Health to identify, promote and develop model projects in the production and distribution of pharmaceuticals in Russia.
2. The Ministry of Health should identify those Russian pharmaceutical associations which would be serious partners in a model project with a realistic foreign producer and distributor. The criteria of such associations should include actual experience in the sourcing, production, and distribution of pharmaceuticals and related products in Russia as well as previous experience in the CMEA system; ongoing local production and distribution; close proximity to foreign markets; and production in immediate demand by the Russian people.
3. The Ministry of Health should promote these model projects by inviting international health organizations, and private foreign pharmaceutical firms to participate. The form of participation should be technical and financial assistance, on a public or private basis. The goal of participation would be to develop and demonstrate at the enterprise level, the methods and means required to transition a Russian pharmaceutical complex from a state-oriented association to a more market-oriented enterprise.
4. The Ministry of Health should develop model projects which have the potential to be self-sustaining, technically and financially, as soon as possible.

These projects should also have some export capability. The Russian enterprise must be willing to integrate its management, production and distribution with that of the foreign partner and permit the foreign partner to restructure the enterprise accordingly. As the foreign partner moves the Russian enterprise closer to a more market-oriented form, the support of the Russian Federation allocated to that specific enterprise should be decreased. In short, the Russian enterprise should undergo a "phased conversion" from a state entity into a private venture.

5. The Ministry of Health should monitor the progress of the project and should ensure that throughout the project the production and distribution of pharmaceuticals meets the needs of the market.

C. Establish a mechanism to support projects

1. The Russian Federation is eligible for a variety of forms of assistance. The Ministry of Health should be granted a priority allocation of international technical and financial assistance for the exclusive purpose of supporting and overseeing a limited number of model projects in the pharmaceutical sector. Qualifying model projects should be realistic in scale; focused on specific types of production and distribution; of a direct relationship between an existing Russian producer and foreign firm; and integrated locally.
2. The Russian Federation should establish a Russian Pharmaceutical Development Fund, the sole purpose of which shall be to identify, promote and develop a

limited number of model projects. The Ministry of Health should be responsible for the work of the Fund. International organizations, such as the World Bank, European Bank for Reconstruction and Development, UNIDO, and regional assistance programmes should be invited to participate in these model projects as well as to participate in developing the criteria by which qualifying foreign pharmaceutical firms will be identified.

3. Each model project must involve three partners - the qualifying foreign pharmaceutical firm, a Russian enterprise, privatized or not; and the local government to ensure that local needs for drugs will be considered as a priority over the pressures to distribute local production in other regions of Russia or exclusively for export.

D. Analyze the methods and means recommended by the UNIDO team to transition the Leningrad Chemical, Industrial and Pharmaceutical Association, OKTYABR, from a State enterprise to an integrated private manufacturer.

1. It is most expedient to apply these policies and goals to a concrete example. OKTYABR is such an example. If it is possible to propose recommendations which can be implemented by the Russian government and local authorities in the City of St. Petersburg without the need for a significant political or economic action on behalf of either, then it may be possible to develop an investment programme for other production complexes in Russia. Therefore, the following recommendations are made with regard to OKTYABR as a pilot project. If successful, these recommendations could lead to more general policies, legislation or decrees by the

government which could accomplish its overall goals of improving the production and distribution of pharmaceuticals throughout Russia's other markets. The Russian state enterprise, OKTYABR, must stabilize its management, labor relations, means of production and distribution if it is anticipated to continue as a viable producer of pharmaceuticals. The UNIDO team recommends the best method of stabilization for OKTYABR as integration with a foreign partner. The foreign partner, however, will be reluctant to invest significant amounts of capital without adequate assurances by the Ministry of Health and the Russian Federation that certain conditions favorable to the investor will be provided, e.g. regulatory, financial, technical. Consequently, the UNIDO team recommends an investment strategy for OKTYABR which "phases in" the foreign investors risk as the state's responsibility to sustain this enterprise is "phased out." The "phased" or transitional investment model, as recommended by the UNIDO team is as follows and pertains solely to the conditions found in OKTYABR:

2. Privatize OKTYABR as a joint stock company, open type, with the majority ownership and control of the enterprise belonging to the workers' collective and current management:
 - i) Stabilizes the legal form of the enterprise
 - Legal entity with rights
 - Specific ownership by shares
 - Specific management (for at least one year)
 - Workers' collective has vested interest in success of enterprise
 - Specific rights in plant and equipment
 - ii) Compels enterprise to operate on a market basis

- Means of production become key management concerns, e.g. sourcing, wages, operating capital.
- Forms of production shift to market needs away from state orders
- Training (management and worker) seen as investment

iii) Management and labor relations becomes more reciprocal

- Workers' collective demands more accountability from management as to profits and investment
- Basis exists for introduction of modern management, quality assurance, programme techniques
- Work force reductions more effectively managed
- Management decisions more likely oriented toward improving working conditions, training, productivity and new plant/equipment

iv) Appears more attractive to foreign investor than state enterprise

- Stable ownership, management, labor force
- Certain ownership rights to plant and equipment
- Market orientation

3. Continue State support of OKTYABR for "phased" or transitional period:

I) Incentive to attract foreign investment

- ii) Permits enterprise to treat State as a guaranteed customer, thereby ensuring near-term operating capital
- iii) Ensures that a specific volume of production will be available to the public, e.g. State should not permit shortages of crucial pharmaceuticals
- iv) Involves State in some planning decisions, labor relations, and joint venture negotiations thereby adding additional stability to the development of the enterprise
- v) Permits State and enterprise to balance mutual needs (State orders for operating capital)
- vi) Ensures potential investor of minimal State regulatory interference

4. Promote and facilitate foreign investment in "OKTYABR":

- I) Publicize OKTYABR as a potential partner with a foreign producer of pharmaceuticals;
- ii) Offer clear criteria as to the type of foreign investor sought for OKTYABR, and publish that criteria among international organizations and enterprises;
- iii) Offer investment incentives, regulatory, technical and financial, to any qualified investor equal to a commitment to invest directly in plant and equipment in Russia;

- iv) Permit reinvestment of tax revenues, federal and local, into the joint project;
- v) Permit special licenses to import/export means of production without tariffs or duty in order to source the most cost-effective raw, semi-finished materials thereby reducing production costs;
- vi) Permit importation of plant and equipment essential to the operation of the joint enterprise without delay or custom duties;
- vii) Require integrated management between the foreign partner and the Russian enterprise, thereby ensuring modern techniques of production and distribution will be introduced into the Russian pharmaceutical industry;
- viii) Require a minimum volume of production be exported to adjacent markets;
- ix) Ensure local/regional support for the joint enterprise by permitting municipal participation;
- x) Review structure of joint enterprise for fairness and the protection of all parties;
- xi) Establish with the Russian and foreign partners a schedule of gradual elimination of special conditions (regulatory, technical, and financial) in favor of assumption of greater risk by the joint enterprise;

- xii) Review periodically the progress of the joint enterprise, its level of production, types of pharmaceuticals produced, ownership changes, and results of shared research, e.g. new compounds.
5. Integrate the joint enterprise of OKTYABR and a foreign partner into the regional and international markets for the production and distribution of Pharmaceuticals:
- I) Introduce international standards for the production of pharmaceuticals in Russia, including the requirement that all new plant and equipment must be GMP certified to international standards.
 - ii) Introduction of international accounting standards to govern the joint enterprise.
 - iii) Facilitate the introduction of generic pharmaceuticals through the joint enterprise.
 - iv) Ensure the protection of intellectual property rights of authorized, license distributors or investors of pharmaceuticals on the territory of Russia.
 - v) Permit distribution of pharmaceuticals on a market basis.

IV. ICN OKTYABR - A RUSSIAN JOINT VENTURE

A. GENERAL STRATEGY

- Identify a partner and establish joint venture to participate in emerging Russian and C.I.S. Markets.
- Develop understanding of Russian market in cooperation with UNIDO and participation of local authorities (City of St. Petersburg).
- Assist Russian partners in transition to a free market economy.
- Analyze and determine potential for the broad range of SPI products in Russian market.
- Analyze and determine any potential of Russian partner products for export to foreign markets.
- Construct new modern pharmaceutical plant for local manufacturing.

B. CURRENT STATUS

1. Partner Identified

- Leningrad Industrial Chemical and Pharmaceutical Association "OKTYABR".
- City of St. Petersburg.

2. Joint Venture established

- New company - ICN OKTYABR

Registered as joint stock company - open type
with foreign investment.

●	Partners: SPI PHARMACEUTICALS	75%
	OKTYABR	24%
	CITY OF ST. PETERSBURG	1%

3. Contribution:

SPI PHARMACEUTICALS

- Facilitation of finances
- Technology, training
- New compounds & product lines
- Management

OKTYABR

- 100% production & distribution
- Management / Labor force
- Approvals / Certifications

CITY OF ST. PETERSBURG

- 10 hectares of land

4. Management:

- Integrated ownership
- Integrated management

- Exclusive cooperation agreement

C. JOINT VENTURE STRATEGY

1. Maintain and enhance existing production and distribution of OKTYABR.

- stabilize OKTYABR
- transition of SPI into the Russian market
- preserve existing market share

2. Continued cooperation with City of St. Petersburg.

- Respond to City's immediate need for drugs

3. Analyze and develop Russian market potential

- Expansion of base product lines;
- Introduction of SPI product lines to Russian markets
- Develop export market potential

4. Construction of new GMP facility

- estimated cost U.S. \$43 million

5. Gradual phase-in to protect SPI'S shareholders

- 1993 Foundation

- 1994-1995 Transition years
 - construction
 - training
 - market development
 - manufacturing process

- 1996 Fully operational

D. BUSINESS DEVELOPMENT

- Russian pharmaceutical market at present meets only 30 percent of medicine needs of the population.

- Lack of hard currency deteriorates the level of supplies (Russia used to import 3 billion dollars of foreign drugs annually).

- Actual needs will not be met in the near future which gives vast opportunities for supplying market with large volume of essential drugs.

- Maintain and improve business in all C.I.S. States (Commonwealth of Independent States) without administrative obstacles.

- Political controversies among some C.I.S. States affect their economic relations and might affect plans for business development of ICN OKTYABR.

- Need for exports to provide hard currency for import of raw materials and servicing loans for the new facility and equipment.

- Continuous production of all pharmaceutical lines and products of "OKTYABR" for as long as possible is an

important component of business development of ICN OKTYABR.

- Immediate and gradual introduction of new products before the new facility is constructed, to start January 1994.
- SPI products already approved in Russia (mazepin, virazole) to be introduced first, followed by products which have analogues in Russian market and can be registered in short time.

E. MARKETING

- Administrative distribution of drugs in Russia is partially eliminated, but marketing is still not introduced.
- State subsidies for pharmaceutical products at the level of wholesalers no longer exist.
- Pricing of drugs, which were kept at extremely low levels as a part of social benefits, one of key issues for future marketing and profitability of pharmaceutical business.
- Present economic conditions put many segments of pharmaceutical consumption into the position of a very limited purchase power.
- Opening of Russian Pharmaceutical market to competition, requires immediate planning of adequate market activities.

- Introduction of new SPI products - the beginning of market research and analysis of indications, incidence, regional prevalence, ways of drugs administration, etc.
- Marketing target for ICN OKTYABR - 10 percent share of the C.I.S. Pharmaceutical market.
- Very ambitious plan in terms of volume of products and sales value (600 million dollars in real terms).
- Export to reach 20 percent of sales of ICN OKTYABR, using worldwide distribution net of SPI subsidiaries, licensees and distributors.
- Introduction of marketing and sales offices of ICN OKTYABR in some or all C.I.S. states before the BUSINESS PLAN construction of new facility is completed.
- Training of Russian staff for marketing and sales activities.
- First recruiting and training of sales force as early as second quarter of 1994.
- All marketing activities in full motion when the new facility becomes fully operational.

F. BUSINESS PLAN ASSUMPTIONS

- Five year plan, 1994-1998, based on OKTYABR product lines and new SPI products
- Constant ruble planned at 812 to U.S. dollar through planning period.

- * Based on average 1st quarter 1993
- * Allows for meaningful comparisons
- * Eliminates inflation in analysis
- Current pharmaceutical pricing in Russia estimated at 3 percent of Western European levels.
- Per annum price increases, in real terms, conservatively planned at following rates:

1994	+5%
1995	+7%
1996	+10%
1997	+12%
1998	+15%
- Unit growth - both base business (OKTYABR) and new introductions planned at 5 percent per annum through planning period.
- Conservative assumption in view of market potential caused by shift to consumer oriented markets.
- Cost of goods sold to increase at real level of 2 percent per annum, with higher productivity in new plant to control cost levels.
- Trends of operating expenses to follow 3 year experience with ICN Galenika.
- Increasing selling / advertising support for new product introductions.

G. DEBT ASSUMPTIONS

- Project financing at U.S. \$43 million to build new facility sustaining sales levels OF U.S. \$144 million by 1998.
- No dividend planned in first 3 years of operation (transition phase).
- In years 4 and 5 dividends planned at 50 percent of net income.
- Repayment of project loans based on operating cash flow.

H. NEW MANUFACTURING FACILITY

- Highest contemporary level of pharmaceutical manufacturing, GMP approved.
- Constructed and completed in 20 months.
- Production facility, warehouse, quality control and administrative and support services totaling 22,760 square metres (Phase I).
- Production lines for finished forms: tablets, capsules, ampules and aerosol.
- Large volume capacity:
 - Tablets: 510 million packs (10 billion tablets)
 - Capsules: 43 million packs (850 million capsules)

- Ampules: 135 million units

- Aerosol: 15 million units

- Phase II - additional facility of 13,790 square metres for ampules manufacturing, with capacity of 510 million units.

I. PRODUCT PRESENTATIONS

1. Old Products

I) Therapeutic category: cardiovascular
 Pharmaceutical forms: ampules - tablets - capsules
 Main products:

- Demand is not satisfied
- Prices are not restricted
- Products are manufactured by other suppliers
- Monopoly in nitroglycerin products

ii) Therapeutic category: Analgesics
 Pharmaceutical forms: Ampules - Tablets
 Main products: Amalimum - Citramonum -
 Novocainum

- Market is not saturated
- Prices are not at the maximum the market will bear
- There are several competitors

iii) Therapeutic category: Vitamins
 Pharmaceutical forms: Ampules - Tablets - Capsules
 Main products: Vitamin C - B6 & B12 -
 Vitamin E - Dekamevil

- The ampules demand is not satisfied while the tablets are falling
- Prices are not restricted
- There are other factories offering the same products

iv) Therapeutic category: Antiseptics
 Pharmaceutical forms: Aerosols
 Main products: Innalipt - Oxyciulalol

- Market is not saturated
- Prices are at a minimum
- There is just one competitor

v) Therapeutic category: others
 Pharmaceutical forms: Ampules - tablets
 Main products: Amaldimum - Poroserinom -
 Methyluracilum ciclodolum

- Market is saturated
- Low growth prospects
- Prices are not limited
- Products are made by other factories in Russia

vi. Raw materials (Calcium gluconate) .

- Demand is increasing
- Prices are not limited
- There are other manufacturers

2. NEW PRODUCTS

<u>PRODUCT</u>	<u>INDICATION</u>
Carbamazepine	Seizure disorders / Neuralgia
Trimexazol	Antibacterial
Virazole	Antiviral
Soltric	Anti-helminthic
Gentamicin	Gram negative infections
Calcitonin	Osteoporosis
Drenural	Hypertension/diuretic
Espaven alcalino	Antiacid/antiflatulent
Espaven Enzimatico	Digestive enzymes
Estovyn-T	Amoebiasis/Trichomoniasis
Dermoxyl	Acne
Dorixina	Analgesic
Allerdryl	Antihistaminic/antiemetic
Antihemorroidal	Hemorrhoids
Asmo Hubber	Asthma/bronchospasm
Corium	Peptic Ulcer/irritable bowel
Bisacolax	Laxative
Bolutol	Hyper lipidemia
Dexasone	Inflammatory process
Diclofenac	Anti-inflammatory
Fusid	Edema
Leucohubber	Leukorrhoea

V. GENERAL ECONOMIC CONTEXT OF THE PROJECT
- by P.L. Kukorelly and Z. Csizer

A SUMMARY

In the Summer of 1993, Russia's economy appears to be in a dire condition. All available economic indicators - statistical data - seem to blink the red lights : for example inflation, external debt, decline in production, the dismal condition of infrastructures.

BUT these indicators only tell the sombre part of the story.

The "pays réel" is infinitely more complex and shows promise of progressive improvement in the future.

A future which seems to have already started. Indeed, behind official Russia, there is the Russian people: they want to use their newly-found freedom and more and more of them try to "do something". A real "economic life", a **market**, is spontaneously emerging in Russian and this not only in commercial activities but also, though it may yet seem embryonic, in production sectors : agriculture, food processing and distribution, and in the form of small light-industry undertakings covering a large spectrum of sectors. Price freedom - in most areas of economic activity - and the possibility to calculate real production costs have put economic theory to work : a market is emerging and is creating growing **solvent** demand.

In the more specific area of social security and particularly the health sector, change appears to be slower, more complicated. One major reason for this is rooted in seven decades of all-state provision of social services and the consequent inertia, not to say fatalism, of a large portion of the population accustomed to be at the mercy of an overwhelming and arbitrary centralized system.

But new developments are emerging also in this sector.

There are three fundamental factors of change.

Russian society is about to start three simultaneous (peaceful) revolutions : it wakes up from the feudal constraints of communism; it is in the process of a 20th century-style industrial revolution; it will, eventually, give birth to a pluralist society.

However painful these developments will be, the social sphere, particularly the provision of health care, will play a vital role.

And there will be a very substantial, growing market for high quality pharmaceuticals. At present, the provision of pharmaceuticals made in Russia is insufficient. Imports of many categories of essential drugs have been increasing. But real, long-lasting improvement can only be achieved in Russia by a strong, innovative and competitive domestic pharmaceutical industry.

It is against this background that the premises of the ICN-OCTOBER project must be analyzed and appreciated.

The "pays réel" is above all its people. Meetings with Russian businessmen, scientists, industry managers, local/regional government officials and "just people" help understand the promise of substantial future improvement. The true economic story of Russia is in its yet small but feverishly increasing private economy, new companies, joint ventures and burgeoning entrepreneurs. The rearguard actions by enemies of reform will not stop the country's economic transformation.

RUSSIA'S ECONOMY IN 1993

What is Russia's present national income? For 1992, the World Bank's and the IMF's conservative calculations show a nominal Gross Domestic Product of US\$ 62 billion and a per capita GDP of about US\$ 435. More recently, a respected Anglo-Saxon source, referring among others to the same institutions, estimated per capita GDP at US\$ 3,200 but indicated the total value of Gross Domestic Product in roubles, not in dollars.

The best guess that can be offered by the present author is that total Gross Domestic Product is about US\$ 250 billion, i.e. a per capita GDP of about US\$ 1,650. It is impossible, however, to propose more than these rough estimates. How to take account, for example, of all the major factors that should be included in the determination of the real purchasing power of the average Russia's income.

The structure of the economy of the USSR (extrapolated to Russia) has been changing very slowly and has yet a composition close to some developing country economy.

EMPLOYMENT BY MAIN SECTOR			
	1975	1990	1992/93*
Agriculture and forestry	22.2%	18.5%	20%
Industry, incl. construction and mining	38.2%	39.4%	35%
Services, incl. government	39.6%	42.1%	45%
* Estimates			
Sources: IMF, IBRD, OECD, EBRD, Interviews			

This structure, an apparent weakness, hides of course ample room for change. And change at medium term should be all the more interesting that the general education level of the population, especially when considering the lower strata, is comparable to

many a developed country. In addition, it is interesting to note that the contribution of agriculture and forestry to "Net Material Product" was about 20% in 1990, while industry's was about 42%. Behind these facts, there should be large "reserves" of productivity waiting to be deployed. The estimates for 1992/93 reflect a transition or survival situation in which workers become superfluous (if not explicitly redundant) in industry had to find some activity either in the primary or the tertiary sectors.

The unique **apparent** bright spot is the US\$ 3 billion foreign trade surplus achieved by Russia in 1992. Of course, with over US\$ 80 billion, the country's foreign debt is big, but per capita debt is the lowest in all of Eastern Europe (except Romania) and, more importantly, the debt/service ratio has been consistently decreasing : 28% in 1986, 24% in 1989 (USSR) and, this time Russia: down to 18% in 1992.

All the other **conventional** indicators¹ are negative for the period 1990 early 1993. Examples:

1. GDP has been declining by 10-15% annually between 1990 and 1992 with industrial output falling 15-20% each year;
2. Gross Fixed Investment collapsed even more dramatically both as regards to productive investment and construction;
3. Agricultural production experienced a relatively small drop;

¹ Russian economic data are characterized by their uncertainty, their lack of sectorial specificity in many cases and divergences according to their sources. In addition, no well-known Russian or international organization is prepared to convert, in their statistics, rouble values into hard currency, for example the US dollar.

4. Prices - both producer and consumer - exploded as a result of :
 - a. price liberalization and reduction and partial cancellation of subsidies, and
 - b. most importantly, the Government's generous monetary policy;

5. Unemployment first appeared during this period as a real social phenomenon, new to Russian society : though the numbers are still moderate in statistics, latent unemployment will increase significantly as a result of:
 - a. the indispensable rationalization of many big industries;
 - b. privatization and their necessary consequences on manning levels;
 - c. the unavoidable redundancies in the government sector in the broadest acception.

BUT there are also positive developments, though they are not all statistically demonstrable:

1. Positive foreign trade balance;

2. New structure of foreign trade (imports and exports):
 - a. the share of Western (OECD) countries in Russia's foreign trade increased by 61% between 1991 and 1992, particularly with the United Kingdom, Spain, Sweden, Belgium, the USA and Canada;
 - b. trade with South East Asia developed just as fast;

- c. trade with the poorer markets of the former CMEA countries lost much of its importance in Russia's external commercial activities;
3. The emergence of an entrepreneurial class : many small enterprises are being created, both in sectors linked to agriculture/food and light industry and services;
 4. The growing number of successful businessmen working in many a major province/sector in Russia and trading with Western and other foreign countries - the new millionaires;
 5. Between 300,000 and 500,000 Russians are now making more than US\$ 2,000 per month, while 4,000,000 to 5,000,000 "earn" over US\$ 500 monthly, a fortune compared to average monthly earning estimated at Rub 50,000 - 70,000, i.e. about US\$ 50 - 70;
 6. Another very important observation : foreign-bound capital flows seem to diminish and more and more Russian businessmen appear to invest again in Russia instead of keeping their capital in the USA or Western Europe;
 7. Finally, it is tempting to include here the idea of CONVERSION (of military industries to civilian production) and the "Peace Dividend", but these are far-fetched promises, except probably the Russian version of the "Peace Dividend".

And perhaps the most important: there is good hope that misconceived and wasteful investment either in spectacular infrastructures or in unprofitable industrial projects are stopped. If this is the case, the apparent (statistical) collapse of Gross Fixed Investment is rather good news. In

addition, account should be taken of the reduction of military spending another type of unprofitable investment.

RUSSIAN SOCIETY AND THE HEALTH CARE MARKET

This is the specific context of the ICN-OCTOBER joint venture and investment project.

More than a fifth of Russia's 150 million population lives in cities of 1 million inhabitants or more. It is in these - and many smaller cities - that market demand for health care provision is concentrated. It is also there that one finds most of the country's approximately 20,000 pharmacies or drug shops/stations and particularly the growing, if yet very small, number of private pharmacies. (It must be noted that by Western standards, Russia should/could have 100,000 retail pharmacies or more).

The medical infrastructure is vast, if not of high standards: there are about 470 doctors and 140 beds per 100,000 inhabitants. The general health condition of the population is poor. A very large potential demand for drugs is combined with sparse, unsatisfactory infrastructure to dispense them.

But what is the purchasing power available to satisfy at least part of this demand? We know that average incomes will be slow to grow, just as well as the probable persistence of problems with public finance.

Overall spending: both from public finance and through private purchase directly from pharmacies will much depend on national income and on how it is spent.

Gross Domestic Product 1992/93 is estimated at US\$ 250 billion annually. Assuming that 3% were spent on health care, the **total**

health market was between US\$ 7-8 billion. The Russian health care system - inherited from the USSR - being what it is, i.e. ill-equipped, not high-tech, with main emphasis on community health care through dispensaries, the share of pharmaceuticals is about 40% in total health expenditure. This, in 1992 (or 1993) probably amounts to US\$ 3 billion.²

It is possible to make estimates for the future? Three years hence, for example! An optimistic forecast would be the following for 1996:

1. **Gross Domestic Product** grows to US\$ 300 billion (from about 250 in 1992/93);
2. **Total Health Expenditure** will reach 5% of GDP, i.e. US\$ 15 billion;
3. **Spending on pharmaceuticals** will stay at about 40% of total health expenditure; which means
 - global annual Russian requirement for pharmaceuticals of US\$ 6 billion by 1996.

This forecast is founded on a number of underlying assumptions about Russia finding a solution to at least some of the following problems or problem areas:

1. The country will give itself a workable Constitution together with a clear definition of what will be the Federation of Russia;

². We have no dependable data on the value of Russian (formerly Soviet) drugs production. A good basis to cross-check the \$ 3 billion estimate is the total annual value of "traditional" USSR imports of pharmaceuticals which amounted to about US\$ 1.5 billion. The main sources of these imports were Poland, Czechoslovakia, Hungary and Bulgaria.

2. Relations with the other members of the C.I.S. will be settled; there will be progress with the currency question, i.e. the potential Rouble Area;
3. There will be progress towards monetary reform, including the status and governance of the Russian Central Bank;
4. The legislative process will be consolidated and fiscal legislation will become more stable, including as regards foreign direct investment;
5. The reform movement continues and privatization, together with the further consolidation of ownership legislation, proceeds further.

Finally, it is necessary to recall, in the guise of a profession of faith, three fundamental ideas:

1. **Democracy:** there will be growing and irresistible pressures for improved social benefits, particularly for better financed, better provided, more widely and evenly distributed health services;
2. The **"Peace Dividend"**: the Soviet Union used to spend well over 25-30% of Gross National Product on defense, while overall health expenditure was hardly more than 2% of GNP. Even in the first half of 1992, about 25-30% of the Russian Government budget was spent on defense and less than 20% on social benefits, including a few percent on health.

The necessary further shift of priorities should help improve the financial potential of health insurance and the provision of health services. Indeed, it will become more and more difficult to hide the dismal condition of the country's health services from the Russian public and though the problem is not hitting the headlines yet, the

Russian (and international) media will inevitably focus on it in the near future.

In addition, improving the general health condition of the population corresponds to the fundamental national interest of Russia. These facts will create relentless pressures to give growing priority to the sector by central governmental and regional/local authorities alike.

3. Private initiatives in the health sector: these has started in the sector of pharmaceuticals. ICN-OCTOBER is a case in point.

What is important is that in addition to the continuous work of the Health Ministry and the continuation of state orders, there is already a very active private wholesale and retail activity in prescription and OTC drugs. It is true that this activity is centered mainly on imported drugs at present, but ICN-OCTOBER will be well-placed to establish credibility, to be competitive and eventually take a substantial share in this private Russian drugs market circuit.

**Backstopping Officer's comments on the next phase
of the programme**

Russians officials at various governmental and regional level display a keen interest in foreign investments into the national production of the modern, high quality pharmaceuticals. Certain steps have been taken in this respect. Thus, a number of projects on joint venture production of pharmaceuticals in Russia have been already in the process of their realization together with such foreign companies as ICI (UK), "Knoll" and "Boehringer Mannheim" (Germany), "Servier" (France), "Boehringer Ingelheim" (Austria). However, the demand for pharmaceuticals is still very high in Russia. According to rather modest calculations, the production capacities of Russia can meet at present only 35-40% of the total demand. Among the most scarce are the groups of heart, vascular, antidiabetic, antiinflammatory, oncological pharmaceuticals.

In the present circumstances when the national economy is still unstable and, as a consequence, the hard currency funds allocated for the purchase of pharmaceuticals from abroad are inadequate, import can not meet the needs of the national health care of the Russian population. It is evident that the provision of such health care plays a vital role in any country and for any government.

On the other hand, it would rather be naive to believe that with the improvement of the economic situation in Russia, import will be the main source of national pharmaceutical demand. Quite to the contrary, bearing in mind great potentials of the country, its tremendous natural and material resources and last but not the least, native mother wit and enterprise of Russian people, it is natural to expect a considerable expansion of the national production of pharmaceuticals in Russia in not too distant future. The following factors are conducive to the above, namely: a gradual turn to economic development of the country; Russia's positive

foreign trade balance; expansion of the privatization and growing number of successful businessmen all over the country, trading with Western and other foreign countries. It is worth mentioning that more and more Russian businessmen tend to reinvest their money in Russia, rather than to keep their capital abroad, which results in growth of solvency. To this, one may add, that with the further process of reform development in Russia, the national legislation will be consolidated and fiscal legislation, in particular, will become more stable which will attract foreign investments.

There is a strong belief among Russian officials that the use of the advanced Western technologies and know-how, as well as the accumulated experience in the field of pharmaceutical production, combined with foreign investments will allow to expedite solution of such a pressing problem. It is understood, at the same time, that foreign partners may wish to invest their money into this business provided their profit is secured. The seriousness of the intentions and a great interest in such an approach to the problem are witnessed by a special order No. 118 issued by the Minister of Public Health of the Russian Federation on 3 June 1993, which states specifically that : "The Departments of Medical Industry and of Medical and Pharmaceutical Supply ... must submit a Programme of the development of medical industry based on foreign investments ..."

OKTYABR has negotiated with several foreign companies to improve their facilities. One of such companies, Asap Ltd. Helsinki, Finland suggested a stage-wise approach for the reconstruction of OKTYABR complying with the requirements of GMP. Asap Ltd.'s proposal of April 1994 can be summarized as follows:

Pharmaceutical factory and storage renovation:

First stage: renovation of tablet packaging and storage facilities

conversion to modern, efficient packaging and warehouse practice facilitated by GMP and business education and training.

Second stage: renovation of tablet mass preparation facilities

Development and manufacturing original Russian drugs on the basis of pharmaceutical manufacturing training programme

Main activities of tablet packaging and storage renovation:

* Reconstruction and repair work:

- renovation of daily material and quarantine storage in the factory;
- renovation of central warehouse, development of warehouse operation to modern clearing house activity;
- renovation of tablet packaging department to meet GMP standards.

* GMP training programme

- theoretical sessions
- outline production planning
- preparation of documents
- production exercises

* Database storage bookkeeping and statistics

* Storage and distribution of drugs

Drawbacks of present situation

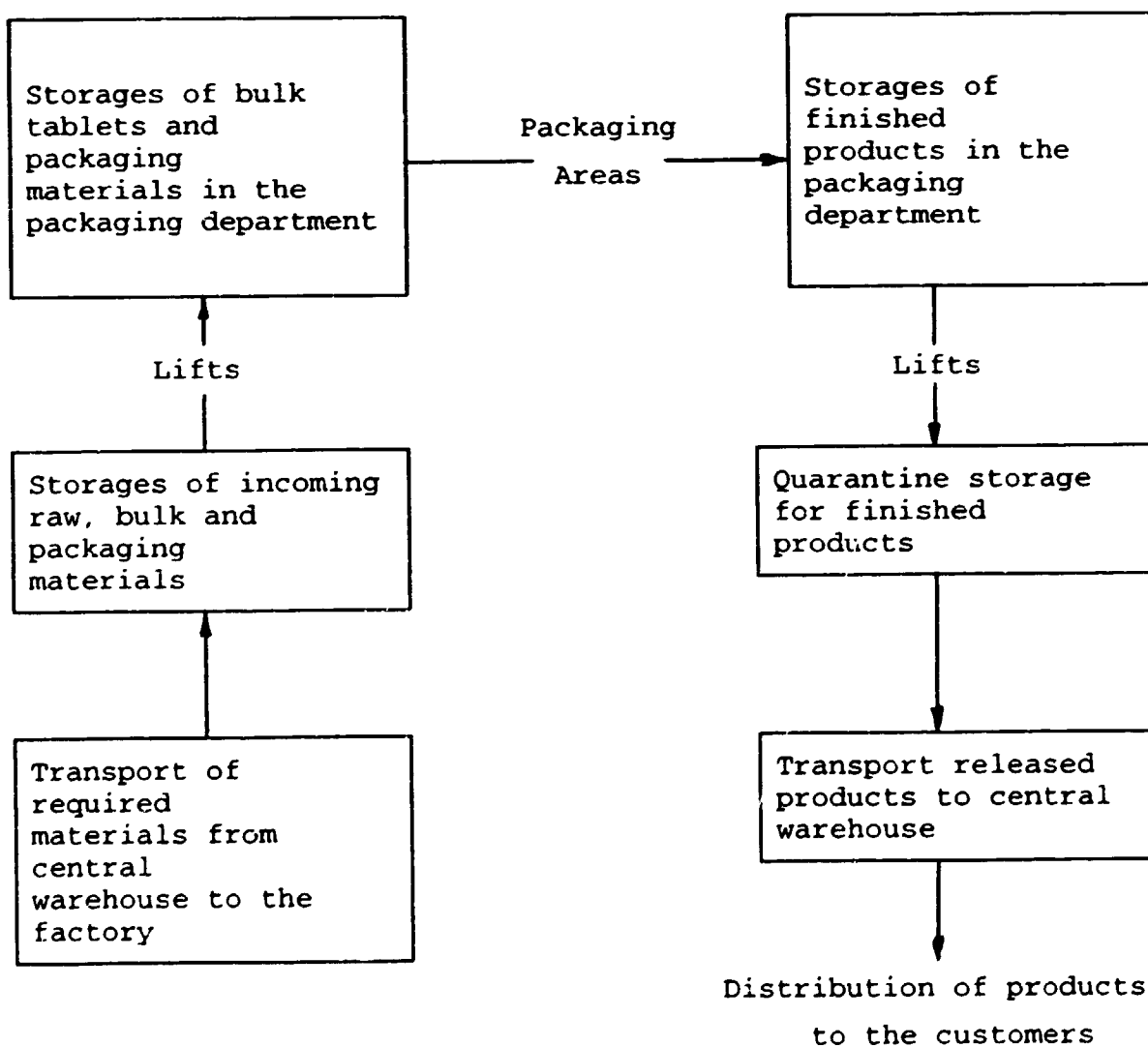
1. No separation between incoming and finished products.
2. Free access to packaging areas.
3. Packaging materials, bulk tablets and finished products are stored in the packaging rooms, hallways and all open areas of the factory.
4. Neither physical nor spatial separation of packaging operation on different drug products.
5. Cracked walls and ceilings, broken floors.
6. Windows cracked and open.
7. No ventilation.
8. Mechanical workshop in connection with packaging operations
9. Equipment inadequately maintained.

After renovation:

1. Separate storage for raw, bulk and packaging materials, quarantine storage for finished products, facilities for sampling and weighing, production of released, finished products by shrink or foil wrapping.
2. Controlled access, dressing room for personnel, clothes maintenance and laundry.
3. Separate daily storage for incoming materials and finished product at the packaging department.
4. Defined packaging area.
5. Exterior walls insulated, new partition walls. Floors fixed hard epoxy composition. Ceiling leveled and painted. Lowered ceiling in the corridors.
6. Windows repaired and fixed not to be opened.

7. Proper ventilation and dust collection. All duct, pipe electric nets are to be installed above the lowered ceiling in the corridors.
8. Workshop situated in storage area.
9. Thorough maintenance of old equipment. New equipment for packaging lines of high capacity.

Model for material flow in the factory



ASAP Ltd.'s more detailed proposal contained production and financial plans. These plans are given as follows:

List of tablet preparations according to packaging machines:

Packaging capacities have been calculated according to 5 day working week in two shifts, 4 effective packaging hours per shift, 11 working months a year.

5 strip packaging units	Denizen
	Diphenan
	Chlorbutin
	Sydnocarb
	Caffeine-sodium benzoate

Packaging capacity for one unit 20000 strips per shift.

Packaging capacity 44 million strips a year in two shifts.

Daily mass flow of tablets 85.9 kg.

Daily mass flow of packaging materials about 100 kg.

5 folio packaging units	Apressin
	Methacin
	Dimedrol
	Proserpine
	Ethimizol
	Cyclodol
	Pyrroxan
	Chinoxydin
	Myelosan
	Riboxin
	Phenobarbital
	Citramon

Packaging capacity for one unit 35000 blisters per shift.

Packaging capacity 77 million blisters a year in two shifts.

Daily mass flow of tablets 602,5 kg.

Daily mass flow of packaging materials about 700 kg.

2 "hassia" packaging units

Ca-gluconate
 Glutamic acid
 Lithium carbonate
 Methyl uracil
 Leucogen
 Hexamidine
 Analgin

Packaging capacity for one unit 50000 blisters per shift.

Packaging capacity 44 million blisters a year in two shifts.

Daily mass flow of tablets 648,8 kg.

Daily mass flow of packaging materials about 700 kg.

Special packaging units

Cystamine
 Taren

Packaging capacity of 3 units 9 million packages a year in two shifts.

Daily mass flow of tablets 54,5 kg.

Daily mass flow of packaging materials about 60 kg.

Nitroglyserole

Packaging capacity of 4 units 50 million packages a year in two shifts.

Daily mass flow of tablets 4,5 kg.

Daily mass flow of packaging materials about 10 kg.

New strip packaging unit

Citramon

Packaging capacity 60 million 6-tablet strips a year in two shifts.

Daily mass flow of tablets 818 kg.

Daily mass flow of packaging materials about 900 kg.

New blistering and
cartoning unit

Demalgon
Salvador
Ascorbic acid
Polyvitamins AB1B2C

Packaging capacity 26,4 million blisters a year in two shifts.

Daily mass flow of tablets about 500 kg.

Daily mass flow of packaging materials about 500 kg.

Proposal for production list of tablet preparations
in October factory

Name of preparation	Tablet weight /g	Pack size	Amt. Million PCS/yr	Mass kg/yr	Mass flow/ day	Price Mill. Roubles/yr
Cholinolytic and spasmolytic agents						
Apressin	0,01	N10	2	200		16.8
		N20	1,5	300		42.9
	0,025	N10	2	500		28.4
		N20	1	500	6,8	40.4
Methacin	0,002	N10	1,5	30	0,2	27.6
Anticholine sterase Agents						
Proserpine	0,015	N10	1.0	150	0,7	24.8
		N20	0,5	150	0,7	6
Antiadre- nergic Agents						
Pyrroxan	0,015	N10	1.0	150		23
		N50	1.0	750	4,1	116

Name of preparation	Tablet weight /g	Pack size	Amt. Million PCS/yr	Mass kg/yr	Mass flow/day	Price Mill. Roubles/yr
Analeptics						
Ethimizol	0.1	N10	1.0	1000		19.2
		N50	1.0	5000	27.3	104
Anti-Parkinsonism Agents						
Cyclodol	0,002	N10	1,0	20		15
		N50	3,0	300	1,5	229.2
Denizen	0.1	N10	3,0	3000		85.2
		N50	1,0	5000	36.4	142.6
Amino acids						
Glutamic Acid	0,25	N10	5,0	12500		297
		N40	0,5	5000	79,5	74.4
Neuroleptics						
Lithium carbonate	0,3	N10	2,0	6000		21.2
		N50	0,5	7500	61,4	30
Antimicrobial Agents						
Chinoxidin	0,25	N10	2,5	6250	28,4	168
Leucopoietic Stimulants						
Leucogen	0,02	N10	5,0	1000	4,5	22
Methyl uracil	0,5	N10	5,0	25000		853
		N50	1,0	25000	227,3	860
Non-Narcotic Analgesics						
Analgin	0,5	N 6	4,0	12000		340
		N10	1,0	5000	77,3	166
Citramon		N 6	60,0	180000	818,0	8460
		N10	22.0	110000	500,0	2200

Name of preparation	Tablet weight /g	Pack size	Amt. Million PCS/yr	Mass kg/yr	Mass flow/day	Price Mill. Roubles/yr
Medicines for Prevention and Therapy of Radiation Disease						
Cystamine	0,2	N 6	8,0	10800	49,0	97.6
Anticonvulcent agents						
Hexamidine	0,25	N10	5,0	12500		216.5
		N50	0,5	6250	85,2	114.5
Diphenan	0,117	N10	5,0	5850	26,5	182
Chemotherapeutic Agents						
Chlorbutin	0,002	N100	0,2	40		10.2
	0,005	N100	0,35	175	0,1	18.2
Myelosan		N50	1	100	0,5	34.2
Psycho stimulant Agents						
Sydnocarb	0,005	N10	2.0	100		23.2
		N50	1.0	250		64
	0,01	N10	2.0	200		29.6
		N100	0,5	500		57
		N50	0,5	250	5,9	40
Caffeine-sodium benzoate	0,075	N10	5	3750	17	48
Soporific Agents						
Phenobarbital	0,005	N 6	1.0	30		33
	0,05	N 6	0,5	150		5
	0,1	N 6	0,5	300	2,2	14

Name of preparation	Tablet weight /g	Pack size	Amt. Million PCS/yr	Mass kg/yr	Mass flow/day	Price Mill. Roubles/yr
Anabolic Non-Steroid Agents						
Riboxin	0,2	N10	0,5	1000		200
		N50	0,5	5000	27,3	980
Antihistaminic Agents						
Dimedrol	0,02	N 6	1.0	120		13.2
		N10	1.0	500	2,8	38.6
Vitamins						
Ascorbic Acid	0,25	N10	2	5000	22,7	76
Polyvitamins AB1B2C	0,5	N30	1	15000	68,2	336
Others						
Nitroglycerine	0,0005	N40	50	1000	4,5	2510
Calciumgluconate	0,5	N10	5	25000	79,5	200
Salvador		N10	10		409,1	770
Demalgon		N10	10			3276
Taren	0,2	N 6	1	1200	5,5	138
Total			245		27142	23947.5

Principles for Finance Plan

- * Figures are reported starting from the beginning of investment project (from August 1994 to the end of 1999). Cash based transactions are planned in half year-periods except year 1994, which includes only 5 months.

- * Opening balance is 0. The finance of the project will be separated from the current business.
- * Object of closing balance level is 0,5 million US\$.
- * Operational income are estimated to start-up after investment programme so that in the first year-period II/1995-I/1996 (12 months) about half of the standard year level (planned) will be reached. Standard level will be actual during fifth year (year 1999).
- * "Others" investment includes at least controlling and reporting of the project, training for facilities of the manufacturer, other general training of personnel and costs of documentation (incl. costs of traveling and working abroad).
- * Investment for increase of working capital (acc. receivable, acc. payable, inventories : material and finished goods) is estimated for amount of 1/3 of the first year income.
- * New loans are planned to be free of installments in the first 5 years.
- * Repayments of the loans for finance of working capital will be actual first.
- * Interest rate level of the loans is estimated 6 % p.a. and payments will happen every half year.
- * Inflation is 0 % p.a.
- * Figures are reported in thousands US\$D (1000\$), exchange rate is 1 US\$ = 1504 Rbl (Rate of the Central Bank of Russia from date 19.1.1994).

KEY FIGURES IN PLAN

Accounts receivable	Receivables are divided to income in Rbl (home market) and in other currencies (US\$, DEM ...)
Operational income	Includes all cash based transaction of sale figures
Expenses	Plan report divides figures according to flexibility of the volume of production (from raw materials to social expenses) and fixed costs (rest of expenses)
Operational expenses	Include all financial expenses including production, administration, marketing and taxes including costs of finance (interests)
Investments	Divided to OKTYABR factory, Parnas warehouse and Other = costs of consulting, controlling and reporting of the whole project. Extra working capital for increasing current capacity and volume of production and facilities to much higher level.
Loans	Total need is estimated about 20 million US\$. Installments are planned to start from the year 2000 on.

Loans for working capital will be repaid in years 1996-1998

Financial

Incloses interest payments (and other financial expenses) of the loans of investments.

Balance of period

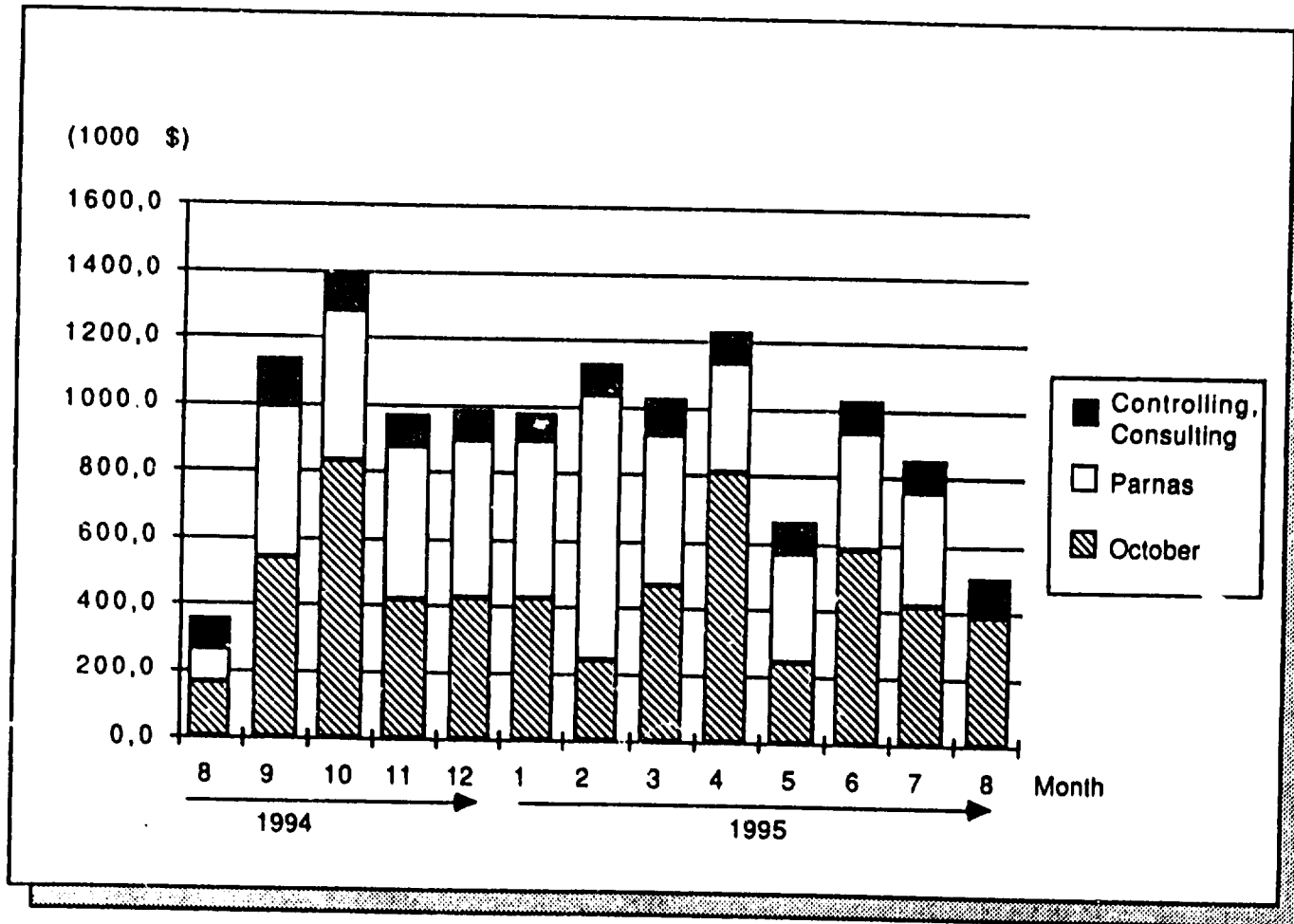
Net cash flow after financial costs and before installments of the investment loans. This row is calculated per period. Cumulative cash flow is in the row "closing balance".

FINANCE PLAN FOR YEARS 1994-1999

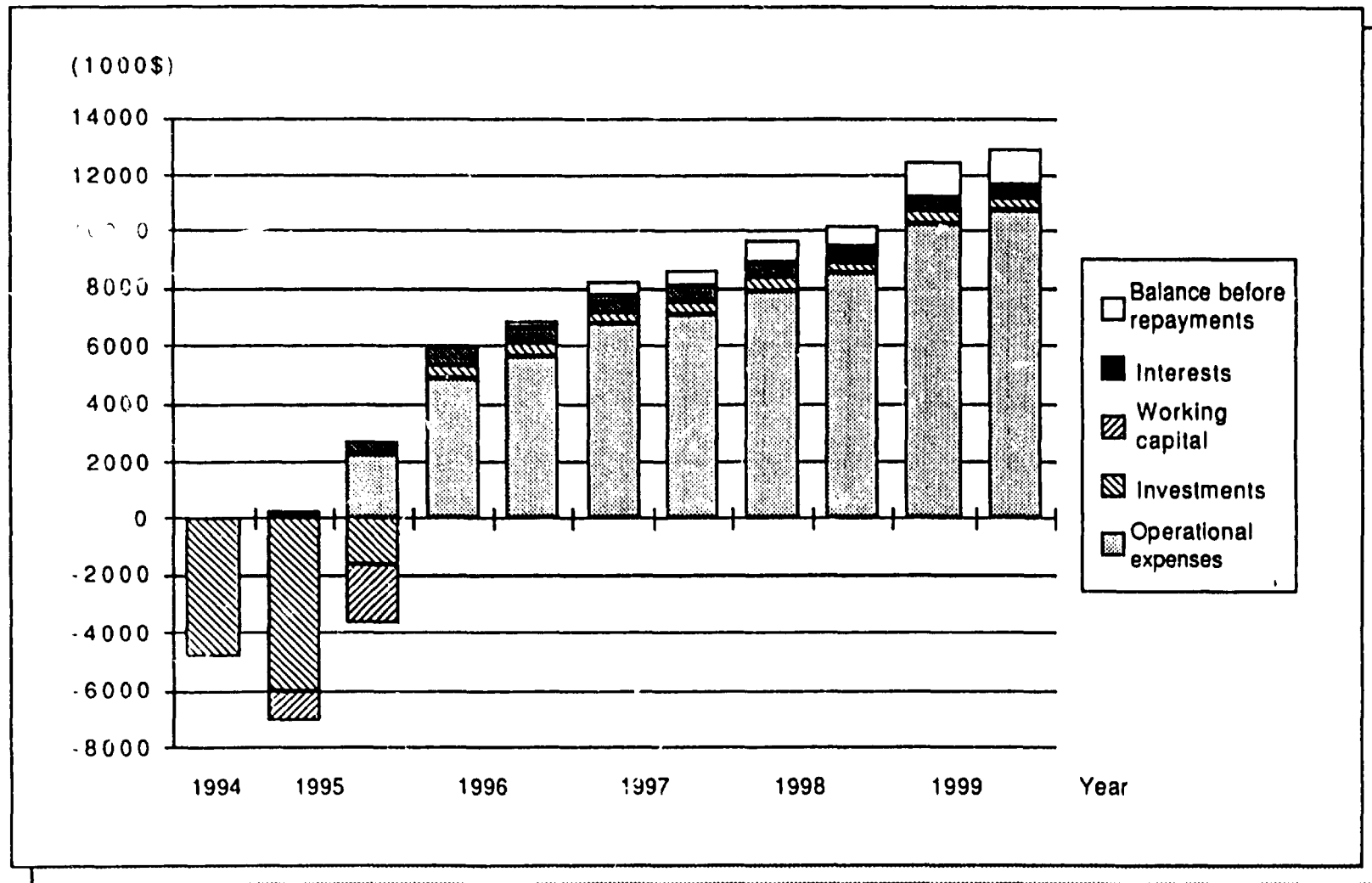
(1000\$)	II/94	I/95	II/95	I/96	II/96	I/97	II/97	I/98	II/98	I/99	II/99	TOTAL
ACCOUNTS RECEIVABLE												
Home market	0	0	2500	5200	6000	7400	7700	8500	9000	11000	11200	68500
Export	0	0	0	300	400	400	500	700	800	1000	1300	5400
OPERATIONAL INCOME	0	0	2500	5500	6400	7800	8200	9200	9800	12000	12500	73900
EXPENSES												
Raw materials	0	0	-1200	-2700	-3100	-3720	-3870	-4320	-4600	-5580	-5760	-34850
Packing materials	0	0	-40	-60	-80	-100	-110	-110	-120	-150	-150	-920
Transports	0	0	-100	-220	-250	-300	-310	-340	-360	-440	-460	-2780
Wages & salaries	0	0	-400	-900	-1070	-1300	-1390	-1560	-1700	-2050	-2180	-12550
Social exp. (ins.&cost)	0	0	-160	-360	-430	-520	-560	-620	-680	-820	-880	-5030
Rents and leases	0	0	-10	-10	-10	-10	-10	-10	-10	-10	-10	-90
Water & energy	0	0	-20	-20	-20	-20	-20	-20	-20	-20	-20	-180
Heating	0	0	-60	-60	-60	-60	-60	-60	-60	-60	-60	-540
Services/repairs	0	0	-30	-30	-30	-30	-30	-30	-30	-30	-30	-270
Adm. mgmt costs	0	0	-40	-90	-90	-90	-100	-100	-100	-100	-110	-820
Marketing costs	0	0	-10	-10	-10	-10	-10	-20	-20	-20	-20	-130
Interest payments	0	0	-20	-20	-20	-20	-20	-20	-20	-20	-20	-180
Taxes	0	0	-150	-370	-450	-590	-620	-730	-760	-980	-1020	-5670
OPERATIONAL EXPENSES	0	0	-2240	-4850	-5620	-6770	-7110	-7940	-8480	-10280	-10720	-64010
OPERATIONAL CASH FLOW	0	0	260	650	780	1030	1090	1260	1320	1720	1780	9890
INVESTMENTS												
October	-2378	-2771	-803									-5952
Parnas	-1935	-2730	-385	-35	-35							-5120
Others	-535	-552	-468	-420	-420	-420	-420	-420	-420	-420	-420	-4915
Yhteensä	-4848	-6053	-1656	-455	-455	-420	-420	-420	-420	-420	-420	-15988
Working capital	0	-1000	-2000	0	0	0	0	0	0	0	0	-3000
LOANS (+/-)	8000	8000	4000	-1000	-1000	-500	-500	-500	-500	0	0	16000
FINANCIAL (+/-)	0	-240	-480	-600	-570	-540	-520	-510	-500	-480	-480	-4920
BALANCE OF PERIOD	3152	707	124	-1405	-1245	-430	-350	-170	-100	820	880	1982
OPENING BALANCE	0	3152	3859	3983	2578	1333	903	553	383	283	1103	0
CLOSING BALANCE	3152	3859	3983	2578	1333	903	553	383	283	1103	1983	1982

INVESTMENTS PER MONTH IN PERIOD 8/1994 - 8/1995

(Investments total = 12,3+3,7 mill.\$)

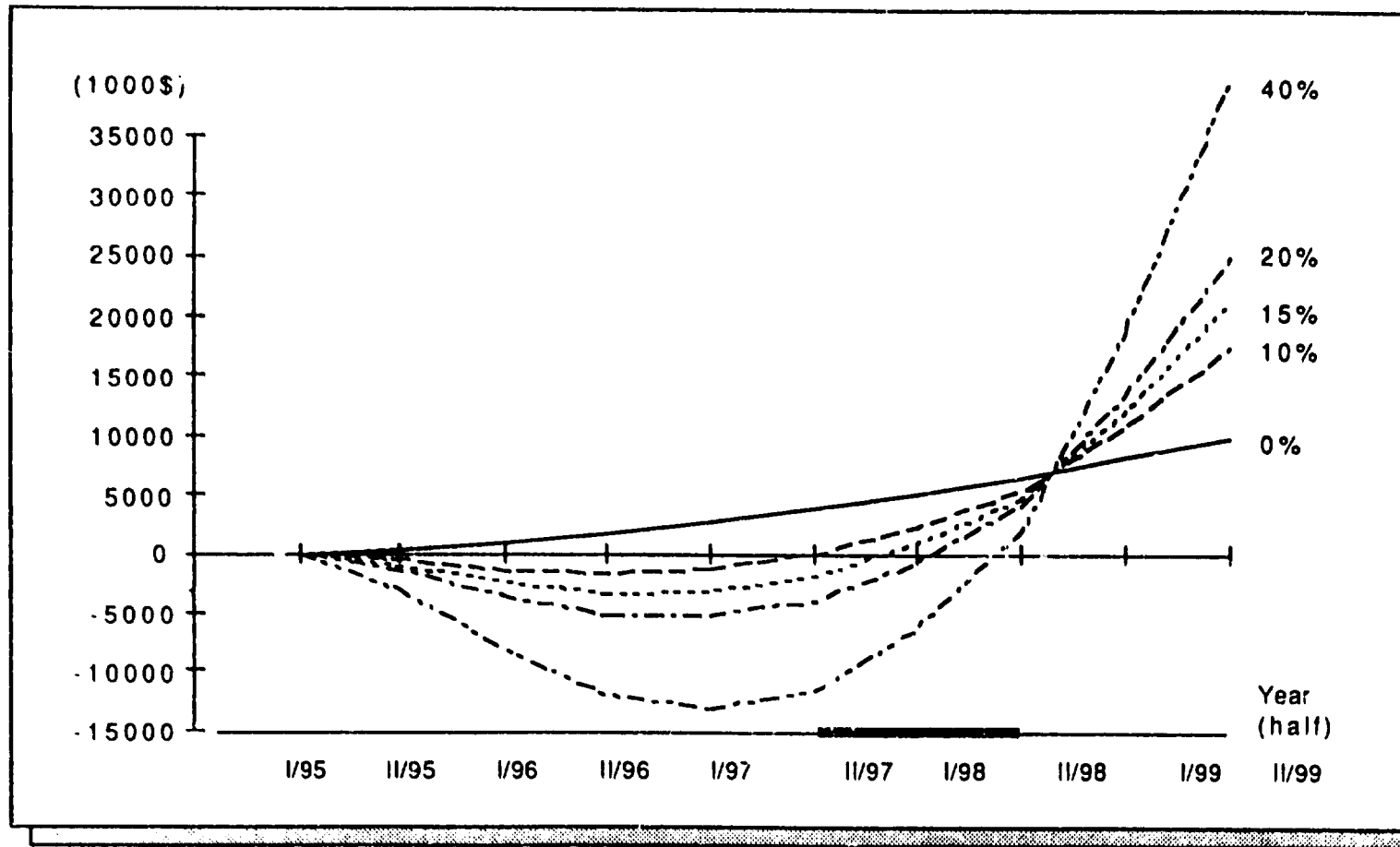


BALANCE PER PERIOD BEFORE NEW LOANS AND REPAYMENTS YEARS II/1994 - II/1999



OPERATIONAL CASH FLOW (CUMULATIVE) IN DIFFERENT INFLATIONS

(Balance before investments and finance = Operational income - Operational expenses)



Inflation in costs immediately from 11/1994 on, and
in income about half year later = from 1/1995 on

It is the views of UNIDO that without reconstruction, OKTYABR cannot comply with the current regulatory requirements of the pharmaceutical industry. To plan, design, approve and execute the reconstruction and remodeling work without interrupting production operations needs a phase-wise approach. The most pragmatic and logical approach would be to carry out the reconstruction in a backward up-stream manner. This is, by the way, how the renovation was proposed by ASAP Ltd. Since there might be a lack of actual working experience and expertise in the quality management of modern pharmaceutical industry in the Russian Federation, the required know-how could be obtained from a well established pharmaceutical enterprise of international regulation. It should be, however, noted that the international requirements for pharmaceutical manufacturing are different in the USA, EU and Japan. The new project, that is the reconstruction of OKTYABR would therefore be the most cost-efficient if it would be guided and possibly carried out by the same foreign enterprise.