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Economic Analysis of a New Business for Liposome Manufacturing Using a High-Pressure System

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Abstract: Supercritical assisted Liposome formation (SuperLip) is a lab-scale process for the production of liposomes. SuperLip was recognized as being a versatile supercritical assisted technique for the encapsulation of molecules for different industrial applications, such as pharmaceutic, cosmetic, textile, and nutraceutic purposes. The aim of this work was to perform an economic analysis to assess the profitability of the SuperLip process. The liposomes market was analyzed and the SuperLip process was compared to other techniques in terms of manufacturing advantages using the Canvas and Strengths, Weaknesses, Opportunities, and Treats (S.W.O.T.) models. SuperLip Plant Capital Expenditures (CAPEX) were estimated, and plant Operating Expenditures (OPEX) were also evaluated and integrated with personnel cost and other plant goods and services. A profit and loss statement was generated, together with a cash flow analysis. According to the market average selling price, liposome price is 1.8 €/mL; in order to join the market rapidly, the selling price of liposomes produced using SuperLip was set at 1.1 €/mL. A payback time has been identified at the fourth year of business. Economic indexes such as ROI and ROS were calculated on a 10-year business prospect, obtaining about a 230% return on investment and a 26.7% return on sales.

Keywords: economic indexes; liposomes; market analysis; processes; supercritical fluids

1. Introduction

Liposomes are spherical drug carriers characterized by an inner water nucleus surrounded by a lipidic barrier [1]. The increasing interest in engineered liposome development [2] has encouraged the production of vesicles loaded with antibiotics [3], proteins [4], genes [5], antioxidants [6], dyes [7], and dietary supplements [8]. However, the liposome production methods proposed in the literature suffer from drawbacks such as low cellular uptake [9], difficult-to-control particle size distribution [10], low encapsulation efficiency [11], and discontinuous layout [12]. Among these, low entrapment efficiencies and the difficult-to-control particle size distribution of liposomes [13] are responsible for the waste of huge percentages of the entrapped amount of molecules and, as a consequence, the production cost increases significantly [14]; moreover, the use of solvents negatively contributes to environmental impact [15]. The batch layout caused difficulty in the scaling up of these techniques to the industrial level [16]. According to the description of conventional methods reported in the

literature [17–19], their main problem was linked to the hydration step of the lipidic layer, which caused a low replicability of the produced vesicles [20]. This was generally followed by post-processing steps, such as sonication or extrusion, obtaining homogenous vesicles at the nanometric level [21]; on the other hand, post-processing steps caused the leakage of a huge amount of the entrapped drug [22].

A good control of particle size distribution and high entrapment efficiency, especially for expensive compounds, is a fundamental key parameter for the development of a successful liposome production process. Indeed, a supercritical assisted process has been proposed to overcome the problems linked to conventional production methods [23–25]. This process has been named SuperLip (Supercritical assisted Liposome formation), and its novelty consists of inverting the main liposomes production steps: First, water droplets are created through water atomization into a carbon dioxide-ethanol-phospholipid-based expanded liquid, operating at pressures between 100 bar and 200 bar. Atomized water droplets are fast covered by phospholipids, thanks to the high diffusivity of supercritical carbon dioxide [26]. According to this mechanism, the main advantage of this process is referred to the one-shot production of liposomes with a continuous and reproducible plant layout. The high versatility of SuperLip has been already recognized in terms of the process greenness (low solvent residue), high biocompatibility, and different applications in several industrial fields, such as nutraceutical, cosmetics, and pharmaceutics [27].

According to the international scale (from 1 to 9) for Technology Readiness Level (TRL) reported in the literature [28,29], the SuperLip process achieved a TRL of 7, meaning that the system is under a prototyping working environment. Indeed, this process has been developed in continuous configuration, and its scalability to the industrial level could be also achievable. SuperLip potential applications have been recognized by external customers, interested in a Business To Business (B2B) production of liposomes formulations on demand. The idea at the basis of this process has been already validated and certified by product development and sample characterization, as reported in previously published works [30–32].

The advantages of the SuperLip process were compared with the main drawbacks of the conventional techniques, as summarized in Table 1, where the advantages of SuperLip and the drawbacks of the other techniques are mainly reported.

Table 1. Advantages of the SuperLip process and the disadvantages of other liposome production methods.

General Drawbacks of Other Liposomes Processes	SuperLip Process Advantages	SuperLip Potential Application
Production of vesicles at micrometric level (0.5–50 μm) [33]	Production of vesicles at nanometric level (100–300 nm)	Pharmaceutical formulations
Polydisperse samples PDI > 0.2 [34]	Monodispersed samples PDI < 0.2	
Solvent Residue over FDA threshold Use of toxic solvents [35]	Low solvent residue: a green process Use of carbon dioxide (not toxic)	Food industry for the production of additives and dietary supplements
Low encapsulation efficiencies Waste increased [36]	Molecule Encapsulation efficiencies higher than 95% Cost reduction	Encapsulation of markers, genes and high weight proteins
Vesicles aggregation/instability [37]	Vesicles stability	Long-circulating liposomes
Possible drug degradation [38]	Drug protection from heat and oxidation	Cosmetic industries for skin penetration products
Post-production steps required [39]	1-step production of vesicles	Production of liposome-based vaccines in short times
Discontinuous processes [40]	Continuous process	Large-scale production

As with all the processes designed for the production of liposomes, there is always a weak point. In our case, the SuperLip process manages to solve the drawbacks of the previously proposed techniques; however, it requires a larger investment and operative cost. One of the aims of this paper is to demonstrate that this does not represent a limitation, since it adds value to the produced liposomes, reaching a significant economic profitability. Indeed, the production of vesicles at the nanometric level enables drug administration to the nanometric interstices of human tissues. Moreover, the production of monodispersed samples gives the advantage of producing liposomes in a replicable manner. The one-step production and the continuity of this process are the main advantages of SuperLip, guaranteeing several industrial applications (reported in the third columns of Table 1), and thus reducing the cost and providing a larger profitability than other processes. However, the economic evaluations of lab-scale chemical plants are generally not performed by researchers, causing a lack of data that would be useful for a possible industrial scale-up. Therefore, the scope of this work is to assess the economic profitability of the SuperLip process. The liposomal market will be studied and estimated; then, a profit and loss statement, followed by a cash flow analysis, will be performed for the SuperLip process. Finally, the calculation of economic indexes will be shown.

2. Economic Analysis: First Reference Market

SuperLip can be used in numerous fields of applications; however, the necessity to sell liposomes at the beginning of the business needs to be addressed easily and rapidly. The most accessible field that does not require particularly difficult trial tests is the nutraceutic.

Nutraceuticals are substances that occur naturally, since they can be extracted by plants, leaves, flowers, and fruit. The word "nutraceutical" was introduced by Dr. Stephen De Felice in 1989 to indicate natural compounds that can have beneficial effects for human beings, preventing people from developing illnesses [41]. These kinds of products are indicated as functional food; their main functionalities and advantages are the possibility of reinforcing the production of antibodies, regulating the gastro-intestinal apparatus, functionalizing the cardiovascular system, and even delaying the body's aging process. The major nutraceuticals are omega-3 and omega-6; folic acid; creatinine; probiotics; maltodextrin; mineral salts such as magnesium, calcium, sodium, zinc, and many others. The importance of entrapping these molecules into liposomes is fundamental, since these vesicles enhance molecule bioavailability and favor direct administration to target organs, avoiding leakage.

The nutraceutic market could provide the selling of 20–30% of the maximum SuperLip productivity per year in order to create the conditions to join other fields of applications, such as pharmaceutical, which could be started by the fourth year. Then, by the fifth year, the estimation of goods selling will be increased to 50%.

Nutraceutic is a scientific field related to the application in foods of naturally occurring compounds. Even if several liposome-based formulations can be developed for pharmaceutical applications using SuperLip, the segment related to the nutraceutical market represents a good starting level, since the market barriers are less severe than in the pharmaceutical and cosmetic fields [42]. Italy is ranked as the first European country for the consumption of nutraceutical products, since the Italian market of dietary supplements has grown 7.4% between 2014 and 2016, especially for multi-vitamin additives [43]. These products are sold in pharmacies, gyms, and mass markets; for this reason, each Italian citizen pays about 40 €/year for buying dietary supplements, followed by Austrian and Belgian citizens, with 33 € each. The last place in the European rankings has been given to France, with 12 €/year [44].

The main reason for this large increase in the market derives from the recommendations of medical doctors, personal trainers, and specialists. A huge number (90%) of Italian family doctors generally advise the use of food supplements for patients during their daily life. Not only liposomes, but also other kind of Drug Delivery Systems (DDS), such as nanocrystals, polymer microspheres, gold nanoparticles, micelles, nanotubes, and patches, are commonly employed to deliver nutraceutical compounds [45–47]. In Figure 1, a comparison among the worldwide overall drug delivery systems sold and liposome (a subset of DDS) is proposed.

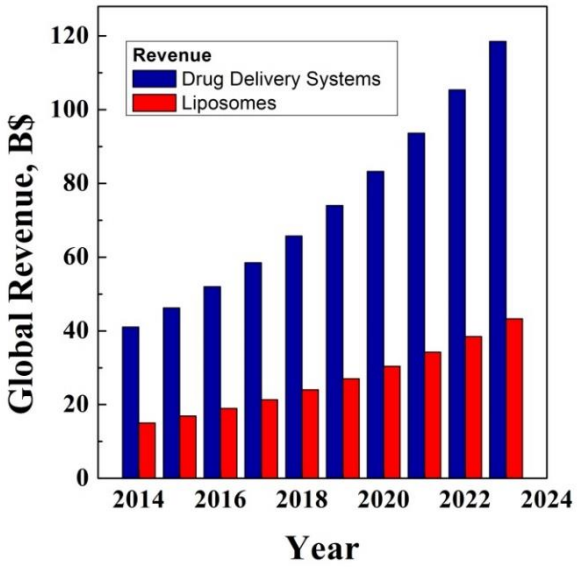

Figure 1. Comparison among Drug Delivery Systems (DDS) and liposomes revenues, registered worldwide for nutraceutical applications [48].

As shown in Figure 1, the worldwide market is represented by all the types of DDS sold for nutraceutical purposes (blue columns). The business volume linked to the DDS of nutraceuticals starts from 40 B€ in 2014, with an estimated growth of more than 100 B€ in 2024. Liposomes, instead, had a market value lower than 20 B€ in 2014, and they were estimated to be worth about 40 B€ in 2024 [49].

The nutraceutical field also guarantees a smaller payback time than pharmaceutics [50]. By the end of 2020, the estimation of liposomes requests for nutraceutical purposes was around 1.7 M€ worldwide, with an estimated market volume of 3.12 B€ (data deducted from the source: Nutraceutical Excipients Market 2020, Segmented by Type, Application and Geography, Growth, Trends, and Forecast (2020–2027)).

SuperLip production at the lab-scale consists of about 720 L/year, using a calculation basis of 300 working days (8 h per day) and considering a prudent daily production of 300 mL/h. These data are quantified in terms of the feeding flow rate, since the concentration of lipids can be varied according to customer request. The lipid concentration cost is considered among the plant Opex cost of reagents.

3. Proposal of A Business Model

A Business to Business (B2B) model was proposed here to join the market. Potential customers are companies that would be interested in encapsulating their own molecules, employing SuperLip technology for the production of liposomes on demand. The typical Canvas business model [51] has been summarized in Table 2.

Table 2. Canvas business model scheme for the SuperLip process.

Key Partners	Key Activities	Value Propositions	Customer Relationships	Customer Segments
Department of Industrial Engineering, University of Salerno, Italy Local low consultant	Production of liposomes on demand **Key Resources** An innovative production technology High qualified personnel	A green and continuous technology. 1-shot production Replicability of the products Solvent-free High versatility and encapsulation efficiency	Continuous dialog with customers with request of feedback Transparency of contracts **Channels** Internet and Social Fairs and Events Word of Mouth	Factories Laboratories Academies Research Groups Multinationals
Cost Structure Personnel, Legal consultancy Marketing, Reagents purchasing Operating (power) cost Shipping of products			**Revenue Streams** Selling of liposomes formulations on demand	

4. S.W.O.T. Analysis

To complete the Canvas model, a scheme of the Strengths, Weaknesses, Opportunities, and Treats (S.W.O.T.) of SuperLip process is proposed in Table 3.

The main risk, as indicated in the S.W.O.T. analysis shown in Table 3, is that the largest industries will remain linked to the conventional methods of production of liposomes. However, the academic community is raising the big problems of replicability; societies are also complaining about the poor quality of the lipidic vesicles produced using low-pressure techniques. The increased number of papers in the drug delivery field is attracting great attention among private industries. Additionally, government institutions are starting to finance projects of developing processes for the advancement of drug delivery. This will bring more credibility to the SuperLip process, solving simultaneously all the weakness points. Moreover, the absence of a patent will be easily overcome by associating to the SuperLip process some patents of liposome-based products. This will also solve the problems raised in this SWOT analysis. Another aspect is characterized by risks; in these fields of drug carriers produced using supercritical fluids, there are not significant industrial competitors at the moment. This is a pioneering field in which it is important to act now and in a fast manner.

Table 3. S.W.O.T. analysis of the SuperLip process.

Strengths	Weaknesses
Liposomes produced using SuperLip showed an encapsulation efficiency higher than 95% of drugs.	The high potential of SuperLip could not be readily understood by medical doctors and sanitary system.
Possibility to tune drug release, activated by external stimuli on demand.	
Competitive cost compared to average market price.	Several are still linked to conventional methods for the production of liposomes.
Opportunities	**Threats**
Fast growth of the liposomal market	SuperLip process has not been patented. However, SuperLip products can be still patented.

5. Financial Analysis

The commercialization of liposomes produced via SuperLip requires a deep cost analysis. CAPEX (Capital Expenditures) is related to the investment cost for the building of the SuperLip process. This will be considered as the plant asset invested at the first year. Then, the yearly cost will be divided into the Plant OPEX (operative expenditures), personnel cost, and other plant goods and services costs.

The evaluation of Plant OPEX represents the consumption of water, energy, and other reactants during the running of the SuperLip process units.

The SuperLip layout is presented in Figure 2, including working parameters such as reactant flow rates.

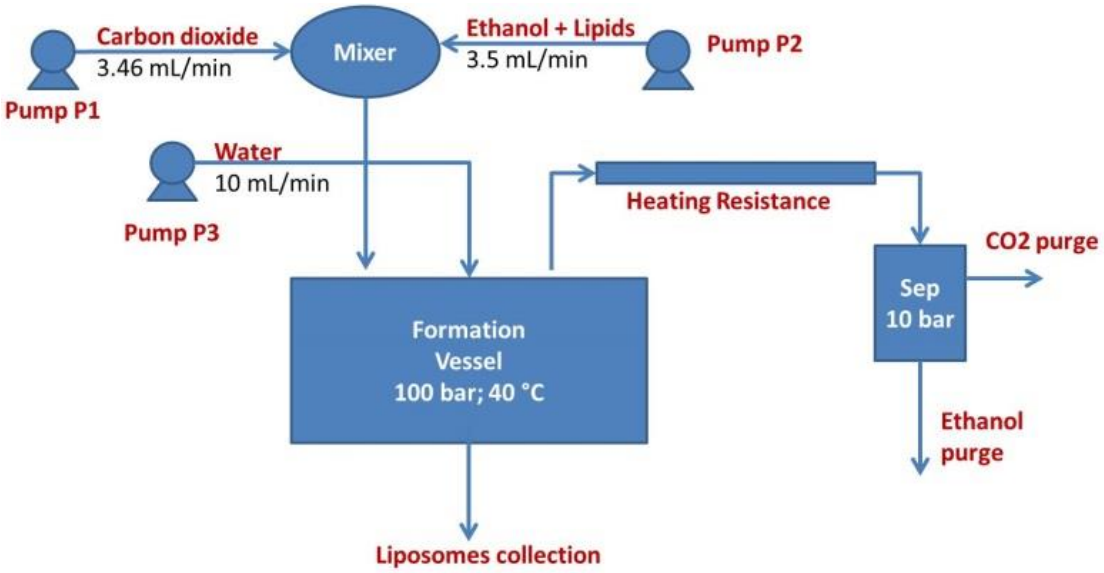

Figure 2. SuperLip layout of the process with operating conditions.

As shown in Figure 2, carbon dioxide is fed at the flow rate of 3.46 mL/min; it is mixed with ethanol containing lipids and pumped at the flow rate of 3.5 mL/min—i.e., 2.76 g/min. In the mixer, an expanded liquid is obtained, setting the pressure at 100 bar and the temperature at 40 °C. Then, this mixture is fed to a formation vessel, where a third feeding line of water (up to 10 mL/min) is sprayed using a nozzle of micrometric dimensions. Liposomes are formed in this vessel and are collected in water suspension from the bottom. Instead, carbon dioxide and ethanol, after depositing the lipids, are eliminated completely from the top of the formation vessel. A depressurization step is then provided for separating the ethanol and carbon dioxide at 10 bar and 20 °C using a heating system. The description of SuperLip formation mechanisms has been provided in previous papers [30–32]; whereas the single SuperLip process units are shown in Figure 3.

In details, Table 4 contains the Capital Expenditures of the SuperLip process assets. For these elements, a 10% linear yearly depreciation was considered.

Table 5 represents the Plant Operating Cost, for which 0.06 €/KWh was used as the power supply unit cost for electricity, with a yearly growth rate of 2%. Moreover, the costs of reagents are intended to be the sum of ethanol, carbon dioxide, and distilled water for the feeding lines of the SuperLip process. This analysis was performed in the case of drug entrapment on demand; this means that the drug will be provided by the customer.

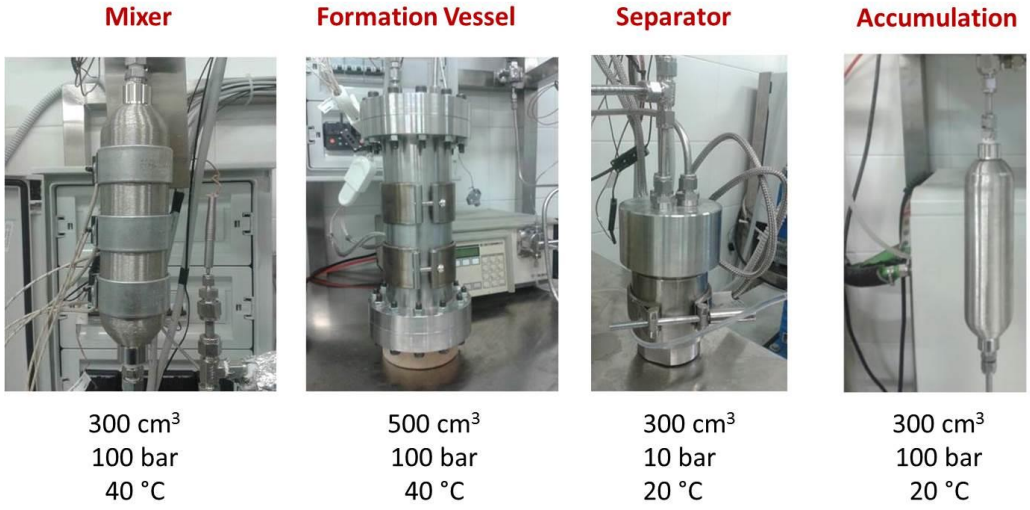

Figure 3. SuperLip main process units and operating characteristics.

Table 4. Plant capital expenditure for the SuperLip apparatus.

ASSET	Cost 1 Unit [€]	Unit Number	Total [€]
Pumps	10,000	3	30,000
heat exchangers	2000	3	6000
On/Off valves	100	4	400
micrometric valves	400	1	400
backpressure valves	2500	1	2500
glass burette	200	2	400
stainless steel piping elements	50	15	750
stainless steel main vessel	2000	1	2000
stainless steel separator	1000	1	1000
thermocouples	500	1	500
compressed gas tank	5000	1	5000
manometers	150	3	450
flow meter	200	1	200
heaters elements	100	2	200
stainless steel plant backbone	1500	1	1500
laboratory extractor hood	6000	1	6000
Laboratory desks	200	5	1000
computers for instrumentations	800	3	2400
sample stock fridge	2000	1	2000
maintenance elements			6270
TOTAL Plant CAPEX			68,970

Table 6 focuses on the personnel cost, consisting of a site manager, who has the responsibility for the overall activity, including the acquisition of reagents and the selling of products. Then, a project manager is included for the coordination of all the operations and the quality control of the plant. Two operators were assigned to the plant production chain, whereas a lab specialist was employed for the characterization of products and quality report. Finally, a worker was assigned to the administration commitments. Due to low increase rate of salaries, a yearly growth rate of 0.5% was defined.

Other plant goods and services are reported in Table 7. In this case, the yearly growth rate was set at 2% for the plant operating cost.

It is necessary to say that this work is only focused on the economic and financial analysis of the process plant, its operative cost, and asset investment. It is not a society analysis cost; indeed, we indicated as "site manager" the person who was enrolled for the supervision of the process plant. In the case of a society constitution, we would have called him/her the chief executive officer.

Table 5. Plant Operating Cost (2020–2030), growth rate 2%.

	Price/Year [€]										
Service	**2020**	**2021**	**2022**	**2023**	**2024**	**2025**	**2026**	**2027**	**2028**	**2029**	**2030**
Power supply	4560	4651	4744	4839	4936	5035	5135	5238	5343	5450	5559
Reagents	24,000	24,480	24,970	25,469	25,978	26,498	27,028	27,568	28,120	28,682	29,256
Water supply	3800	3876	3954	4033	4113	4196	4279	4365	4452	4541	4632
Total	**32,360**	**33,007**	**33,667**	**34,341**	**35,028**	**35,728**	**36,443**	**37,171**	**37,915**	**38,673**	**39,447**

Table 6. Personnel cost (2020–2030), growth rate 0.5%.

	Price/Year [€]										
Role	**2020**	**2021**	**2022**	**2023**	**2024**	**2025**	**2026**	**2027**	**2028**	**2029**	**2030**
SM *	33,600	33,768	33,937	34,107	34,277	34,448	34,621	34,794	34,968	35,143	35,318
PM **	31,200	31,200	31,200	31,200	31,200	31,200	31,200	31,200	31,200	31,200	31,200
Operator 1	28,800	28,944	29,089	29,234	29,380	29,527	29,675	29,823	29,972	30,122	30,273
Operator 2	28,800	28,944	29,089	29,234	29,380	29,527	29,675	29,823	29,972	30,122	30,273
LS ***	26,400	26,532	26,665	26,798	26,932	27,067	27,202	27,338	27,475	27,612	27,750
Administration	21,600	21,708	21,817	21,926	22,035	22,145	22,256	22,367	22,479	22,592	22,705
Total	**170,400**	**171,096**	**171,795**	**172,498**	**173,205**	**173,915**	**174,629**	**175,346**	**176,066**	**176,791**	**177,519**

* ST: Site Manager; ** PM: Project Manager; *** LA: Lab Analyst.

Table 7. Other plant and goods services (2020–2030), growth rate 2%.

	Price/Year [€]										
Service	**2020**	**2021**	**2022**	**2023**	**2024**	**2025**	**2026**	**2027**	**2028**	**2029**	**2030**
Internet services	1200	1224	1248	1273	1299	1325	1351	1378	1406	1434	1463
Air quality monitoring	2000	2040	2081	2122	2165	2208	2252	2297	2343	2390	2438
Plant insurance	3880	3958	4037	4117	4200	4284	4370	4457	4546	4637	4730
Software license	1800	1836	1873	1910	1948	1987	2027	2068	2109	2151	2194
Rentals	24,000	24,480	24,970	25,469	25,978	26,498	27,028	27,568	28,120	28,682	29,256
Total	**32,880**	**33,538**	**34,208**	**34,893**	**35,590**	**36,302**	**37,028**	**37,769**	**38,524**	**39,295**	**40,081**

As is possible to see from Table 4, the total investment cost for the creation of the SuperLip process is 68.97 K€. As said, it is possible to apply a 10% yearly depreciation amount, resulting in 6.89 K€, which will be considered as a cost in the following profit and loss statement. For the first year, 20% of prudent goods sold has been estimated. Then, a productivity of 300 mL/day has been set, and the selling price was indicated at 1.1 €/mL, lower than the market average selling price of 1.8 €/mL (data obtained from liposome-based online selling platforms). The advantage of this SuperLip is not only the advantages and the stability of its products, but also the competitive price for joining the market. For the generation of the profit and loss statement, the Operating Cash Flow (CFO) was calculated according to the following equation:

$$CFO = S - C - D - T_1 - T_2, \quad (1)$$

where S represents sold goods (that already contains the yearly sold percentage), C represents the sum of all the plant yearly costs (OPEX, Personnel, other goods and services), D represents the plant yearly depreciation, T_1 is the 4% taxes that will be paid independently from the positive or negative yearly profit, and T_2 is the 26% taxes paid on sold products in the case of the positive income for the year. Using this equation, the profit and loss statement is calculated in Table 8.

Considering this Table 8, the sold products increase the revenue from 158 K€ of 2020 to 594 k€ of 2030 due to the increase in the estimated selling percentages of products. This is related to the differentiation of the application fields of liposomes, starting from the fourth year of business. Under this simulation, there will be no positive profit in the first three years, which means that only 4% taxes will be paid. From the fourth year, the positive difference among the sold products and the total

working cost will raise the total taxes to about 30% (see Table 8). The operating cash flow becomes positive by the fourth year.

Data, calculated from 2020 to 2030 under this cost simulation, will be used to determine the cash flow analysis using the following equation:

$$CF = CFO + D - Inv + G, \quad (2)$$

where CF is the final yearly flux of cash, D is again the depreciation (which is re-added since it does not count as cash liquidity), Inv is the total plant investment cost, and G is the eventual grants or loans obtained for this business. In this case, reported in Table 9, Inv is represented by the plant capex expenditures, already calculated in Table 4 as 68.970 K€, that will be detracted only for the first year, when the plant is built. Then, depreciation needs to be added again to CFO, since it is an imaginary flux of cash. No grants or loan are considered in this simulation.

Tables 8 and 9 were then summarized in Figure 4 as bar diagrams, comparing the profit and loss statement with the cash flow.

Table 8. Profit and loss statement (2020–2030).

Profit/Loss Statement	2020	2021	2022	2023	2024	2025	2026	2027	2028	2029	2030
Sold products [%]	20%	25%	30%	50%	60%	62%	67%	70%	70%	75%	75%
Sold products	158,400	198,000	237,600	396,000	475,200	491,040	530,640	554,400	554,400	594,000	594,000
Sum of cost	235,640	237,641	239,671	241,732	243,823	245,945	248,099	250,286	252,505	254,759	257,046
Depreciation (10%)	6897	6897	6897	6897	6897	6897	6897	6897	6897	6897	6897
Fixed tax (4%)	6336	7920	9504	15,840	19,008	19,642	21,226	22,176	22,176	23,760	23,760
Tax on profit (26%)	0	0	0	102,960	123,552	127,670	137,966	144,144	144,144	154,440	154,440
CFO *	−90,473	−54,458	−18,472	28,571	81,920	90,886	116,452	130,897	128,678	154,144	151,857

* CFO: Operating Cash Flow.

Table 9. Cash flow analysis (2020–2030).

Cash Flow	2020	2021	2022	2023	2024	2025	2026	2027	2028	2029	2030
CFO	−90,473	−54,458	−18,472	28,571	81,920	90,886	116,452	130,897	128,678	154,144	151,857
Asset Depreciation	6897	6897	6897	6897	6897	6897	6897	6897	6897	6897	6897
1st-year Investment *	68,970	0	0	0	0	0	0	0	0	0	0
Grant and Loan	0	0	0	0	0	0	0	0	0	0	0
Cash Flow	**−152,546**	**−47,561**	**−11,575**	**35,468**	**88,817**	**97,783**	**123,349**	**137,794**	**135,575**	**161,041**	**158,754**

* Count of assets calculated in Table 4.

The scenario shown in Figure 4 simulates a payback time of 4 years. As it is possible to see, in the year 2020, the investment cost is evident if compared with the profit and loss statement, but it is fast recovered by the following years. In particular, the cash flow begins from about −152 K€ and becomes about 35.47 K€ by the fourth year, becoming 158.75 K€ in 2030.

At this point of the simulation study, it was possible to calculate financial indexes such as the Return on Investment (ROI) and the Return on Sales (ROS). In particular, ROI represents the profitability of the business related to the capital invested for the fabrication of the process, whereas ROS shows the return in terms of plant operating cost and selling products. These two indexes were calculated following these equations:

$$\text{ROI } [\%] = \frac{yierly\ cash\ flow}{Inv}\ 100, \quad (3)$$

$$\text{ROS } [\%] = \frac{yearly\ sold\ products}{yiearly\ cash\ flow}\ 100. \quad (4)$$

The results of the simulation are reported in Table 10 and diagrammed in Figure 5.

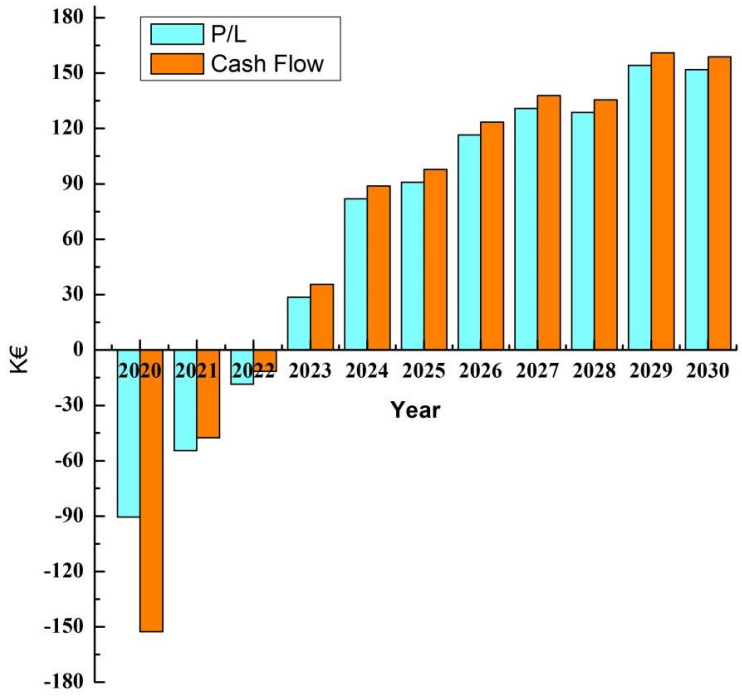

Figure 4. Profit and loss statement bar diagrams.

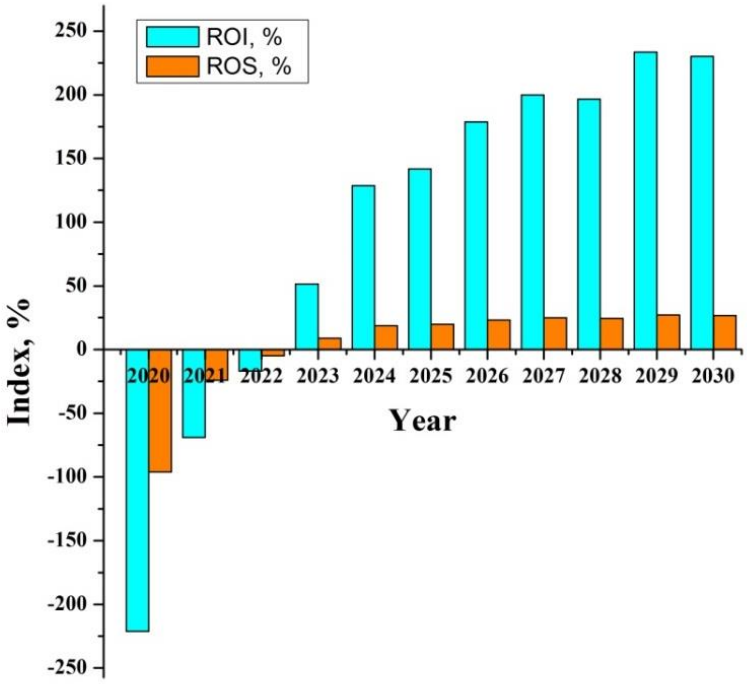

Figure 5. Return on Investment (ROI) and Return on Sales (ROS) indexes bar diagrams.

Table 10. Calculation of the financial indexes (2020–2030).

Index, [%]	2020	2021	2022	2023	2024	2025	2026	2027	2028	2029	2030
ROI	−221.2	−69	−16.8	51.4	128.8	141.8	178.8	199.8	196.6	233.5	230.2
ROS	−93.6	−24	−4.9	9.0	18.7	19.9	23.2	24.9	24.5	27.1	26.7

From the above reported diagram, the return on the investment is more than triplicated by 2030, confirming the payback time at the fourth year of investment.

6. Conclusions and Future Perspectives

SuperLip was demonstrated to be a relatively cheap process, especially for the high potential described. Nutraceutical application will open the business, joining the market with a prudent estimation of 20% selling products. The investment will be paid back by the fourth year, obtaining a yearly positive income of about 158 K€, at the steady-state production selling rate of products. A ROI of about 230% was estimated for this business, confirming the high advantage of the high-pressure process compared to conventional techniques. The market will be easily joined by a decreased selling price of 1.1 €/mL, which is 0.7 €/mL lower than the average market price.

SuperLip was demonstrated to be a profitable process for two main reasons: the quality of the products and the relatively low investment cost of the process. Once a significant market share is obtained, it could be possible to increase the selling price, especially once the application fields have been differentiated for the selling of products. The production rate could be also increased, building more SuperLip plants working in parallel. Additionally, in the future the scale up of the process plant to the industrial level will be considered in order to produce a larger amount of liposomes in a continuous layout.

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Abbreviation

TRL	Technology Readiness Level
CF	Cash Flow
CFO	Operating Cash Flow
ROI	Return on Interest
ROS	Return on Sales
SuperLip	Supercritical assisted Liposome formation
S.W.O.T.	Strength, Weaknesses, Opportunities, Treats
CAPEX	Capital Expenditures
OPEX	Operative Expenditures
PDI	Polydispersity Index
FDA	Food and Drug Administration

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