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# BETTER

Product introductions, M&A transactions and rising share prices all point to one thing:

The market for biosimilars is taking off......

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Dr. Carsten Brockmeyer, CEO

Dr. Nicolas Combé, CFO

# Letter to Shareholders

# Dear shareholders of Formycon &G.

We look back today upon FORMYCON'S most successful fiscal year yet. For the first time ever, we were able to present our annual financial statements showing a clear profit. In doing so, we finished the fiscal year well ahead of our own earlier forecasts. 2014 has convincingly demonstrated, moreover, that the long-term investments we have been making to develop biopharmaceuticals similar to established products on the market – "biosimilars" – is paying off for the long haul.

Our remarkable success already in this early stage of our journey is thanks to several factors. You, our shareholders, made a considerable contribution towards this through the confidence you showed during 2013. With your support, FORMYCON was able to complete three capital increases. With the funds from these capital-raising transactions, we put the foundations in place which have, since then, have made it possible for us to execute our new strategy – and thus to steadily and deliberately drive forward on our company's path of further growth.

Today we can rightly say that FORMYCON is a leading independent player in the science and business of biosimilars development. A milestone which serves as testimony to the strength of our innovation-based business model, and which put us in an auspicious starting position as we began fiscal year 2014, was the signing in December 2013 of a deal

to out-license our first molecule to Santo Holding GmbH, a company owned and managed by Andreas and Thomas Strüngmann. The fact that these two noted German pharmaceutical market experts and founders of Hexal, a leading German generics producer, were prepared to assume the continued clinical development, production and regulatory approval of our first biosimilar drug, internally referred to as "FYB 201", marks a crowning achievement for FORMYCON, drawing considerable attention to our company within the pharmaceutical world.

The out-licensing transaction is also financially lucrative. If everything goes according to play, the deal could bring us several hundred million euros of licensing fees over the coming years. Market launches in the U.S. and European Union are planned starting already in 2020. Above all, however, this partnering deal for our first product has provided us with the resources and flexibility we need to further intensify our own research activities. As an example, FORMYCON has already been able to enter into discussions on the out-licensing of the second and third product candidates in its development pipeline. On the basis of discussions to date with various pharmaceutical corporations and generics producers, we can say with confidence - and without exaggeration – that prospects for successful conclusion

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Letter to Shareholders

This confidence in our ability to continue upon our path of success is based most importantly upon the recognition which our company has been gaining for its scientific expertise in biosimilars, not only from potential licensing partners but also from the relevant regulatory authorities. This is strongly underscored by the final scientific advice letter which FORMYCON received from the European Medicines Agency (EMA) in December 2014, which now enables our first biosimilar to move directly into critically important phase III clinical trials. The start date of these trials has been moved forward to the second half of 2015, which will put us well ahead of plan.

In North America as well, things are moving forward at a brisk pace. In March of 2014, the scientific advisory board of FORMYCON AG was further strengthered with the addition of Dr. Bernhard Hampl, former CEO of Sandoz USA. Since then, the company's protocol for planned clinical trials and other documents have been submitted to the U.S. Food and Drug Administration (FDA) for review. In this way, the study concept benefits from the guidance and feedback of FDA experts.

2013. By the year 2020, global sales for the "third wave" of biosimilar drugs could well rise tenfold, to USD 25 billion.

Our company's vision is to systematically and comprehensively exploit the enormous market opportunities for biosimilar products in the years ahead.

And FORMYCON has all the ingredients in place to do this: We have a clear business concept, the sophisticated equipment, the scientific expertise and

From the early days of our company, the intensive development work which has been done – with remarkable contributions from our own staff, from our scientific advisory board and from many other partners – has been focused on the "third wave" of biosimilars to reach the global market. These biophar-

maceuticals include established products used in the treatment of ophthalmological and autoimmune diseases, metabolic disturbances and blood clotting disorders. A look at the biopharmaceutical market as it stands today illustrates the sheer magnitude of the forthcoming change in paradigm which will fundamentally transform the healthcare market: In 2015, more biopharmaceuticals will lose their patent protection, measured in terms of sales revenue, than traditional drugs produced through chemical synthesis. According to Insight Health, a highly regarded market research firm, the total sales value of these expiring patents, at EUR 1.34 billion, is significantly greater than forecasted even as recently as 2013. By the year 2020, global sales for the "third wave" of biosimilar drugs could well rise tenfold, to USD 25 billion.

Our company's vision is to systematically and comprehensively exploit the enormous market opportunities for biosimilar products in the years ahead. And FORMYCON has all the ingredients in place to do this: We have a clear business concept, the sophisticated equipment, the scientific expertise and the financial resources. Through continued expansion of our product and technology pipeline, we will realize the true company value within FORMYCON. We are most grateful to you, our shareholders, for your continued confidence and support as we move forward on this path.

Martinsried, May 2015

Dr. Carsten Brockmeyer

FORMYCON AG

Dr. Nicolas Combé





Product introductions, M&A transactions and rising stock prices all point to one thing: The market for biosimilars is taking off – a market in which Formycon is ideally positioned because its concept is tailored to the growing hunger of the world's pharmaceutical industry.

# better team

Because Formycon has shown that it has superior scientists, superior management, superior board members and advisors – in short, superiority in the specialized know-how needed to successfully develop biosimilars.



ust a few years ago, the word "biosimilars" was virtually unknown outside of scientific circles. Since then, however, the general and business media has been filled with ever more articles and columns about these new-generation drugs, which imitate existing state-of-the-art biopharmaceuticals already approved and in wide use. In contrast to traditional simple-molecule generic drugs, which are easy to produce and have long been commonplace, biosimilar drugs are based on large and extremely complex molecules, which may consist of more than 20,000 atoms. Perhaps the similarities and differences might be best illustrated through an analogy: Biosimilars are to simple generic drugs what today's smartphones are to basic pocket calculators. While both are portable computing devices with electronic circuitry and a display, no one would ever dream of lumping them together as part of the same product category.

It is becoming ever more clear that a change in paradigm towards biosimilars is sweeping through the world's healthcare industry and pharmaceutical market. In this, FORMYCON is specifically focused on the "third wave" of biosimilars, meaning new drugs that

will start coming to market as the biopharmaceuticals they imitate lose their patent protection starting in the year 2020. These biopharmaceuticals include established products used in the treatment of ophthalmological and autoimmune diseases, metabolic disturbances and blood clotting disorders. Biosimilars will lead to dramatic changes in the way healthcare is provided, a transformation which is already beginning: The European Medicines Agency (EMA) has approved two competing biosimilar variants of infliximab, a monoclonal antibody, which are now available to treat patients. And in the United States, the Food and Drug Administration (FDA) has likewise opened the American market for its first-ever biosimilar, the first such regulatory approval in the U.S. – with others likely to follow soon.

The major pharmaceutical groups have long since recognized the potential impact of biosimilars. Pfizer, one of the biggest, recently announced its acquisition of Hospira, a U.S. company specializing in biosimilars. Through this shrewd chess move, Pfizer has ensured its access to, and market share in, a highgrowth market. The acquisition, moreover, will help to offset revenue declines in patent biopharmaceuticals expected to begin in 2020.

# s with other areas of biotechnology, the up-and-coming market for biosimilars is being reflected in the capital markets with a long-term upward trend in stock prices. Over the past year, German biotech stocks far outpaced the overall market, with the DAX biotechnology subsector posted a full-year 2014 rise of 23.8% compared to a gain of only 4.3% in the DAX German market index as a whole. On the other side of the Atlantic, the technology-heavy NASDAQ Composite index rose by 18.9%,

while the Biotechnology Index soared by 33.9%.

As the "third wave" of biosimilars approaches, FORMYCON is ideally positioned. Every aspect of its business model is focused on it and designed around it, from its market analysis and protein analytics, to its production development and clinical development, all the way through to its activities and resources for regulatory approval and patent protection. There are currently three products in FORMYCON R&D pipeline, partly in advanced stages of development. In December 2013, a deal was signed with Santo Holding for the out-licensing of the first of these FORMYCON-developed biosimilars. In addition to initial amounts already received under the agreement, this transaction will provide a steady stream of future licensing income which the company will be able to use to further intensify its R&D activities.

Through its out-licensing strategy, FORMYCON is helping to meet a fundamental need within the global pharmaceutical industry. Even the biggest of the pharma majors are now looking to license in the future products they need and can thus benefit from a partnership with a biosimilars developer such as FORMYCON. There are some particular reasons why even the giants of the industry are finding themselves unable to achieve this objective through inhouse R&D: The development process requires an enormous investment in cost and time, and it requires highly specialized expertise. On average, the development of a new biosimilar drug through to market launch costs EUR 100 million and takes seven to eight years.

By the year 2020, some 80% of the most important original biopharmaceuticals on the market today will lose their patent protection, with a combined annual sales value of USD 100 billion. Competing biosimilar drugs, which will then come to the market at a significantly lower price, will change the rules of the game. To put the size of this opportunity into perspective: Seven of the world's top-selling drugs today are biopharmaceuticals, including Humira, Enbrel and Remicade for rheumatoid arthritis, Lantus for diabetes, and Rituxan, Herceptin and Avastin for treating cancer.

# better technology

Because Formycon already has, in its own laboratories, the highly specialized equipment for protein analysis needed to rapidly and successfully decode the structure of the target biopharmaceutical.

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# better performance

Because Formycon's expertise has, in a short period of time, already produced lucrative licensing deals, ensuring its financial stability along with the strong performance its shareholders expect.



hese top-selling drugs are very expensive because they are still under patent protection. Once biosimilars can be brought to market, these new and competing drugs will cost roughly 20 to 30% less, thus making these leading-edge biotech treatments available to more patients.

The Institute for Healthcare and Social Research (IGES) in Berlin has estimated the annual savings potential of biosimilars at EUR 12 billion by the year 2020 – and that's just for the German statutory health insurers. For all of Europe, the figure is EUR 33 billion. As they become more affordable, it's quite possible that biosimilar drugs could make huge inroads into emerging market countries such as China, India, Brazil and Russia. To a far greater degree than in the wealthy industrialized countries, original biopharmaceuticals have until now been simply out of reach for most patients in these

developing economies. The growing demand for lower-cost drugs to treat serious diseases thus has a human dimension of global proportions. Not to mention an economic dimension: By the year 2020, global sales revenues from biosimilar drugs of the "third wave" could well grow the market size tenfold, to USD 25 billion.

Through its commitment to long-term investment and its many years of intensive R&D work,

FORMYCON has ideally positioned itself to participate in these major global changes – as one of the world's leading players and innovators in the "third wave" of biosimilars.





Dr. Olaf Stiller, Chairman of the Supervisory Board

# Report of the Supervisory Board

During the fiscal year, the Supervisory Board received regular written and oral reports on the company's business and financial performance. These reports also addressed strategic issues and important developments. The Supervisory Board maintained ongoing oversight over the company's management. In the course of four board meetings, all business transactions and pending decisions requiring concurrence of the Supervisory Board under governing law or under the company's articles of association were discussed in depth. All members of the Supervisory Board were in attendance at these meetings.

The meetings of the Supervisory Board focused primarily on ensuring that the company's financial resources are secure and on the current and future development of its areas of business, in particular with regard to the state of its technology and its progress toward commencing preclinical studies and clinical trials, as well as related questions regarding key staff. At each of these quarterly meetings, the Executive Board and Supervisory Board together reviewed the company's financial performance and plan. In conjunction with the approval of the annual financial statements, discussions specifically focused on key details of valuations and the resulting consequences for the company's capital structure.

In addition, the Chairman of the Supervisory Board remained in continual contact with the Executive Board. These communications addressed issues of company strategy, business performance, patent protection, and important company developments. The Supervisory Board, moreover, discussed and debated important strategic projects with the Executive Board. The discussions centered around ways to ensure the company's competitiveness and strategic concepts for its future growth.

The annual financial statements and consolidated financial statements as of December 31, 2014, for fiscal year 2014 were prepared under the supervision of Dr. Heinfried Brunsmann, a German chartered account and tax advisor, who also examined the company's accounting systems. The Supervisory Board also completed its own careful review of the annual financial statements. The documents to be reviewed were distributed to all members of the Supervisory Board within the prescribed time to allow proper examination.

The Supervisory Board asserted its right to inspect the accounts and papers of the company, in particular by requesting presentation of certain legal agreements it deemed important, including documents not specifically required its concurrence. All transactions requiring concurrence of the Supervisory Board under governing law or under the company's articles of incorporation were examined by the Supervisory Board before reaching its decision on such concurrence.

All members of the Supervisory Board were present at all meetings of the Board. The Supervisory Board did not form any committees. The annual financial statements as proposed by the Executive Board were approved by the Supervisory Board at its meeting of April 13, 2015 and have been adopted accordingly.

The Supervisory Board would like to thank the Executive Board along with the entire staff of FORMYCON for their dedication and commitment and their considerable efforts in the course of 2014.

Munich, April 2015

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**Dr. Olaf Stiller**Chairman of the Supervisory Board

# Profit and Loss Account for the Fiscal Year 2014

Appendix 2

	2014		2013	
	€	€	K€	K€
1. Revenue		10,529,856.35		276
2. Other operating income		85,226.34		95
3. Cost of materials				
a) Cost of raw materials and supplies	827,539.65		239	
b) Cost of purchased services	3,037,150.23	3,864,689.88	1,252	1,491
4. Personal expenses				
a) Wages and salaries	2,521,934.66		2,546	
b) Social costs thereof retirement benefits: 28,114.44 EUR (30,3 K€)	372,312.77	2,894,247.43	362	2,908
5. Depreciation and amortization				
a) of fixed assets		1,071,931.20		1,103
6. Other operating expenses		1,905,182.24		2,640
7. Other interest and similar income		165.54		7
8. Interest expense and similar expenses		7,583.12		2
10. Other taxes		1,674.00		1
11. Annual net profit / loss		869,940.36		-7,767

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# Balance Sheet as of December 31, 2014

Assets	2014	2013
	€	K€
A. Fixed Assets		
I. Intangible Assets		
<ol> <li>Purchased concessions, industrial property, rights and assets as well as licenses for such rights and assets</li> </ol>	120,070.75	178
2. Goodwill	1,221,555.00	1,379
II. Property, plant and equipment		
1. Land, titles to land and buildings	240,094.58	291
2. Plants, technical equipment and machinery	2,448,761.46	2,696
III. Financial Assets		
1. Shares in affiliated companies	50,000.00	25
2. Loans to affiliated companies	1,667,965.88	1,668
B. Current Assets		
I. Inventory		
1. Raw materials, consumables and supplies	345,561.84	274
II. Receivables and other assets		
1. Trade accounts receivable	303.36	0
2. Receivables from affiliated companies	2,390,087.50	0
3. Other assets	27,076.44	222
III. Securities		
1. Other securities	8,934,969.39	9,500
IV. Cash on hand, bank, deposits	261,073.69	881
C. Accrued Income	26,913.87	6
	17,734,433.76	17,120

Liabilities	2014	2013
	€	K€
A. Equity		
I. Subscribed capital	8,626,683.00	8,627
II. Capital reserve	18,247,524.34	18,247
III. Loss carry-forward	-12,946,286.43	-5,179
IV. Annual net profit / loss	869,940.36	-7,767
	14,797,861.27	13,928
B. Provisions		
1. Other provisions	519,000.00	494
C. Liabilities		
1. Trade accounts payable	1,423,251.15	2,493
thereof with a maturity of up to one year: 1,423,251.15 EUR (1,293 K€)		
2. Other liabilities	994,321.34	205
thereof with a maturity of up to one year: 994,321.34 EUR (205 K€)		
thereof taxes: 429,220.32 EUR (55 K€)		
	17,734,433.76	17,120

# Fixed Assets Schedule

	Historical Acquisition/ Production Costs	Acquisitions
	€	€
A. Fixed Assets		
I. Intangible Assets		
<ol> <li>Purchased concessions, industrial property, rights and assets aswell as licenses for such rights and assets</li> </ol>	261,614.42	1,166.20
2. Goodwill	1,576,200.00	0.00
	1,837,814.42	1,166.20
II. Property, plant and equipment		
1. Lands, titles to land and buildings	353,823.64	0.00
2. Other equipment, factory and office equipment	3,887,111.30	569,665.59
	4,240,934.94	569,665.59
III. Financial Assets		
1. Shares in affiliated companies	25,000.00	25,000.00
2. Loans to affiliated companies	1,667,965.88	0.00
	1,692,965.88	25,000.00
	7,771,715.24	595,831.79

# Appendix 3

Disposals at Historical Cost	Accumulated Depreciation	Depreciation	Book Value as of 31.12.2014	Book Value as of 31.12.2013
€	€	€	€	K€
0.00	142,709.87	58,413.98	120,070.75	178
0.00	354,645.00	157,620.00	1,221,555.00	1,379
0.00	497,354.87	216,033.98	1,341,625.75	1,557
0.00	113,729.06	50,546.28	240,094.58	291
102,899.65	1,905,115.78	805,350.94	2,448,761.46	2,696
102,899.65	2,018,844.84	855,897.22	2,688,856.04	2,987
0.00	0.00	0.00	50,000.00	25
0.00	0.00	0.00	1,667,965.88	1,668
0.00	0.00	0.00	1,717,965.88	1,693
102,899.65	2,516,199.71	1,071,931.20	5,748,447.67	6,237

# Notes to the Financial Statements for the Fiscal Year 2014

Appendix 4

## I. General Information

The financial statements have been prepared in accordance with §§ 242, §§ 264 et seq. of the German Commercial Code (HGB), the relevant regulations of the German Stock Corporation Act (AktG) and the Articles of Association of the Company.

The regulations of HGB for small companies according to § 267 HGB have been applied.

The profit and loss account was drawn up in accordance with the "type of expenditure"-method

# II. Accounting Policies

# 1. General

The accounting and valuation methods used in the previous year's financial statements have been maintained.

The valuation of assets and liabilities takes into account all ascertainable risks in accordance with the principles of conservative commercial assessment.

# 2. Currency Translation

Assets and liabilities in foreign currency are translated at the average spot exchange rate at the date of the transaction. If the rate on the balance sheet date is lower for accounts receivable or higher for liabilities, the valuation is performed at the exchange rate on the balance sheet date. Income and expenses from currency translation are shown in the profit and loss account under other operating income/expenses.

## 3. Deferred Taxes

Deferred taxes assets and liabilities are netted and recorded for temporary differences between valuation of assets and liabilities according to tax regulations and HGB. A resulting asset surplus after netting the deferred taxes is not capitalized. An average tax rate of 30% was applied for calculating the deferred taxes.

# 4. Manufacturing Costs

Manufacturing costs encompass all individual costs, appropriate portions of the material and production overhead as well as production-related depreciation. General administrative costs, social expenses and expenses for voluntary social benefits provided by the company are also included in the manufacturing costs. Costs of debt are not included in the manufacturing costs.

# 5. Derivative Financial Instruments

Derivative financial instruments are measured on the basis of current market prices in line with the imparity and realisation principle.

# 6. Fixed Assets

Purchased intangible assets, with the exception of low-value software, are recognised at acquisition cost and are amortised systematically over their estimated useful lives by utilizing the straight-line method. Purchased low-value software is amortized in full in the year of acquisition. The option to capitalize self-created intangible assets according to § 248 Abs. 2 HGB is not being used.

Statement

Notes to the Financial

- b) Property, plant and equipment are stated at ac- e) quisition or manufacturing cost less systematic depreciation. Depreciation is computed on a time-apportioned basis. Property, plant and f) equipment are depreciated systematically over their estimated useful lives (straight-line method). Low value assets (individually below EUR 410) are written off in full in the year of purchase.
- Long-term financial assets are valued at acquisition cost and in the case of expected permanent impairment with the lower value of cost or **8. Provisions** market value.

# 7. Current Assets

- Raw materials, auxiliary materials, consumables and merchandise shown under the inventory are valued at the average acquisition costs. In case of an impairment, the inventory is valued with the lower of cost or market value.
  - Unfinished products are value at manufacturing costs.
- Receivables and other assets are stated at their nominal value. Unless interest-bearing, in case of a maturity of more than one year, receivables and other assets are discounted. All identifiable risks have been taken into account. For the general credit risk additional global value adjustments have been made.
- Securities in the investment portfolio are stated at acquisition cost, provided that they are not permanently depreciated.
- Cash and cash equivalents are recorded at their nominal value.

- Prepaid expenses and deferred income are carried in accordance with § 250 HGB.
- Assets, that may only be used for the purpose of meeting pension obligations and are protected from other creditors are netted with the pension obligations. The covering assets are stated at their fair value. Income and expenses for discounting of the pension obligations are netted with the income and expenses resulting from the covering assets.

- Provisions for pensions are calculated actuarially on the basis of § 253 Abs. 1 and 2 HGB. The discounting of the provisions for pensions occurred at the average market interest rate for the past seven years with an assumed remaining maturity of 15 years, as determined and published by the German Bundesbank.
- Other provisions are calculated in accordance with reasonable business judgment and reflect the amounts considered necessary to cover future payment obligations. Price and cost increases are taken into account. Other provisions with a remaining term of more than one year were discounted on the basis of the matching average market interest rates for the past seven years, as determinded and published by the German Bundesbank.
- Tax provisions are calculated in accordance with reasonable business judgment and reflect the amounts considered necessary to cover future payment obligations.

# 9. Liabilities

Liabilities are included in the balance sheet at their repayment value.

## III. Balance Sheet Information

The development of the individual fixed asset items is shown in the fixed asset movement schedule in appendix 1 to the notes.

Company name, place of business and the amount 3. Contingent Liabilities of shares are shown in appendix 2 to the notes.

# IV. Other Information

# 1. Information on Organs of the Company

Notes to Members of the Executive Management, § 285 Nr. 10 HGB:

- Dr. Carsten Brockmeyer, Marzling (Chairmen)
- Dr. Nicolas Combé, Marburg (Chairmen)

In accordance with § 286 Abs. 4 HGB the information on the remuneration of the executive management as per § 285 Nr. 9a HGB will not be disclosed.

Nr. 10:

- Dr. Olaf Stiller, Weimar (Chairman)
- Hermann Vogt, Dieburg (Deputy Chairman)
- Peter Wendeln, Oldenburg

The remuneration of the members of the supervisory board for the fiscal year as per § 285 Nr. 9a HGB amounts to 22,500 €.

# 2. Employees

In accordance with § 285 Nr. 7 HGB, the following table includes all information on the average number of employees during the fiscal year:

Industrial Employees	35
Commercial Employees	4
Executive Staff	0
Gesamt	39

As of the balance sheet date, the following contingent liabilities exist:

С	ontingent leasing liabilities	164,593.56

A utilization is not expected.

# V. Notes to § 160 AktG

The subscribed capital of the company amounts to 8,626,683.00 € and is divided into 8,626,683 bearer shares.

As per resolution of the general shareholder's meeting, the executive management is authorised un-Notes to Members of the Supervisory Board, § 285 til 02.10.2018 – after approval of the supervisory board – to increase the capital of the company by up to 2,427,801.00€ against cash contributions or contributions in kind through issuance of up to 2,427,801.00 bearer shares.

> The subscribed capital of the company is conditionally increased by up to 423,912.00€ by issuing up to 423,912 bearer shares (conditional capital 2010). The conditional capital increase serves the purpose of securing subscription rights arising from share options, which have been issued in accordance with the

Annex 2 to Appendix

resolution of the general shareholder's meeting on options, which are being issued until June 29th, 2019, October 22nd 2010. The conditional capital increase are used. will only be carried out to the extent to which the share options are used.

The subscribed capital of the company is condition- thorised capital. ally increased by up to 3,450,673€ by issuing up to 3,450,673 bearer shares (conditional capital 2014). In total, 191,000 subscription rights have been issued accordance with the resolution of the general share- to executive management and employees as part of holder's meeting, the conditional capital increase will only be carried out to the extent to which the share

The supervisory board is authorised to modify the Articles of Association according to the exercise of the au-

the conditional captial (§ 192 Abs. 2 Nr. 3 AktG).

# Ownership of Shares and Companies Included in Consolidation

	Amount of Shares	Equity	Annual Net Profit
		€	€
FORMYCON Services GmbH	100%	25,000.00	-4,317.66
FORMYCON Project 201 GmbH	100%	25,000.00	-5,298.31

# Fixed Assets Schedule

Annex 1 to Appendix

	Historical Acquisition/ Production Costs €	Acquisitions €
I. Intangible Assets		
<ol> <li>Purchased concessions, industrial property, rights and assets aswell as licenses for such rights and assets</li> </ol>	261,614.42	1,166.20
2. Goodwill	1,576,200.00	0.00
II. Property, plant and equipment		
1. Lands, titles to land and buildings	353,823.64	0.00
2. Other equipment, factory and office equipment	3,887,111.30	569,665.59
III. Financial Assets		
1. Shares in affiliated companies	25,000.00	25,000.00
2. Loans to affiliated companies	1,667,965.88	0.00
	7,771,715.24	595,831.79

Annex 1 to Appendix

Disposals at Historical Cost €		Depreciation €	Book Value as of 31.12.2014 €	Book Value as of 31.12.2013 K€
0.00	142,709.87	58,413.98	120,070.75	178
0.00	354,645.00	157,620.00	1,221,555.00	1,379
0.00	113,729.06	50,546.28	240,094.58	291
102,899.65	1,905,115.78	805,350.94	2,448,761.46	2,696
0.00	0.00	0.00	50,000.00	25
0.00	0.00	0.00	1,667,965.88	1,668
102,899.65	2,516,199.71	1,071,931.20	5,748,447.67	6,237

Planegg, April 4, 2015

FORMYCON AG

Dr. Carsten Brockmeyer

Dr. Nicoals Combé

Appendix 5

# Basics of the Group

# Business Model

The business model of the FORMYCON group is done by the FORMYCON AG, which are also develbased on the development of biopharmaceutical imitation products (so-called biosimilars). The target market of the product development is the subsequent out-licensing. The product development is partially financed by new license partners.

The group's structure follows this business model. The actual research and development activities are

oped for the product-specific, outsourced subsidiaries. In addition, the subsidiary FORMYCON Services GmbH offers specialized services on a fee-for-service basis to pharma- and biotech companies.

In the past year, the following group structure has been defined:

FORMYCON AG (R&D)

# FORMYCON Project 201 GmbH

(Outlicensing Partnership-company) FORMYCON Services GmbH

The FORMYCON Project 201 GmbH is the first outsourced company in this financial year. More partnerships are planned in subsequent years. Besides its site in Planegg, FORMYCON does not hare any other facilites. FORMYCON AG holds 100% of the shares in the subsidiaries.

FORMYCON AG is limited to research and development activities. Other business processes are insignificant and relate to support services.

health-related regulations can be mentioned as an important external influence factor.

Compared to the previous year, the FORMYCON Project 201 GmbH had been newly founded.

Project activities and Intellectual Property of the first outsourced biosimilar were incorporated into this

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# 1. Research and Development

During the past year, the activities of the group were limited to research & development activities. In this context, the departments took the following cost blocks:

	K€
External services	5,081
Raw materials, etc.	827
Staff	2,894
Depreciation	1,072
Others	1,927
	11,801

37 employees worked in research and development. The expenditures in the amount of 11,801 K€ were charged as expenses, comprising about 94,4% of net sales. Research & development expenses were not capitalized. Patents and licenses were not notified. Product developments are proceeding as planned, with the result that the market entry can be expected as scheduled. There were no significant changes in the R&D department.

# II. Business and Environment

# 1. Framework

The gross domestic product (GDP) of the world economy grew by 3.3 % last year. There are middle-term risks in the stagnation and a low growth in mature economies as well as decreasing growth potentials of emerging markets. The international monetary fund lowered its growth forecast, due to weaker prospects in China, Russia, Japan and in the Euro zone, even though there are pluses due to lower price of oil.

In 2015, we expect a growth of the economic output of 3.5%, in 2016 of 3.7%. Positive factors are the de-

creasing costs of companies and an increasing consumer purchasing power, with corresponding negative influences because of a investment recession in developed countries and emerging markets. Therefore, the US economy has achieved an average growth of 3.6%, in Germany it's 1.6%.

Despite moderate economic development, the German stock market has been very successful in 2014. The German stock index "DAX" established new records within the year 2014 and grew by 4.3% by the end of the year. The DAX-subsector "Biotechnology" grew much better than the DAX by 23.8% by the end of the year 2014. There is a similar picture in the USA, where the NASDAQ reached a growth of 18.9%. In the US, the NASDAQ Biotechnology Index has outperformed the strong performance of the previous years, with exceptional growth of 33.9% in 2014. To that effect US markets noticed a clear increase of share capital and capital bonds, as well as IPOs.

According to the latest industry report by IMS Health, spending on drugs will, for the first time, exceed the threshold of 1 trillion US-dollars (USD) in 2014 and rise to 1.3 trillion USD by 2018.

The increased demand is attributable to an increase in chronic illnesses and the ageing population in developed countries. The growth of the population and the improved access to medical care in emerging economies will increase the costs for companies. In contrast, the so-called "Phamerging Markets" are looking at growth-rates of 8–11%, of which is China is a 46% component.

Many large European markets continue their cost-saving measures to reduce their expenditures. In Germany, the costs of medication and diagnostic tests increased about 9.6% to 30.8 Billions €, partly due to a statistical effect. So the cost savings pro-

gram of German compulsory health insurance will go on. Due to increased mandatory discounts, voluntary manufacturer discounts, patent expirations and an increased competition on the market, pharmaceutical expenditures in Germany could be significantly reduced in recent years.

Through modern bio-pharmaceutically manufactured drugs, new and successful milestones concerning the treatment of severe diseases such as multiple sclerosis, cancer and rheumatism have been reached. Due to their high treatment costs, those bio-pharmaceutical drugs stand to be the number one cost-driver of statutory health insurance (SHI). The impending patent expirations of modern bio-pharmaceuticals, however, opens a window for generic biopharmaceutical products, the so-called biosimilars. Biosimilars have the potential to reduce the expenditures for medicines significantly. In contrast to classical generic medicines, biosimilars can only be produced with high effort and a large expert-knowledge.

The patent expirations have been going down within the last years. However, the association of Progenerika e.V. expects in 2015 a change of paradigm. The analyses of the market research firm INSIGHT HEALTH shows an expected patent expiration volume of 1.34 Billions € is much higher than forecasted in 2013.. In addition, for the first time there are to be more patent free bio-pharmaceutical drugs on the market than there are chemically synthesized ones. The world wide sales of pharmaceutical products is able to increase tenfold until 2020.

# 2. Business Development in 2014

The business model of FORMYCON AG is based on the development of biopharmaceutical imitation

products (so-called biosimilars) and has been consequently and consistently renewed in 2014, which has been a very successful year. According to the expectations of 2013, FORMYCON AG, as well as the company group, could report a net profit for the year. So the FORMYCON AG was able to carry out one of these projects well ahead of schedule in December 2013 to the Santo Holding GmbH.

On behalf of Santo Holding GmbH – owned by the Strüngmann family, who are the founders and former owners of HEXAL – FORMYCON AG now continues to bring this first development project on the market. In case of a successful development and a following successful introduction to the market, FORMYCON AG can expect contractual payments in the mid three-digit million range for the coming years.

Even in terms of personnel, the foundations for a successful future have been laid. In April 2013, Dr. Carsten Brockmeyer, one of the world's leading experts on biosimilars, joined FORMYCON AG and acts as chief executive officer (CEO). In November 2013, FORMYCON AG also appointed Dr. Gerhard Schaefer, formerly Head of Global Product and Business Development at Sandoz International, to the advisory board. In March 2014, the advisory board was completed with the additions of Dr. Bernhard Hamp, formerly CEO of Sandoz US.

Due to the previously mentioned contract and the stable investor-structure, FORMYCON AG is one of the few independent companies in the growing biosimilar market. The unique expertise of FORMYCON AG's scientists and management and the integrated development processes makes FORMYCON a preferred partner for large pharmaceutical companies.

## 3. Results

FORMYCON AG has continued the development of three biosimilar projects in 2014 and could profit by the out-licensing of the first biosimilar.

# **Results of Operations**

As a result of the first out-licensing, the group generated important product revenues. Net sales were 10,530 K€, while the previous year's sales were 276 K€. The cost of materials rose by 3,865 K€ and gross profits were 6,665 K€.

Because of the market entry, the group achieved an annual net profit of 870 K€. In contrast to the previous year, other operating expenses were relatively constant hence, they are covered by the gross profit.

FORMYCON AG is anticipating increasing coverage rates due to further out-licenses.

# b) Financial Position

The financial situation of the group is very solid and stable. Indicators for liquidity show above-average values. The current assets amounted to 11,958 K€, in to 2,417 K€.

Short-term or long-term loan financing through banks was not needed.

Cash equivalents amounted to 261 K€ on the balance sheet date, the cash-equivalent securities amounted to 8,935 K€. Please see the notes to the financial statements for information regarding the cash flow statement.

to 877 K€ and the EBITDA amounted to 1,949 K€.

# c) Net Assets

The company's equity increased during the reporting period from 81.4% to 83.4%, what is far above average. The fixed assets have been reduced due to depreciation. They are completely covered by equity which implies a very positive structure of the bal-

The current assets consist almost completely of cash and cash-equivalents, which leads to the conclusion that the current assets are virtually risk-free.

# 4. Financial and Non-Financial Performance Indicators

phase, which means that the informative value financial indicators is limited. Relevant performance indicators for our group are those which measure the sustainable financial power of the company.

The working-capital, measured as the difference between short-term assets and short-term liabilities, amounts to 9,022 K€ as of the reporting date.

comparism to this the short-term liabilities amounted 
The cash-flow (annual net profit + depreciation and changes in long-term provisions) amounted to 1,942 € and was positive for the first time. The investment activities, which were below depreciation, came to 584 K€, which lead positive to cash inflows.

> The return on equity was 6,25%, while the return on total investment was 4,94%.

> Non-financial indicators can be found in the research and development report.

Return on sales reached a level of 8.3%, the EBIT came FORMYCON AG develops solutions for each customer, which see themselves as partners. A relatively small existing customer base implies a low conflict potential. We stand out for a high level of customer satisfaction

FORMYCON AG mainly hires employees from the research and development field. The low staff turnover is due to a high employee satisfaction.

# III. Supplementary Report

Significant events that occurred after the end of the financial year were not recorded. Increased risks for the current financial year 2015 are unintelligible.

## IV. Forcast

On the basis of their overall expertise, FORMYCON AG intensified their research activities in 2014. The start of the pivotal registration trial (Phase III) for the first biosimilar product (FYB201) is planned at the end of the year. The immediate licensing of Phase III through the EMA in London as part of a scientific advice in December 2014 equates to an acceleration of the original plan by one year. The strategy needs to be certified by the American Food and Drug Administration (FDA). The development of both biosimilars in the FORMYCON-pipeline, that also aims to imitiate a biopharmaceutical agent from the third wave, runs according to schedule. Here, FORMYCON AG is currently in discussions with different generic pharmaceutical companies. A partnership of these development projects is planed after the finish of the first clinical test in 2016 and 2017.

Following the successful capitalization of the company and the partnership of the first Biosimilar with Santo Holding concluded in 2013, these achievements are still an important milestone for the company. The marketing start of FYB201 in the USA and EU is planed in 2020.

Our subsidiary "FORMYCON Services GmbH" will continue to offer development services for pharmaceutical and biotechnology companies. We anticipate this business model will operate profitably.

Because of a good asset structure and financial situation of the group, it's possible to exploit acquisition opportunities.

For the 2015 fiscal year, the group expects a moderate sales increase, with the start of additional outlicenses of 13,000 K€ and a result of 900 K€.

The outlook for the FORMYCON group for the coming years continues to be positive due to expected moderate, economic growth. For the year 2016, though, we anticipate rising revenues of 3-4% and an improvement of our result.

Concerning the financial situation and the service portfolio, the group is already well positioned in the

As the number of employees increases, we expect a slight increase in our cost structure. This implies consistent business results.

Furthermore, we expect no movements in the exchange rates and risks of inflation as well as other special influences.

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# V. Opportunities and Risk Report

# 1. Risks

# **Industry-Specific Risks**

If the worldwide turbulences on the financial and raw materials markets increase and the economy slows down, they could have a negative impact on the group's economic situation and the demand for our products, as the national and international health-care industry is affected. This may expose the corresponding sales and results risks.

# Profit-Oriented Risks:

Actually, we do not see a direct earnings risk. There is a long-term risk that research and development activities will not be successful and hence, find no acceptance in the relevant market. Throwbacks concerning product developments can never be totally excluded.

# Financial Risks:

There are currently no liquidity risks due to the good In the main risks of future development lie in the unliquidity and equity situation of the group.

The main risks of future development lie in the unliquidity and equity situation of the group.

The liquidity situation is currently excellent.

# 2. Opportunities

FORMYCON AG's Management Board is responsible for systematic identification and exploitation of economic opportunities.

Looking forward to the future, the development of the healthcare industry is seen as positive. There are various reasons for this:

 Medical and technical progress: The progress has made possible the treatment of medical pictures, which just 10 or 20 years ago could not be treated.

- Demographic growth: The German population is aging steadily. There are also more mulitmorbid people.
- By the development of biosimilars, the group is positioning itself at an early stage in one of the most promising healthcare markets of the future. FORMYCON has the aim of exploiting growth opportunities in relevant markets.

This applies especially to the increasing opportunities now arising for organic growth in further outlicensing.

We're entering the contest with our competitors by offering experience, innovative products, reliability as well as a high degree of quality and customer satisfaction

# 3. Summary Statement

The main risks of future development lie in the unstable environment of the world economy. Against the background of our financial stability, we are well equipped to deal with future risks. The group currently faces no risks which may endanger the continued existence of the company.

There has been no change to the company's exposure to several risk areas or the manner in which it manages and measures risk. The overall picture shows no underlying change to the risk situation compared to the previous year. By using internal control mechanisms, we are in a position to identify and handle changes about the risk situation at an early stage.

# VI. Risk Reporting, Related to the Use of Financial Instruments

FORMYCON AG's existing financial instruments mainly include receivables, liabilities and bank balances.

Liabilities are settled within the stipulated period. Potential currency risks, which could have a negative effect on our asset situation, financial position and profitability, will be compensated by avoidance of foreign currency items in our balance sheet.

The biggest currency item of the group arises from purchases of external services in CHF, which were paid promptly in order to minimize currency risks.

The risk management policies of FORMYCON are aimed at hedging profits against financial risks of all kinds

Concerning the management of financial items, the group has followed a conservative risk policy.

As soon as nonpayment risks are identifiable with regard to financial assets, the risks are recorder using value adjustments.

There are no perceived risks perceivable that would endanger the group as a going concern.

# VII. Branches

There are no existing branches.

1/1/1/25

Planegg, April 4, 2015

FORMYCON AG

Dr. Carsten Brockmeyer

Dr. Nicoals Combé

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# **Audit Opinion**

Appendix 6

We have audited the annual financial statements pre- the annual financial statements. We believe that our pared by FORMYCON AG, Planegg comprising the balance sheet, the profit and loss accounts for the business year from January 1, 2014 to December 31, 2014, Our audit has not led to any reservations. the notes to financial statements, together with the bookkeeping system. The maintenance of the books In our opinion, based on the findings of our audit, the and records and preparation of the annual financial statements in accordance with the requirements of German commercial law and the Company's statutes ("German Commercial Code HGB") are the responsibility of the Company's Board of Managing Directors. Our responsibility is to express an opinion on the annual financial statements, together with the bookkeeping system based on our audit.

We conducted our audit of the annual financial statements in accordance with § 317 HGB (German Commercial Code) and German generally accepted standards for the audit of financial statements promulgated by the Institut der Wirtschaftsprüfer. Those standards require that we plan and perform the audit in a way, that misstatements materially affecting the presentation of the net assets, financial position and results of operations in the annual financial statements in accordance with principles of proper accounting are de- Dr. Brunsmann tected with reasonable assurance. Knowledge of the business activities and the economic and legal environment of the Company and expectations as to possible misstatements are taken into account in the determination of audit procedures. The effectiveness of the accounting-related internal control system and the evidence supporting the disclosures in the books and records, the annual financial statements are examined primarily on a test basis within the framework of the audit. The audit includes assessing the accounting principles used and significant estimates made by the Company's Board of Managing Directors, as well as evaluating the overall presentation of

audit provides a reasonable basis for our opinion.

annual financial statements comply with German commercial law and the additional rules of the company's statutes and give a true and fair view of the net assets, financial position and results of operations of the Company in accordance with (German) principles of proper accounting.



Düsseldorf, April 4, 2015



# Consolidated Profit and Loss Account for the Fiscal Year 2014

Appendix 2

			2014	2013
		€	€	€
	1. Revenue		12,585,017.94	276,173.13
:	2. Other operating income		86,117.11	136,522.80
:	3. Cost of materials			
	a) Cost of raw materials and supplies	-827,539.65		-239,378.28
	b) Cost for purchased services	-5,081,154.84	-5,908,694.49	-1,251,659.20
	Gross profit or loss		6,762,440.56	-1,078,341.55
4	Personal expenses			
	a) Wages and salaries	-2,521,934.66		-2,545,791.69
	b) Social costs	-372,312.77	-2,894,247.43	-362,880.11
į	<ol> <li>Depreciation and amortization of fixed intangible and tangible assets</li> </ol>		-1,071,931.20	-1,103,126.30
(	6. Other operating expenses		-1,926,924.96	-2,654,250.97
	Operating income or loss		869,336.97	-7,744,390.62
	7. Other interest and similar income		165.54	7,396.77
8	Interest expense and similar expenses		-7,583.12	-2,040.87
	Financial results		-7,417.58	5,355.90
9	9. Profit before tax		861,919.39	-7,739,034.72
•	10. Other taxes		-1,595.00	-1,614.00
	11. Annual net profit/loss		860,324.39	-7,740,648.72

# Consolidated Annual Statement Formycon Group

FORMYCON Annual Report 2014

Appendix 1

# Consolidated Balance Sheet as of December 31, 2014

Assets		2014	2013
	€	€	€
A. Long-term capital			
I. Intangible assets			
<ol> <li>Purchased concessions, industrial property rights and assets as well as licences for such rights and assets</li> </ol>	120,070.75		177,318.53
2. Goodwill	1,221,555.00	1,341,625.75	1,379,175.00
II. Property, plant and equipment			
1. Tenant installations	240,094.58		290,640.86
2. Other equipment, factory and office equipment	2,448,761.46	2,688,856.04	2,696,209.53
B. Short-term capital			
I. Inventories			
1. Raw materials, consumables and supplies		345,561.84	273,442.75
II. Receivables and other assets			
1. Trade receivables	3,252,360.28		380.80
2. Other assets	27,076.44	3,279,436.72	222,035.70
III. Securities			
1. Other securities		8,934,969.39	9,500,000.00
IV. Cash and cash equivalents		288,898.53	899,311.60
C. Deferred expenses			
Other deferred expenses		26,913.87	6,399.47
		16,906,262.14	15,444,914.24

Liabilities		2014	2013
	€	€	€
A. Equity			
I. Subscribed capital	8,626,683.00		8,626,683.00
II. Capital reserve	18,247,524.34		18,247,524.34
III. Loss carry-forward	-14,623,462.57		-6,882,813.85
IV. Annual net profit/loss	860,324.39	13,111,069.16	-7,740,648.72
B. Provisions			
1. Other Provisions		530,222.64	495,762.64
C. Liabilities			
1. Trade accounts payable	2,270,649.00		2,493,123.69
2. Other liabilities	994,321.34	3,264,970.34	205,283.14
		16.906.262.14	15.444.914.24

# Notes to the Consolidated Annual Statement

# Notes to the Consolidated Financial Statements for the Fiscal Year 2014 (German Commercial Code (HGB))

Appendix 3



## Basic Rules

Such items of the balance sheet and income statement which did not show any amounts in this fiscal year or in the previous year have not been recognized, in accordance with §§ 298 (1), 265 (8) of the HGB.

The Consolidated Financial Statements are prepared according to the German Commercial Code for large corporations in addition to the regulations of the German Stock Corporation Act (AktG).

The consolidated Financial Statements are prepared in accordance with the accounting and valuation policies applicable to large capitalized companies (§§ 297, 298 HGB).

The classification of the consolidated balance sheet complies with §§ 298 (1), 266 (2), (3) HGB.

The Financial Statements of all consolidated companies, including the parent company, have been prepared along the same rules as in the previous year. The Profit and loss accounts have been prepared according to § 275 HGB in the total expenditure format.

To enhance the clarity of presentation, the items in the consolidated balance sheet and the consolidated profit and loss account are presented in the notes to the consolidated financial statements. For the reasons given above, the structure and layout of the notes to the Consolidated Financial Statements for the fiscal year 2014 have been adapted. There were no changes with respect to valuation and disclosure of assets, liabilities, income and expenses.

# Fiscal Year and Period of Consolidation

The balance sheet date of the Consolidated Financial Statements is December 31, 2014. The balance sheet included companies use the calendar year as their financial year. Thus, the financial statements for the financial year 2014 formed the basis for consolidation.

# Consolidated Entity

In addition to FORMYCON AG, the parent company, the consolidated financial statements include all subsidiaries for which FORMYCON AG directly or indirectly holds the majority of shares.

There is an overview of subsidiaries consolidated in appendix 1 to these notes.

# **Consolidation Principles**

Subsidiaries, which are included as part of full consolidation in the consolidated financial statements of FORMYCON AG (§ 301 HGB), the capital consolidation war performed according to the revaluation method. Assets and liabilities are valued at their full fair value, the investments' acquisition costs of the shareholdings concerned are set off against the prorata share in the fair value of the equity capital of the companies concerned to the purchase method. Differences on the assets side after completion of this offsetting exercise were included as goodwill on the assets side of the group balance sheet. A remaining negative differential amount produced by the capitalization of capital was shown on the liabilities side as "adjustment item".

According to §§ 303, 305 HGB results, sales, expenses and income, as well as receivables and liabilities between the companies included in the consolidation, are eliminated.

Inter-company profits from deliveries effected or services rendered between group companies are not eliminated because the amounts arising from these date is the same for all group companies. All of the transactions are not material to the presentation of the group's assets, financial position, and results of operations.

The deferred taxation principle has been applied to consolidation entries affecting net income, in so far as the deviating tax amount is expected to balance out in later fiscal years.

# **Foreign Currency Translation**

The Consolidated Financial Statements are as well as the Financial Statements of the consolidated companies are prepared in EURO unless stated otherwise. A Foreign Currency translation was not required.

# **Derivative Financial Instruments**

There are no derivative financial instruments.

# **Principles of Capitalization and Valuation**

and all prepaid and deferred items.

The valuation followed the principle of single-asset valuation.

The valuation of the assets and liabilities follows the accounting principle of prudence.

Intangible and tangible assets are stated at cost less accumulated depreciation and accumulated impairment loss. The initial cost of property, plant and equipment comprises its purchase price and any directly attributable costs to bring the asset to its working condition.

Depreciation is computed on a straight-line basis over their estimated useful lives following the tax depreciation tables.

Purchased software, where the purchase cost does not exceed 410.00€, will be recorded as a moveable item corresponding to the tax regulations ("Trivialprogramme", R 5.5 (1) S. 2, 3 EStR).

The option for recognition as an intangible asset pursuant to § 248 (2) HGB is not exercised in the FORMYCON AG.

Financial assets are stated at historical cost or the lower market value, according to the lower-of-costor-market principle.

The depreciation period for Goodwill is 15 years. This period is chosen because of the estimated time for long-term chances of licensing.

Inventories, including raw materials and supplies, are valued at the lower of cost or market value. Moveable assets are depreciated on a time-apportioned basis. Low-value items with acquisition costs up to The balance sheet contains all assets, all liabilities 150.00€ have been accounted for in the income statement. Low-value items with acquisition costs from 150.00 to 410.00€ are fully written off in the year of acquisition.

> The receivables and other assets are recorded at the original invoice amount, minus a valuation adjustment for uncollectible receivables. Based on consideration of the credit risk, general provisions are formed. Receivables are written off if they cannot be

> Inventories were valued using the moving average price method. The valuation of the finished and unfinished products is based on the cost of production according to §§ 298 (4), 255 (2) S.2 HGB. Appropriate devaluations are carried out to cover all recognizable risks in inventory assets resulting from reduced salability, obsolescence or above-average storage periods.

Other provisions were recorded when a liability to third parties exists, likelyhood of payment appears probable and the anticipated size of the provision can be reliably estimated.

The deferred taxes resulted from differences between the HGB balance sheet and the tax balance sheet, unused tax losses and consolidation measures.

As permitted by the option in § 274 (1) and § 298 (1) HGB, deferred tax assests for this are not recognized in the financial statements.

Tax provisions and other provisions are recognized in the amount that is likely to be utilized and take all further identifiable and uncertain obligations into account. Provisions with a term of more than one year are discounted at the average market interest rate for the provisions of seven years.

Liabilities are valued at the amount that is required to meet liabilities. Assets and liabilities in foreign currencies are translated using mean rates of exchange on the balance sheet date, §§ 298 (1), 256a HGB.

# Comments on the Balance Sheet

The development of the group fixed assets is shown in the enclosed fixed-asset movement schedule.

Liabilities are valued at the amount that is required to meet obligations. The structure of the liabilities is shown in the enclosed "table of liabilities".

# Comments on the Profit and Loss Accounts

Sales are arranged by service spectrum (Information about the sales according to § 314 (1) Nr.3 HGB):

	absolute	relative
Outlicensing	11,932,046.74	94.8%
Research	586,904.01	4.7 %
Services	66,067.19	0.5%

The other operating income includes income in the amount of 890.77 €, realized by currency translation (previous year: 0,00 €).

Pension schemes are not included in personnel

The other operating expenses include currency translation expenses: 3,940.32 € (previous year: 0.00 €)

# Other Information

Information on the members of the Executive Board and Supervisory Board in accordance with § 314 (1)

Members of the Executive Board:

- **Dr. Carsten Brockmeyer,** Marzling (Chairmen)
- Dr. Nicolas Combé, Marburg (Chairmen)

Supervisory Board:

- **Dr. Olaf Stiller,** Weimar (Chairman)
- Hermann Vogt, Dieburg (Deputy Chairman)
- Peter Wendeln, Oldenburg

The overall remuneration of the Supervisory Board amounted to 22,500.00€ (§ 314 Nr. 6 HGB).

According to § 314 Abs. 2 HGB the information according to § 314 Nr. 6 is not given.

Annex 1 to Appendix

Information about the auditor's fee concerning § 314 In accordance with § 314 (1) Nr.4 HGB the following (1) Nr. 9 HGB:

	€
Auditing	15,000.00
Tax Advice	0.00
Other Services	2,405.52

The overall amount according to § 314 (1) Nr. 9 HGB is 17,405.52€.

Necessary disclosures about subsidiaries, associated companies and investments are made in Appendix 1 to the notes in accordance with § 313 (2) Nr. 1-4 HGB.

information concerning the average number of employees must be provided:

Whole company	39
Administration	4
Research and development	35

Disclosures on the subsidiaries, associated companies and participations are shown in appendix 1 to

# Ownership of Shares and Companies Included in Consolidation

	Shares	Equity	Net Profit
		€	€
FORMYCON Services GmbH	100%	-1,656,493.80	-4,317.66
FORMYCON Project 201 GmbH	100%	19,701.69	-5,298.31

Planegg, April 7, 2015

FORMYCON AG

Dr. Carsten Brockmeyer

Dr. Nicoals Combé

# Annex 2 to Appendix

# Group Fixed-Asset Movement Schedule of December 31, 2014

	Historical cost	Additions
	€	€
I. Intangible assets		
Purchased concessions, industrial Property and assets as well as licences for such rights and assets	261,614.42	1,166.20
2. Goodwill	1,576,200.00	0.00
II. Property, plant and equipment		
1. Tenant installations	353,823.64	0.00
2. Other equipment, factory and other equipment	3,887,111.30	569,665.59
	6,078,749.36	570,831.79

Disposals at historical cost	Accumulated depreciation	Book value 12.31.2014	Book value 12.31.2013	Depreciation business year	Disposals at book value
€	€	€	€	€	€
0.00	142,709.87	120,070.75	177,318.53	58,413.98	0.00
0.00	354,645.00	1,221,555.00	1,379,175.00	157,620.00	0.00
0.00	113,729.06	240,094.58	290,640.86	50,546.28	0.00
102,899.65	1,905,115.78	2,448,761.46	2,696,209.53	805,350.94	11,762.72
102.899.65	2.516.199.71	4.030.481.79	4.543.343.92	1.071.931.20	11.762.72

# Table of Liabilites December 31, 2014

Annex 3 to Appendix

		amounts falling due			hereof
	12.31.2014	< 1 year 1 – 5 years > 5 years		> 5 years	secured
	€	€	€	€	€
1. Trade accounts payable	2,270,649.00	2,270,649.00	0.00	0.00	0.00
2. Other Liabilities	994,321.34	994,321.34	0.00	0.00	0.00
	3.264.970.34	3.264.970.34	0.00	0.00	0.00

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# Consolidated Cash Flow Statements for Fiscal Year 2014

Annex 4

	<b>2014</b> €	2013 €
Result of the year	860,324.39	-7,740,648.72
Depreciation and amortization of intangible assets and plant, equipment and other fixed assets	1,071,931.20	1,103,126.30
Increase /decrease in inventories, trade receivables and other assets not attributable to investing or financing activities	-2,584,623.10	-9,767,242.73
Increase/decrease in trade payables and other liabilities not attributable to investing or financing activities	601,023.51	-245,275.98
Gain/loss on disposal of fixed assets	11,762.72	79,180.24
Interest expense/interest income	7,417.58	-5,355.90
Income taxes paid	0.00	0.00
Cash Flow from operating activities	-32,163.70	-16,576,216.79
Payments received from the disposal of intangible assets	0.00	0.00
Payments for capital expenditures	-570,831.79	-188,166.26
Interest received	165.54	7,396.77 €
Dividends received	0.00	0.00
Cash Flow from investing activities	-570,666.25	-180,769.49
Proceeds from capital contributions by shareholders of the parent entity	0.00	17,435,296.50
Interest paid	-7,583.12	-2,040.87
Dividends paid to shareholders of the parent entity	0.00	0.00
Dividends paid to minority shareholders	0.00	0.00
Cash Flow from financing activities	-7,583.12	17,433,255.63
Net change in cash funds	-610,413.07	676,269.35
Effect on cash funds of exchange rate movements and remeasurements	0.00	0.00
Effect on cash funds of changes in the basis of consolidation	0.00	0.00
Cash funds at beginning of period	899,311.60	223,042.25
Cash and cash equivalents at end of fiscal year	288,898.53	899,311.60

# Development of Group Equity for the Fiscal Year 2014

Appendix **5** 

	January 1, 2014	Receive of increase of capital	Result	December 31, 2014
	K€	K€	K€	K€
Subscribed capital	8,627			8,627
Capital reserves	18,248			18,248
Consolidated loss carry forward	-6,883	-7,741		-14,624
Group profit	-7,741	-7,741	860	860
Equity	12,251	0.00	860	13,111
	12,251	0.00	860	13,111

# I. Basics of the Group

# 1. Business Model

The business model of the FORMYCON group is based done by the FORMYCON AG, which are also develon the development of biopharmaceutical imitation oped for the product-specific, outsourced subsidiarproducts (so-called biosimilars). The target market ies. In addition, the subsidiary FORMYCON Services of the product development is the subsequent outlicensing. The product development is partially fi-vice basis to pharma- and biotech companies. nanced by new license partners.

The group's structure follows this business model. The actual research and development activities are

GmbH offers specialized services on a fee-for-ser-

In the past year, the following group structure has been defined:

FORMYCON AG (R&D)

# FORMYCON Project 201 GmbH

(Outlicensing Partnership-company) FORMYCON Services GmbH

The FORMYCON Project 201 GmbH is the first outsourced company in this financial year. More partnerships are planed in subsequent years. Besides its site in Planegg, FORMYCON does not have any other the subsidiaries.

FORMYCON AG is limited to research and development activities. Other business processes are insignificant and relate to support services.

The target market is the pharmaceutical market, so health-related regulations can be mentioned as an important external influence factor.

facilities. FORMYCON AG holds 100% of the shares in Compared to the previous year, the FORMYCON Project 201 GmbH had been newly founded.

> Project activities and Intellectual Property of the first outsourced biosimilar were incorporated into this company.

# Group Management Report

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# 2. Research & Development

During the past year, the activities of the group were limited to research & development activities. In this context, the departments took the following cost blocks:

	K€
External services	5,081
Raw materials, etc.	827
Staff	2,894
Depreciation	1,072
Others	1,927
	11,801

37 employees worked in research and development. The expenditures in the amount of 11,801 K€ were charged as expenses, comprising about 94,4% of net sales. Research & development expenses were not capitalized. Patents and licenses were not notified. Product developments are proceeding as planned, with the result that the market entry can be expected as scheduled. There were no significant changes in the R&D department.

# II. Business and Environment

# 1. Framework

The gross domestic product (GDP) of the world economy grew by 3.3% last year. There are middle-term risks in the stagnation and a low growth in mature economies as well as decreasing growth potentials of emerging markets. The international monetary fund lowered its growth forecast, due to weaker prospects in China, Russia, Japan and in the Euro zone, even though there are pluses due to lower price of oil.

In 2015, we expect a growth of the economic output of 3.5%, in 2016 of 3.7%. Positive factors are the de-

creasing costs of companies and an increasing consumer purchasing power, with corresponding negative influences because of a investment recession in developed countries and emerging markets. Therefore, the US economy has achieved an average growth of 3.6%, in Germany it's 1.6%.

Despite moderate economic development, the German stock market has been very successful in 2014. The German stock index "DAX" established new records within the year 2014 and grew by 4.3% by the end of the year. The DAX-subsector "Biotechnology" grew much better than the DAX by 23.8% by the end of the year 2014. There is a similar picture in the USA, where the NASDAQ reached a growth of 18.9%. In the US, the NASDAQ Biotechnology Index has outperformed the strong performance of the previous years, with exceptional growth of 33.9% in 2014. To that effect US markets noticed a clear increase of share capital and capital bonds, as well as IPOs.

According to the latest industry report by IMS Health, spending on drugs will, for the first time, exceed the threshold of 1 trillion US-dollars (USD) in 2014 and rise to 1.3 trillion USD by 2018.

The increased demand is attributable to an increase in chronic illnesses and the ageing population in developed countries. The growth of the population and the improved access to medical care in emerging economies will increase the costs for companies. In contrast, the so-called "Phamerging Markets" are looking at growth-rates of 8–11%, of which is China is a 46% component.

Many large European markets continue their cost-saving measures to reduce their expenditures. In Germany, the costs of medication and diagnostic tests increased about 9.6% to 30.8 Billions €, partly due to a statistical effect. So the cost savings pro-

gram of German compulsory health insurance will go on. Due to increased mandatory discounts, voluntary manufacturer discounts, patent expirations and an increased competition on the market, pharmaceutical expenditures in Germany could be significantly reduced in recent years.

Through modern bio-pharmaceutically manufactured drugs, new and successful milestones concerning the treatment of severe diseases such as multiple sclerosis, cancer and rheumatism have been reached. Due to their high treatment costs, those bio-pharmaceutical drugs stand to be the number one cost-driver of statutory health insurance (SHI). The impending patent expirations of modern bio-pharmaceuticals, however, opens a window for generic biopharmaceutical products, the so-called biosimilars. Biosimilars have the potential to reduce the expenditures for medicines significantly. In contrast to classical generic medicines, biosimilars can only be produced with high effort and a large expert-knowledge.

The patent expirations have been going down within the last years. However, the association of Progenerika e.V. expects in 2015 a change of paradigm. The analyses of the market research firm INSIGHT HEALTH shows an expected patent expiration volume of 1.34 Billions € is much higher than forecasted in 2013. In addition, for the first time there are to be more patent free bio-pharmaceutical drugs on the market than there are chemically synthesized ones. The world wide sales of pharmaceutical products is able to increase tenfold until 2020.

# 2. Business Development in 2014

The business model of FORMYCON AG is based on the development of biopharmaceutical imitation products (so-called biosimilars) and has been consequently and consistently renewed in 2014, which has been a very successful year. According to the expectations of 2013, FORMYCON AG, as well as the company group, could report a net profit for the year. So the FORMYCON AG was able to carry out one of these projects well ahead of schedule in December 2013 to the Santo Holding GmbH.

On behalf of Santo Holding GmbH – owned by the Strüngmann family, who are the founders and former owners of HEXAL – FORMYCON AG now continues to bring this first development project on the market. In case of a successful development and a following successful introduction to the market, FORMYCON AG can expect contractual payments in the mid three-digit million range for the coming years.

Even in terms of personnel, the foundations for a successful future have been laid. In April 2013, Dr. Carsten Brockmeyer, one of the world's leading experts on biosimilars, joined FORMYCON AG and acts as chief executive officer (CEO). In November 2013, FORMYCON AG also appointed Dr. Gerhard Schaefer, formerly Head of Global Product and Business Development at Sandoz International, to the advisory board. In March 2014, the advisory board was completed with the additions of Dr. Bernhard Hamp, formerly CEO of Sandoz US.

Due to the previously mentioned contract and the stable investor-structure, FORMYCON AG is one of the few independent companies in the growing biosimilar market. The unique expertise of FORMYCON AG's scientists and management and the integrated development processes makes FORMYCON a preferred partner for large pharmaceutical companies.

## 3. Results

FORMYCON AG has continued the development of three biosimilar projects in 2014 and could profit by the out-licensing of the first biosimilar.

# Results of operation

As a result of the first out-licensing, the group generated important product revenues. Net sales were 12,585 K€, while the previous year's sales were 276 K€. The cost of materials rose by 5,908 K€ and gross profits were 6,762 K€.

achieved an annual net profit of 862 K€. In contrast to the previous year, other operating expenses were relatively constant hence, they 
The group is currently in a production development are covered by the gross profit.

The group is anticipating increasing coverage rates due to further out-licenses.

# Financial position

The financial situation of the group is very solid and stable. Indicators for liquidity show above-average values. The current assets amounted to 12,859 K€, in comparism to this the short-term liabilities amounted to 3,795 K€.

Short-term or long-term loan financing through banks was not needed.

Cash equivalents amounted to 290 K€ on the The return on equity was 6,56%, while the return on balance sheet date, the cash-equivalent securities amounted to 8,935 K€. Please see the notes to the financial statements for information regarding the cash flow statement.

Return on sales reached a level of 6.8%, the EBIT came to 869 K€ and the EBITDA amounted to 1.941 K€.

# Net assets

The company's equity increased during the reporting period from 72.5% to 77.6%, what is far above average. The fixed assets have been reduced due to depreciation. They are completely covered by equity which implies a very positive structure of the balance sheet.

The current assets consist almost completely of cash and cash-equivalents, which leads to the conclusion that the current assets are virtually risk-free.

# Because of the market entry, the group 4. Financial and Non-Financial Performance Indicators

phase, which means that the informative value financial indicators is limited. Relevant performance indicators for our group are those which measure the sustainable financial power of the company.

The working-capital, measured as the difference between short-term assets and short-term liabilities, amounts to 9,054 K€ as of the reporting date.

The cash-flow (annual net profit + depreciation and changes in long-term provisions) amounted to 1,932 € and was positive for the first time. The investment activities, which were below depreciation, came to 569 K€, which lead positive to cash inflows.

total investment was 5,13%.

Non-financial indicators can be found in the research and development report.

The group develops solutions for each customer, which see themselves as partners. A relatively small existing customer base implies a low conflict potential. We stand out for a high level of customer satisfaction.

The group mainly hires employees from the research and development field. The low staff turnover is due to a high employee satisfaction.

# III. Supplementary Report

Significant events that occurred after the end of the financial year were not recorded. Increased risks for the current financial year 2015 are unintelligible.

## IV. Forecast

On the basis of their overall expertise, FORMYCON AG intensified their research activities in 2014. The start of the pivotal registration trial (Phase III) for the first biosimilar product (FYB201) is planned at the end of the year. The immediate licensing of Phase III through the EMA in London as part of a scientific advice in December 2014 equates to an acceleration of the original plan by one year. The strategy needs to be certified by the American Food and Drug Administration (FDA). The development of both biosimilars in the FORMYCON-pipeline, that also aims to imitiate a biopharmaceutical agent from the third wave, runs according to schedule. Here, FORMYCON AG is currently in discussions with different generic pharmaceutical companies. A partnership of these development projects is planed after the finish of the first clinical test in 2016 and 2017.

Following the successful capitalization of the company and the partnership of the first Biosimilar with Santo Holding concluded in 2013, these achievements are still an important milestone for the company. The marketing start of FYB201 in the USA and EU is planed in 2020.

Our subsidiary "FORMYCON Services GmbH" will continue to offer development services for pharmaceutical and biotechnology companies. We anticipate this business model will operate profitably.

Because of a good asset structure and financial situation of the group, it's possible to exploit acquisition opportunities.

For the 2015 fiscal year, the group expects a moderate sales increase, with the start of additional outlicenses of 13,000 K€ and a result of 900 K€.

The outlook for the FORMYCON group for the coming years continues to be positive due to expected moderate, economic growth. For the year 2016, though, we anticipate rising revenues of 3-4% and an improvement of our result.

Concerning the financial situation and the service portfolio, the group is already well positioned in the

As the number of employees increases, we expect a slight increase in our cost structure. This implies consistent business results.

Furthermore, we expect no movements in the exchange rates and risks of inflation as well as other special influences.

# V. Opportunities and Risk Report

# 1. Risks

# Industry-specific risks:

If the worldwide turbulences on the financial and raw materials markets increase and the economy slows down, they could have a negative impact on the group's economic situation and the demand for our products, as the national and international healthcare industry is affected. This may expose the corre-

## Profit-oriented risks:

sponding sales and results risks.

Actually, we do not see a direct earnings risk. There is a long-term risk that research and development activities will not be successful and hence, find no acceptance in the relevant market. Throwbacks concerning product developments licensing. can never be totally excluded.

# Financial risks:

There are currently no liquidity risks due to the good liquidity and equity situation of the group.

The liquidity situation is currently excellent.

# 2. Opportunities

The group Management Board is responsible for systematic identification and exploitation of economic opportunities.

Looking forward to the future, the development of the healthcare industry is seen as positive. There are various reasons for this:

- has made possible the treatment of medical pictures, which just 10 or 20 years ago could not be treated.
- Demographic growth: The German population is aging steadily. There are also more mulitmorbid people.

By the development of biosimilars, the group is positioning itself at an early stage in one of the most promising healthcare markets of the future. FORMYCON has the aim of exploiting growth opportunities in relevant markets.

This applies especially to the increasing opportunities now arising for organic growth in further out-

We're entering the contest with our competitors by offering experience, innovative products, reliability as well as a high degree of quality and customer satisfaction.

# 3. Summary Statement

The main risks of future development lie in the unstable environment of the world economy. Against the background of our financial stability, we are well equipped to deal with future risks. The group currently faces no risks which may endanger the continued existence of the company.

There has been no change to the company's exposure to several risk areas or the manner in which it manages and measures risk. The overall picture Medical and technical progress: The progress shows no underlying change to the risk situation compared to the previous year. By using internal control mechanisms, we are in a position to identify and handle changes about the risk situation at an early stage.

# 4. Risk Reporting Related to the Use of Fnancial instruments

The group's existing financial instruments mainly include receivables, liabilities and bank balances. Liabilities are settled within the stipulated period. Potential currency risks, which could have a negative effect on our asset situation, financial position and profitability, will be compensated by avoidance of foreign currency items in our balance sheet.

The biggest currency item of the group arises from purchases of external services in CHF, which were paid promptly in order to minimize currency risks.

The risk management policies of FORMYCON are There are no existing branches.

aimed at hedging profits against financial risks of all

Concerning the management of financial items, the group has followed a conservative risk policy.

As soon as nonpayment risks are identifiable with regard to financial assets, the risks are recorder using value adjustments.

There are no perceived risks perceivable that would endanger the group as a going concern.

# 5. Branches

Planegg, April 7, 2015

FORMYCON AG

Dr. Carsten Brockmeyer

Dr. Nicolas Combé

I have audited the consolidated financial statements prepared by FORMYCON AG, Planegg comprising the balance sheet, the profit and loss accounts for the business year from January 1, 2014 to December 31, 2014, the cash flow statement, the statement of changes in equity and the notes to the consolidated financial statements – and the group management report for the business year from January 1, 2014 to December 31, 2014. The preparation of the consolidated financial statements and the group management report in accordance with the requirements of German commercial law and the Company's statutes ("German Commercial Code HGB") are the responsibility of the parent Company's management. My responsibility is to express an opinion on the consolidated financial statements and on the group management report based on my audit.

I conducted my audit of the consolidated financial statements in accordance with § 317 HGB and German generally accepted standards for the audit of financial statements promulgated by the Institut der Wirtschaftsprüfer. Those standards require that I plan and perform the audit such that misstatements materially affecting the presentation of the net assets, financial position and results of operations in the consolidated financial statements in accordance with the applicable financial reporting framework and in the group management report are detected with reasonable assurance. Knowledge of the business activities and the economic and legal environment of the group and expectations as to possible misstatements are taken into account in the determination of audit procedures. The effectiveness of the accountingrelated internal control system and the evidence supporting the disclosures in the books and records, the consolidated financial statements and the group management report are examined primarily on a test basis within the framework of the audit. The audit in-

cludes assessing the annual financial statements of those entities included in consolidation, the determination of entities to be included in consolidation, the accounting and consolidation principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements and the group management report. I believe that our audit provides a reasonable basis for my opinion.

My audit has not led to any reservations.

In my opinion, based on the findings of my audit, the consolidated financial statements comply with German commercial law and the additional rules of the company's statutes and give a true and fair view of the net assets, financial position and results of operations of the group in accordance with these requirements. The group management report is consistent with the consolidated financial statements and as a whole provides a suitable view of the group's position and suitably presents the opportunities and risks of future development.



Düsseldorf, April 4, 2015

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Dr. Brunsmann WP/StB

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