search result

Surname	Area	information	V. date
Vetter Pharma-Manufacturing GmbH & Co. KG	Accounting / financial reports	Annual and consolidated financial statements for the business year from 01/01/2018 to 12/31/2018	02/01/2020

Vetter Pharma-Manufacturing GmbH & Co. KG

Ravensburg

Annual and consolidated financial statements for the business year from 01/01/2018 to 12/31/2018

Certificate

In the documents intended for disclosure - consolidated balance sheet and annex to the consolidated balance sheet, as well as the notes to the consolidated financial statements and the group management report - the simplifications pursuant to Section 13 (3) sentence 2 in conjunction with V. m. Section 5 (5) sentence 3 PublG has been correctly used. In addition, the consolidated balance sheet has been reduced to the statutory structure and the notes to the consolidated financial statements have been adjusted accordingly. We have issued the following auditor's report on the complete consolidated financial statements and the group management report:

Independent auditor's report

To Vetter Pharma-Fertigung GmbH & Co. KG

Examination Opinions

We have the consolidated financial statements of Vetter Pharma-Fertigung GmbH & Co.KG, Ravensburg and its subsidiaries (the group) - consisting of the consolidated balance sheet as of December 31, 2018, the consolidated income statement for the financial year from January 1 to December 31, 2018 and the notes to the consolidated financial statements, including the presentation of the accounting and valuation methods. In addition, we have audited the group management report of Vetter Pharma-Fertigung GmbH & Co. KG for the fiscal year from January 1 to December 31, 2018.

According to our assessment based on the knowledge gained during the audit

- the attached consolidated financial statements correspond in all material respects to those for companies i. S. d. Section 11 PublG, which falls under Section 13 (3) sentence 2 PublG, applies to German commercial law and, in compliance with German generally accepted accounting principles, provides a true and fair view of the Group's net assets and financial position as of December 31, 2018, and its earnings position for the financial year from January 1 to December 31, 2018 and
- the attached group management report gives an overall accurate picture of the group’s position. In all material respects, this group management report is consistent with the consolidated financial statements, complies with German legal requirements and accurately presents the opportunities and risks of future development.

In accordance with Section 322 (3) sentence 1 of the German Commercial Code (HGB), we declare that our audit has not led to any objections to the correctness of the consolidated financial statements and the group management report.

Basis for the examination results

We have carried out our audit of the consolidated financial statements and the group management report in accordance with Section 14 (1) PublG i. V. m. Section 317 of the German Commercial Code (HGB) in compliance with the German principles of proper auditing established by the Institut der Wirtschaftsprüfer (IDW). Our responsibility in accordance with these regulations and principles is described in more detail in the section “Responsibility of the auditor for the audit of the consolidated financial statements and the group management report” of our auditor's report. We are independent of the group companies in accordance with German commercial and professional regulations and have fulfilled our other German professional obligations in accordance with these requirements.

Responsibility of the legal representatives for the consolidated financial statements and the group management report

The legal representatives are responsible for the preparation of the consolidated financial statements, which are for companies i. S. d. Section 11 PublG, which falls under Section 13 Paragraph 3 Clause 2 PublG, complies with the applicable German commercial law provisions in all material respects, and ensures that the consolidated financial statements, in compliance with the German principles of proper bookkeeping, provide a true and fair view of assets and finance - and the Group's earnings position. In addition, the legal representatives are responsible for the internal controls that they have determined to be necessary in accordance with the German principles of proper accounting to enable the preparation of consolidated financial statements,

When preparing the consolidated financial statements, the legal representatives are responsible for assessing the Group's ability to continue as a going concern. They are also responsible for disclosing issues relating to the going concern of the company, if relevant. In addition, they are responsible for accounting for the going concern basis of accounting, unless actual or legal circumstances conflict with this.

In addition, the legal representatives are responsible for the preparation of the group management report, which as a whole provides an accurate picture of the group’s position, is consistent with the consolidated financial statements in all material respects, complies with German legal requirements and appropriately presents the opportunities and risks of future development . Furthermore, the legal representatives are responsible for the precautions and measures (systems) that they have deemed necessary to enable the preparation of a group management report in accordance with the applicable German legal regulations and to provide sufficient suitable evidence for the statements in the group management report can.

Auditor's responsibility for the audit of the consolidated financial statements and the group management report

Our objective is to obtain sufficient certainty as to whether the consolidated financial statements as a whole are free of material - intended or unintentional - misrepresentation, and whether the group management report as a whole gives an accurate picture of the Group's position and, in all material matters, with the consolidated financial statements as well is consistent with the knowledge gained during the audit, complies with German legal requirements and correctly presents the opportunities and risks of future development, and issues an auditor's report that includes our audit opinions on the consolidated financial statements and the group management report.

Adequate security is a high level of security, but no guarantee that an audit carried out in accordance with Section 317 of the German Commercial Code (HGB) in accordance with the German principles of proper auditing established by the Institute of Auditors (IDW) will always reveal a material misrepresentation. Misrepresentations can result from violations or inaccuracies and are regarded as material if it could reasonably be expected that they individually or collectively influence the economic decisions of the addressees made on the basis of these consolidated financial statements and the group management report.

During the examination, we exercise due discretion and maintain a critical attitude. Furthermore

- We identify and assess the risks of material - intentional or unintentional - misrepresentations in the consolidated financial statements and the group management report, plan and carry out audit procedures in response to these risks, and obtain audit evidence that is sufficient and suitable to serve as a basis for our audit opinions. The risk that material misrepresentations are not detected is higher in the case of violations than inaccuracies, since violations can include fraudulent interaction, forgeries, intentional incompleteness, misleading representations or the overriding of internal controls;
- We gain an understanding of the internal control system relevant to the audit of the consolidated financial statements and the provisions and measures relevant to the audit of the group management report in order to plan audit procedures that are appropriate under the given circumstances, but not with the aim of providing an audit opinion on the effectiveness of these Dispense systems;
- we assess the appropriateness of the accounting methods used by the legal representatives as well as the acceptability of the estimated values presented by the legal representatives and related information;
- we draw conclusions about the appropriateness of the going concern accounting principle applied by the legal representatives and, on the basis of the audit evidence obtained, whether there is any material uncertainty in connection with events or circumstances, the significant doubts about the Group's ability to continue as a going concern can raise. If we come to the conclusion that there is material uncertainty, we are obliged to draw attention to the relevant information in the consolidated financial statements and in the group management report in the auditor's report, or if this information is inappropriate, to modify our respective audit opinion. We draw our conclusions based on the audit evidence obtained up to the date of our auditor's report. Future events or circumstances can, however, mean that the Group can no longer continue its business activities;
- we assess the overall presentation, structure and content of the consolidated financial statements, including the information, and whether the consolidated financial statements present the underlying business transactions and events in such a way that the consolidated financial statements provide a true and fair view of the assets, financial and earnings position of the group conveyed;
- We obtain sufficient, suitable audit evidence for the accounting information of the companies or business activities within the group in order to issue audit opinions on the consolidated financial statements and the group management report. We are responsible for the direction, supervision and execution of the group audit. We are solely responsible for our audit opinions;
- we assess the consistency of the group management report with the consolidated financial statements, its compliance with the law and the picture it provides of the group's position;
- we perform audit procedures on the future-oriented information presented by the legal representatives in the group management report. On the basis of adequate, suitable audit evidence, we particularly review the significant assumptions on which the legal representatives are based on the future-oriented information and assess the appropriate derivation of the future-oriented information from these assumptions. We do not issue an independent audit opinion on the future-oriented information or the underlying assumptions. There is a significant unavoidable risk

Among other things, we discuss with those responsible for monitoring the planned scope and timing of the audit as well as significant audit findings, including any deficiencies in the internal control system that we discover during our audit.

Ravensburg, March 15, 2019

Ernst & Young GmbH
auditing company

Arnold, auditor

Guard, auditor

Consolidated balance sheet as of December 31, 2018

assets

				December 31, 2017
	€	€	€	T €
A. Fixed assets				
I. Intangible Assets				
1. Computer software acquired against payment	7,149,981.34			3,396
2. Advance payments and software under development	5,724,378.54			0
		12,874,359.88		3,396
II. Tangible assets				
1. Land and buildings including buildings on third-party land	149,140,408.36			141.017
2. Technical systems and machines	162,811,491.44			151.401
3. Other equipment, factory and office equipment	38,668,223.18			38,231
4. Advance payments and assets under construction	198,601,323.50			128,517
		549,221,446.48		459.166
III. Financial assets				
Shares in affiliated companies		67,212.67		67
			562,163,019.03	462.629
B. Current Assets				
I. Inventories				
1. Raw materials and supplies	54,371,817.75			45,484
2. Work in progress	24,049,391.52			22,500
3. Finished products and merchandise	19,850,840.40			20,365
4. Advance payments made	12,150.00			75
5. Advance payments received	-7,183,217.69			-6,788
		91,100,981.98		81,636
II. Receivables and other assets				
1. Trade accounts receivable	107,811,738.94			107,367
2. Claims against companies of the Vetter Group	212,091.84			18th

				December 31, 2017
	€	€	€	T €
3. Other assets	17,922,238.02			20,776
		125,946,068.80		128.161
III. Cash on hand, bank balances		3,945,245.37		1,702
			220,992,296.15	211,499
C. Prepaid expenses			2,710,324.78	2,387
			785,865,639.96	676.515

liabilities

			December 31, 2017
	€	€	T €
A. Equity		313,455,266.50	294,790
B. Adjustment items for capitalized own shares		41,000.00	41
C. Provisions			
1. Tax provisions	1,719,234.76		513
2. Other provisions	31,295,741.44		31,409
		33,014,976.20	31,922
D. Liabilities			
1. Liabilities to banks	315,753,783.63		246,800
2. Advance payments received on orders	40,066,264.58		35,367
3. Trade accounts payable	21,329,232.71		22,480
4. Liabilities to shareholders	50,296,336.99		30,442
5. Liabilities to companies of the Vetter Group	28,523.04		87
6. Other Liabilities	11,880,256.31		14,586
of which from taxes € 9,310,283.66 (previous year: € 12,279 thousand)			
of which in the context of social security € 34,429.67 (previous year: € 137 thousand)			
		439,354,397.26	349,762
		785,865,639.96	676.515

Annex to the consolidated balance sheet as of December 31, 2018

	€
Sales	594,949,892.38
Wages and salaries, social security contributions and expenses for pensions and support	265,562,364.64

The group employed an average of 4,212 people in 2018

The valuation and depreciation methods are explained in the notes to the consolidated financial statements.

Notes to the consolidated financial statements for 2018

I. General information on the consolidated financial statements

Vetter Pharma-Fertigung GmbH & Co. KG, based in Ravensburg, is entered in the commercial register of the Ulm District Court under HRA No. 550954.

The present consolidated financial statements were prepared in accordance with the provisions of the Act on Accounting for Certain Enterprises and Groups (Publicity Act) in conjunction with the relevant provisions of the Commercial Code.

Scope of consolidation

In addition to Vetter Pharma Fertigung GmbH & Co. KG, the following companies are included in the consolidated financial statements:

	Amount of shares in the capital
	%
Vetter Pharma International GmbH, Ravensburg	100.00
Vetter Development Services USA, Inc., Skokie, Illinois (USA)	100.00 [1)]
Vetter Pharma International USA Inc., Des Plaines, Illinois (USA)	100.00 [1)]
Arzneimittel GmbH Apotheker Vetter & Co. KG, Ravensburg	100.00
Vetter Pharma International Japan KK, Tokyo (Japan)	100.00 [1)]
Vetter Commercial Manufacturing USA, LLC, Des Plaines, Illinois (USA)	100.00 [1)]

[1)] Indirect participation, held by Vetter Pharma International GmbH, Ravensburg.

Vetter Pharma-Fertigung Verwaltungs-GmbH, Bregenz / Austria and Vetter Consulting GmbH, Graz / Austria were not included in the consolidated financial statements due to their small business volume in accordance with Section 296 (2) HGB. They are of subordinate importance for the obligation to convey a true and fair view of the Group's asset, financial and earnings position. The sole shareholder of Vetter Pharma-Fertigung Verwaltungs-GmbH and Vetter-Consulting GmbH is Vetter Pharma-Fertigung GmbH & Co. KG.

Consolidation principles

Capital consolidation was carried out using the revaluation method at the time of initial inclusion in the consolidated financial statements.

The negative difference from the initial consolidation of Arzneimittel GmbH Apotheker Vetter & Co.KG in the 2013 financial year was transferred to the reserves with no effect on income, as it arose from the fact that the shares in this company acquired through the contribution in kind were included in the annual financial statements of Vetter Pharma-Fertigung GmbH & Co. KG were valued at a value below the fair value.

Receivables and liabilities, sales, expenses and income within the scope of consolidation have been eliminated. There were no interim results.

Currency conversion

With the exception of equity, which was converted into euros at the historical rate, the assets and liabilities items in foreign currency balance sheets were converted into euros at the mean spot exchange rate on the reporting date. The items in the income statement have been converted into euros at the average rate for the year. A resulting conversion difference was shown in the item "Equity difference from currency conversion".

The currency differences resulting from debt consolidation are also recognized directly in equity in the item "Equity difference from currency conversion".

II. Information on accounting and valuation methods

The following accounting and valuation methods were decisive for the preparation of the consolidated financial statements.

The intangible fixed assets acquired against payment are valued at acquisition cost, reduced by scheduled, pro-rata straight-line depreciation (with a normal useful life of up to five years).

Property, plant and equipment is reported at acquisition or production cost and, if depreciable, reduced by scheduled, pro-rata linear or degressive depreciation based on the expected useful life. Additions to assets after December 31, 2010 are only depreciated using the straight-line method.

Assets with individual acquisition costs of more than € 250.00 to € 1,000.00 are recorded in a collective item that is depreciated on a straight-line basis over 5 years. Their departure is assumed in the fifth year after acquisition. Assets with individual acquisition costs of up to € 250.00 are not capitalized.

The financial assets are stated at acquisition cost or at the lower applicable value.

The valuation of raw materials, consumables and supplies is based on average acquisition costs or the last lower acquisition price, less a deduction for discounts. All inventory risks for raw materials, consumables and supplies, which result from the storage period or reduced usability, are taken into account by means of appropriate value deductions.

The unfinished and finished goods are valued according to the degree of manufacture at the manufacturing costs in accordance with Section 255 of the German Commercial Code. Material and manufacturing overheads are also taken into account.

Receivables and other assets are always valued at their nominal value. All risky items are taken into account by making appropriate individual value adjustments. The general default and credit risk is adequately taken into account by a general value adjustment of 1% on the net receivables. Receivables in foreign currency are valued at the mean spot exchange rate on the balance sheet date. With a remaining term of more than one year, the realization and acquisition cost principles are observed.

Bank balances in foreign currencies are converted at the mean spot exchange rate on the balance sheet date.

The other provisions take into account all identifiable risks and uncertain liabilities and are recognized at the settlement amount. Other provisions with a remaining term of more than one year have been discounted using the interest rate appropriate to the term in accordance with the Provision Discounting Ordinance.

The liabilities are shown at the settlement amount. Liabilities in foreign currencies are converted using the mean spot exchange rate on the balance sheet date. With a remaining term of more than one year, the realization and acquisition cost principles are observed.

III. Information on the balance sheet

1. Assets

Capital assets

The development of the individual items of fixed assets is shown in the separate overview "Development of Group Fixed Assets".

Receivables and other assets

As in the previous year, all receivables have a remaining term of less than one year.

As of July 1, 2018, the Group introduced a working time account model. The obligations from the time value accounts were allocated to the plan assets i. S. d. Section 246 (2) sentence 2 HGB, which is accounted for at fair value, is offset. The plan assets serve exclusively to meet the debts from the time value account obligations and are not accessible to all other creditors.

The information on offsetting in accordance with Section 246 (2) sentence 2 of the German Commercial Code (HGB) for the time value accounts is shown in the following overview:

	December 31, 2018
	T €
Settlement amount of the offset debts	1.939
Acquisition costs of the offset assets	1,947
Fair value of the offset assets	1.939
Offset expenses from the discounting of offset debts	0
Offset income from offset assets	0

2. Liabilities

Other provisions

The other provisions essentially contain obligations from the personnel area, provisions for guarantee obligations and provisions for energy costs.

liabilities

		Amounts with a remaining term		
	total	up to 1 year	from 1 to 5 years	of more than 5 years
	T €	T €	T €	T €
Liabilities to banks	315.754	84.166	80.215	151.373
(Previous year)	(246,800)	(20,300)	(139,937)	(86,563)
Advance payments received on orders	40,066	12,882	23,629	3,555
(Previous year)	(35,367)	(9,624)	(24.094)	(1,649)
liabilities from goods and services	21,329	21,329	0	0
(Previous year)	(22,480)	(22,480)	(0)	(0)
Liabilities to shareholders	50,296	50,296		
(Previous year)	(30,442)	(30,442)	(0)	(0)
Liabilities to companies of the Vetter Group	29	29		
(Previous year)	(87)	(87)	(0)	(0)
Other liabilities	11,880	11,880		
(Previous year)	(14,586)	(14,586)	(0)	(0)
	439.354	180,582	103,844	154,928

Deferred taxes

Deferred tax assets arise in property, plant and equipment, inventories, other assets and other provisions. They outweigh the deferred tax liabilities from currency conversion as well as from bank balances and other assets. The tax rates applied are 12.8% and 28.53%, respectively.

The right to vote according to § 298 Paragraph 1 i. V. m. Section 274 (1) sentence 2 of the German Commercial Code (HGB) not to account for an excess of deferred tax assets over deferred tax liabilities is used.

IV. Other information

1. Contingent liabilities and other financial obligations

The total amount of the other financial obligations is T € 217,291. These are essentially purchase contracts for capital goods, obligations from rental and leasing contracts and a supply contract for biogas and logistics services.

2. Derivative Financial Instruments

Contracts for derivative financial instruments exist as of the balance sheet date to the following extent:

Type of financial instrument	Nominal amount kEUR	Market value kEUR	Book value kEUR
Forward foreign exchange transactions	27,262	+119	0
Interest rate swaps	20,000	-312	0
Interest rate caps	40,000	+185	+332

Derivative financial instruments are only used to hedge currency and interest rate risks from operational business and, if applicable, from financing transactions. The aim is to reduce fluctuations in the cash and earnings flows of the Vetter Group due to changes in exchange rates and interest rates. The market value of the derivative financial instruments is determined using recognized calculation methods, taking into account the market data available on the balance sheet date.

To minimize interest rate risks, the Group has hedged variable interest liabilities with a nominal volume of EUR 60,000 thousand and a remaining term until 2025 by means of interest rate swaps with matching maturities and interest rate caps of the same amount ("portfolio hedge"). The underlying and hedging transactions were combined in valuation units so that negative market values are not recognized as a liability under the freezing method. The prospective effectiveness of the valuation units is measured using the critical term match method, the retrospective effectiveness is determined using the hypothetical derivative method.

To cover the currency risks from operational cash flows in foreign currencies (mainly USD) and a loan in USD, the company concluded forward exchange transactions with a nominal volume of T € 27,262 and terms of up to three years ("macro hedge") on the balance sheet date. Underlying and hedging transactions have been completely combined in valuation units, the effectiveness of which is measured prospectively using the critical term match method and retrospectively using the cumulative dollar offset method. The anticipated underlying transactions have a very high probability of occurrence,

The book value of the interest rate caps of EUR 332 thousand is included in the prepaid expenses.

3. Transactions with related persons and companies

In 2018, the Group paid a total of T € 2,925 for the use of services, T € 989 for interest and T € 186 for rent to related companies.

T € 76 was paid to related parties for services.

Related companies earned € 472 thousand for services, € 98 thousand for interest and € 12 thousand for rentals.

4. Supplementary report

There were no events of particular importance after the end of the financial year.

5. Disclosure

Vetter Pharma-Fertigung GmbH & Co. KG, Ravensburg, presents its annual financial statements using Section 5 (6) PublG i. V. m. Section 264 (3) HGB not open.

6. Total auditor's fee

The fee for auditing the consolidated financial statements of Vetter Pharma-Fertigung GmbH & Co. KG as well as the individual financial statements of the parent company and Vetter Pharma International GmbH amounts to a total of € 124 thousand.

Ravensburg, March 15, 2019

signed Oliver Albrecht, Managing Director

signed Thomas Otto, Managing Director

signed Peter Sölkner, Managing Director

Development of group assets in 2018

	Acquisition and production costs 1.1.2018 €	Currency differences €	Accesses €
I. Intangible Assets			
1. Computer software acquired against payment	30,626,652.06	1,429.67	1,556,994.38
2. Advance payments and software under development	0.00	0.00	10,559,345.24
	30,626,652.06	1,429.67	12,116,339.62
II. Tangible assets			
1. Land and buildings including buildings on third-party land	182,830,900.30	203,977.24	6,257,600.88
2. Technical systems and machines	484,600,682.11	269,370.07	136,643.97
3. Other equipment, factory and office equipment	121,671,197.21	203,365.32	3,060,755.22
4. Advance payments and assets under construction	128,516,804.21	252,652.05	129,141,779.07
	917,619,583.83	929,364.68	138,596,779.14
III. Financial assets			
Shares in affiliated companies	67,212.67	0.00	0.00
	948,313,448.56	930,794.35	150,713,118.76

	Acquisition and production costs Rebookings €	Departures €	December 31, 2018 €
I. Intangible Assets			
1. Computer software acquired against payment	4,834,966.70	3,966.20	37,016,076.61
2. Advance payments and software under development	-4,834,966.70	0.00	5,724,378.54
	0.00	3,966.20	42,740,455.15
II. Tangible assets			
1. Land and buildings including buildings on third-party land	7,746,233.21	857,729.85	196,180,981.78
2. Technical systems and machines	41,420,156.34	623,233.50	525,803,618.99
3. Other equipment, factory and office equipment	10,143,522.28	1,287,187.86	133,791,652.17
4. Advance payments and assets under construction	-59,309,911.83	0.00	198,601,323.50
	0.00	2,768,151.21	1,054,377,576.44
III. Financial assets			
Shares in affiliated companies	0.00	0.00	67,212.67
	0.00	2,772,117.41	1,097,185,244.26

	Accumulated depreciation 1.1.2018 €	Currency differences €	Accesses €	Departures €	December 31, 2018 €
I. Intangible Assets					
1. Computer software acquired against payment	27,230,550.53	1,429.67	2,638,081.27	3,966.20	29,866,095.27
2. Advance payments and software under development	0.00	0.00	0.00	0.00	0.00

	Accumulated depreciation				
	1.1.2018	Currency differences	Accesses	Departures	December 31, 2018
	€	€	€	€	€
	27,230,550.53	1,429.67	2,638,081.27	3,966.20	29,866,095.27
II. Tangible assets					
1. Land and buildings including buildings on third-party land	41,813,954.42	19,590.97	5,648,603.03	441,575.00	47,040,573.42
2. Technical systems and machines	333,200,085.34	193,630.00	30,165,924.56	567,512.35	362,992,127.55
3. Other equipment, factory and office equipment	83,439,700.41	173,343.13	12,669,216.16	1,158,830.71	95,123,428.99
4. Advance payments and assets under construction	0.00	0.00	0.00	0.00	0.00
	458,453,740.17	386,564.10	48,483,743.75	2,167,918.06	505,156,129.96
III. Financial assets					
Shares in affiliated companies	0.00	0.00	0.00	0.00	0.00
	485,684,290.70	387,993.77	51,121,825.02	2,171,884.26	535,022,225.23

	Book values	
	December 31, 2018	December 31, 2017
	€	€
I. Intangible Assets		
1. Computer software acquired against payment	7,149,981.34	3,396,101.53
2. Advance payments and software under development	5,724,378.54	0.00
	12,874,359.88	3,396,101.53
II. Tangible assets		
1. Land and buildings including buildings on third-party land	149,140,408.36	141,016,945.88
2. Technical systems and machines	162,811,491.44	151,400,596.77
3. Other equipment, factory and office equipment	38,668,223.18	38,231,496.80
4. Advance payments and assets under construction	198,601,323.50	128,516,804.21
	549,221,446.48	459,165,843.66
III. Financial assets		
Shares in affiliated companies	67,212.67	67,212.67
	562,163,019.03	462,629,157.86

Group management report for 2018

Business activity

The Vetter Group is a leading global specialist in the development and aseptic filling of medicines in syringes, cartridges and vials. Vetter has many years of experience in dealing with biotechnological agents and complex substances including monoclonal antibodies, peptides, interferons and vaccines. Vetter supports pharmaceutical and biotech companies from preclinical development to supplying the world market. The Vetter Development Service takes over the clinical production and supports the development of new drugs from the early phases through to the transfer to commercial production. The group offers modern technology and innovative processes for filling,

The Vetter Group is based in Ravensburg and includes the production sites in Upper Swabia, as well as sales and development service sites in the USA, Singapore, Japan and South Korea.

Business development and situation in 2018

The global pharmaceutical market posted sales of around 1.2 trillion US dollars in 2018, which corresponds to an average annual increase in sales of 6.3% from 2014 to 2018. The most important single market is still the USA, followed by China, Japan and then Germany in fourth place.

With the approval of 59 new drugs in the USA in 2018, the peak value of 46 new drugs in the previous year was again significantly exceeded - a sign of the FDA's unbroken innovation-friendly course. In Germany and the EU, 36 and 45 new drugs, respectively, were approved, also an increase compared to 2017. Around a third of all new approvals concentrate on cancer treatment and around 40% of new US approvals are administered parenterally. In particular, about half of the products that the FDA has awarded the so-called "Break-Through Therapy" status or "Orphan Drug Status" are injectables. In Europe, two CAR-T cell therapies for cancer treatment and the Luxturna viral gene therapy received official approval for the first time in 2018. Although seven biosimilars were approved in the USA in 2018, this number is nowhere near the new approval of 14 biosimilars in Europe. In this context, the patent expiry of Humira and the European market entry of its copycat products in October 2018 received particular attention. In the USA, however, most Humira biosimilars cannot be brought onto the market before 2023 due to licensing agreements. this number is nowhere near the number of 14 new biosimilars approved in Europe. In this context, the patent expiry of Humira and thus the European market entry of its copycat products in October 2018 received special attention. In the USA, however, most Humira biosimilars cannot be brought onto the market before 2023 due to licensing agreements. this number is nowhere near the number of 14 new biosimilars approved in Europe. In this context, the patent expiry of Humira and thus the European market entry of its copycat products in October 2018 received special attention. In the USA, however, most Humira biosimilars cannot be brought onto the market before 2023 due to licensing agreements.

Rare diseases that are treated with so-called "orphan drugs" remain an important research focus for pharmaceutical and biotech companies. In the EU, almost 40% and in the US almost 60% of new registrations in 2018 are drugs for the treatment of such diseases. Expectations in this area assume an annual growth rate of 11% until 2024 and are thus almost twice as high as the growth of the overall pharmaceutical market.

The financing situation of small US biotech companies continues to be of great importance for the entire pharmaceutical industry against the background of the research projects and innovations they drive. In 2018, venture capital funding increased by almost 40% year-on-year, again reaching a record $ 16.8 billion. At the same time, despite the hoped-for positive effects from the US tax reform, the trend towards a declining number of company takeovers that has been observed for several years has continued. The reasons for this are, on the one hand, the availability of capital for startups, which can thus drive drug development independently for longer, and, on the other hand, high company valuations make acquisitions less attractive. Geo and trade policy uncertainties such as Brexit, the increasingly uncertain economic situation in China and ongoing drug price discussions in the USA also contributed to the reluctance. The only exception was the major acquisition of Shire by Takeda for 62 billion US dollars at the end of 2018. There were also no significant mergers and acquisitions in the aseptic contract manufacturing segment.

Sales development

In the 2018 financial year, we were able to increase sales by 6% to EUR 595 million under unchanged positive framework conditions. Our business areas in Commercial Manufacturing grew by around 2% and Development Service by 20%. The high increase in the Development Service area, which forms the basis of future commercial manufacturing sales, underpins our growth plans and confirms the ongoing trend towards specialized drugs. The diversification of our customer structure also continued in the past financial year and thus supports our solid business model.

Regulatory environment

As in previous years, the market segment relevant for Vetter in the area of aseptic filling of drugs was subject to increasing regulatory requirements in 2018. Despite the challenging environment, we were able to successfully complete all inspections by the authorities. Particularly noteworthy are the three US FDA inspections, two of which were completed with zero observations and one inspection with only one observation - this once again underlines our quality leadership.

Earnings situation

The earnings before interest and taxes of the Vetter Group developed disproportionately well compared to the previous year against the background of increasing expense items with moderate sales growth. Sales and earnings for the financial year are within or slightly above the forecast range. We therefore rate the overall development as still very satisfactory.

Financial position

In the past 2018 financial year, the balance sheet total again grew by around 16% to EUR 786 million.As in previous years, the expansion is primarily due to the investment strategy and the associated increase in fixed assets.

Liquidity / cash flow

The company's operating cash flow increased further on the basis of the positive business development in 2018. In contrast, the outflow of funds from investment activities rose again slightly compared to the previous year. All in all, these effects led to a negative free cash flow, which, however, was significantly lower than expected. The underlying investment projects in the past financial year mainly related to the expansion of our production capacities in Ravensburg.

Financing structure

The equity of the Vetter Group in the financial year amounted to EUR 313 million. In the course of the expansion of investments, the volume of liabilities to banks rose by around EUR 69 million to a total of EUR 316 million.

The Vetter Group's financing strategy aims to ensure long-term, solid corporate financing using various financing instruments. Borrowed capital is raised exclusively through the parent company. In addition to various long-term promotional loan commitments and promissory note loans, Vetter also has a syndicated credit line from 2017 with a remaining term until the end of March 2023, the utilization of which is less than a third at the end of the financial year, to implement further planned investment projects in the following years.

Use of financial derivatives

In the reporting year, Vetter only used derivative financial instruments to hedge currency and / or interest positions in order to minimize currency risks and financing costs caused by exchange rate and interest rate fluctuations. We use marketable currency forwards and interest rate swaps or interest rate caps as instruments. Such derivatives are used as part of our continuously monitored risk strategy, which also includes hedging measures in the medium and long term.

Research and Development

In addition to customer-specific process development as part of the customer projects of the Vetter Development Service, we are constantly developing our innovative packaging systems and internal processes. In addition, we are going with new formats in the area of innovation management, such as B. the Open Innovation Challenge (based on the Design Thinking methodology) new ways to identify future fields in the field of user-oriented drug injection.

Opportunities and risk report

The risk policy defined by the management is the basis for the actions of all those involved. The overriding principle of this policy is to take advantage of opportunities, but only to take the risks associated with business activity if added value is created for the company and the company's goals are not jeopardized.

The Vetter Group has established a group-wide risk management system for the early detection and proactive control of significant risks. The guidelines for risk management are defined company-wide in an overarching risk manual.

To assess and delimit the relevant risks, Vetter has developed a five-level relevance scale that shows possible negative effects on company results. As part of the risk aggregation, the individual risks assessed in this way can be combined and assessed to form an overall corporate risk. In the risk assessment carried out periodically at the end of 2018, no risks to the company's existence were identified. Furthermore, receiving a so-called "Warning Letter" from the FDA is the greatest risk for the Vetter Group. We counter this risk with the continuous development of our pharmaceutical quality and risk management,

Overall, the assessment of the current risk situation shows that there are no risks going beyond the general market and industry-typical influences that could jeopardize the continued existence of the company and that no future risks are currently discernible. The key criteria for the positive implementation of the strategy are the maintenance of the market position and the underlying reputation, the ability to innovate and the attractiveness of the employer. The demanding situation in the area of recruiting suitable personnel is one of the main challenges in the coming years.

Outlook for further development in 2019

Die Aussichten für die Entwicklung des globalen Pharmamarktes sind trotz Anzeichen einer Abkühlung des globalen Wirtschaftsklimas und einer damit erschwerten Prognostizierbarkeit weiterhin positiv. Bis 2023 wird ein globales Wachstum des Pharmamarktes im mittleren einstelligen Prozentbereich (ca. 3 % bis 6 %) erwartet, welches vor allem durch Produktinnovationen in den USA und Volumenwachstum in den Schwellenländern getrieben wird. Von den über 50 erwarteten Neuzulassungen pro Jahr, wird der Anteil an biologischen Wirkstoffen (zumeist Parenteralia), Orphan Drugs und Krebsmedikamenten ansteigen. Die gute Finanzierungssituation der kleinen Biotechfirmen, Gewinnzuwächse der großen Pharmafirmen und eine nachhaltige Innovationsförderung der FDA schaffen unverändert günstige Rahmenbedingungen für die Entwicklung innovativer Medikamente. Die Marktentwicklung in der Pharmabranche wird auch weiterhin durch die demographische Entwicklung, den ungebrochenen Trend zu Spezialmedikamenten (viele davon Injektabilia), sowie zu immer mehr personalisierten und digitalisierten Arzneimittelanwendungen gestützt. Der Regierungsstillstand in den USA Anfang 2019 könnte jedoch zu einer Verlangsamung der US-Wirtschaft und zu einer Verschiebung von FDA-Neuzulassungen ins Folgejahr führen. Eine der größten Herausforderungen wird der zunehmende Druck von Kostenträgern und Patienten auf die Preisgestaltung sein, so dass Preistransparenz, Kosten-Nutzenanalysen und neue Erstattungsmodelle (z. B. für Gen- und Zelltherapien) verstärkte Bedeutung erhalten werden. Die Auswirkungen der Patentausläufe von biologischen Präparaten im Vergleich zu kleinen Molekülen werden kurz- bis mittelfristig als moderat eingeschätzt, vor allem in den USA liegt die Marktdurchdringung von Biosimilars noch hinter der Entwicklung in Europa zurück. Die kontinuierliche Ausrichtung zu einem kleinvolumigen, hochwertigen Produkt-Modell, die Konzentration auf Kerntherapiegebiete und Fokussierung der Ressourcen auf Spezialmedikamente und „Orphan Drugs“ setzen sich unverändert fort.

Vetter‘s Marktsituation hängt erheblich von den Aktivitäten und der Leistungsfähigkeit der Pharma- und Biotechnologie-Unternehmen ab. Hier zeichnen sich folgende Trends für 2019 ab:

Im Bereich der Arzneimittelinnovationen wird sich die Entwicklung weiterhin auf biotechnologisch hergestellte Medikamente fokussieren, so dass deren Umsatzanteil bei den Top 100 Produkten voraussichtlich auf 52 % in 2024 ansteigen wird. Hierbei werden Krebstherapien wie in den Vorjahren den größten Umsatz erwirtschaften, gefolgt von Therapien zur Behandlung von Diabetes, Rheuma und Impfstoffen. Für die in letzter Zeit vermehrt auftretende Lebererkrankung NASH, die u. a. durch Adipositas und Diabetes verursacht wird und derzeit noch nicht medikamentös behandelt werden kann, wird in den nächsten Jahren ein großes Marktpotential für neue Arzneimittel erwartet.

In 2019 wird sich der Trend zu Akquisitionen mit kleinerem Transaktionsumfang fortsetzen, darunter bevorzugt in den Therapiegebieten Onkologie und seltene Erkrankungen. Für den Fall des Eintretens eines wirtschaftlichen Abschwungs in 2019 könnten M&A Transaktionen für Käufer wieder attraktiver werden. Vor allem US-Biotechunternehmen, Firmen die Orphan Drugs, Zell- und Gentherapien oder digitale Geschäftsmodelle entwickeln und Ausgründungen von großen Pharmafirmen dürften als Übernahmekandidaten auf besonderes Interesse stoßen.

Der Markt für Lohnherstellung wird auch in 2019 weiterwachsen, wobei für innovationsgetriebene aseptische CDMOs nach wie vor bessere Entwicklungschancen erwartet werden als für kapazitätsgetriebene Lohnhersteller. Eine wirtschaftliche Abkühlung könnte sich durch verstärktes Outsourcing positiv für CDMOs auswirken, wohingegen ein starker Rückgang der Risikokapitalfinanzierungen zu einem Volumenrückgang bei der Klinikproduktion führen könnte, wenn Biotechfirmen ihre Ressourcen auf die Entwicklung der erfolgversprechendsten Pipelinekandidaten konzentrieren. Durch den Trend zu kleinvolumigen Spezialprodukten, die Investition der großen Pharma- und Biotechfirmen in eigene Produktionsanlagen, die zunehmende Kostenbelastung der Gesundheitssysteme und die hohen Anforderungen der regulatorischen Behörden wird die Branche unter hohem Wettbewerbsdruck bleiben.

Against this background, we will maintain our high investment volume in 2019 and also increasingly advance the digitization of our company processes. We expect growth with an increase in sales and operating income in the single-digit percentage range.

Ravensburg, March 15, 2019

The Board

signed Oliver Albrecht, Managing Director

signed Thomas Otto, Managing Director

signed Peter Sölkner, Managing Director
