

## **Azanta Danmark A/S**

Gearhalsvej 1

DK-2500 Valby

Central Business Registration No  
25260279

## **Annual report 2019**

The Annual General Meeting adopted the annual report on 12.05.2020

### **Chairman of the General Meeting**

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Name: Thomas Gjør-Trønning

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## Entity details

### Entity

Azanta Danmark A/S  
Gearhalsvej 1  
DK-2500 Valby

Central Business Registration No: 25260279

Registered in: Valby

Financial year: 01.01.2019 - 31.12.2019

### Board of Directors

David Carl Christian von Kauffmann, Chairman  
Christian Gunni Pedersen  
Jens Munch-Hansen

### Executive Board

Gitte Nøhr Ludvig , Managing Director

### Auditors

Deloitte Statsautoriseret Revisionspartnerselskab  
Weidekampsgade 6  
Postboks 1600  
0900 København C

## Statement by Management on the annual report

The Board of Directors and the Executive Board have today considered and approved the annual report of Azanta Danmark A/S for the financial year 01.01.2019 - 31.12.2019.

The annual report is presented in accordance with the Danish Financial Statements Act.

In our opinion, the financial statements give a true and fair view of the Entity's financial position at 31.12.2019 and of the results of its operations for the financial year 01.01.2019 - 31.12.2019.

We believe that the management commentary contains a fair review of the affairs and conditions referred to therein.

We recommend the annual report for adoption at the Annual General Meeting.

Copenhagen, 20.03.2020

### Executive Board

Gitte Nøhr Ludvig  
Managing Director

### Board of Directors

David Carl Christian von  
Kauffmann  
Chairman

Christian Gunni Pedersen

Jens Munch-Hansen

# Independent auditor's report

## To the shareholders of Azanta Danmark A/S

### Opinion

We have audited the financial statements of Azanta Danmark A/S for the financial year 01.01.2019 - 31.12.2019, which comprise the income statement, balance sheet, statement of changes in equity and notes, including a summary of significant accounting policies. The financial statements are prepared in accordance with the Danish Financial Statements Act.

In our opinion, the financial statements give a true and fair view of the Entity's financial position at 31.12.2019 and of the results of its operations for the financial year 01.01.2019 - 31.12.2019 in accordance with the Danish Financial Statements Act.

### Basis for opinion

We conducted our audit in accordance with International Standards on Auditing (ISAs) and additional requirements applicable in Denmark. Our responsibilities under those standards and requirements are further described in the Auditor's responsibilities for the audit of the financial statements section of this auditor's report. We are independent of the Entity in accordance with the International Ethics Standards Board of Accountants' Code of Ethics for Professional Accountants (IESBA Code) and the additional requirements applicable in Denmark, and we have fulfilled our other ethical responsibilities in accordance with these requirements. We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our opinion.

### Management's responsibilities for the financial statements

Management is responsible for the preparation of financial statements that give a true and fair view in accordance with the Danish Financial Statements Act, and for such internal control as Management determines is necessary to enable the preparation of financial statements that are free from material misstatement, whether due to fraud or error.

In preparing the financial statements, Management is responsible for assessing the Entity's ability to continue as a going concern, for disclosing, as applicable, matters related to going concern, and for using the going concern basis of accounting in preparing the financial statements unless Management either intends to liquidate the Entity or to cease operations, or has no realistic alternative but to do so.

### Auditor's responsibilities for the audit of the financial statements

Our objectives are to obtain reasonable assurance about whether the financial statements as a whole are free from material misstatement, whether due to fraud or error, and to issue an auditor's report that includes our opinion. Reasonable assurance is a high level of assurance, but is not a guarantee that an audit conducted in accordance with ISAs and the additional requirements applicable in Denmark will always detect a material misstatement when it exists. Misstatements can arise from fraud or error and are considered material if, individually or in the aggregate, they could reasonably be expected to influence the economic decisions of users taken on the basis of these financial statements.

As part of an audit conducted in accordance with ISAs and the additional requirements applicable in Denmark, we exercise professional judgement and maintain professional scepticism throughout the audit. We also:

## Independent auditor's report

- Identify and assess the risks of material misstatement of the financial statements, whether due to fraud or error, design and perform audit procedures responsive to those risks, and obtain audit evidence that is sufficient and appropriate to provide a basis for our opinion. The risk of not detecting a material misstatement resulting from fraud is higher than for one resulting from error, as fraud may involve collusion, forgery, intentional omissions, misrepresentations, or the override of internal control.
- Obtain an understanding of internal control relevant to the audit in order to design audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Entity's internal control.
- Evaluate the appropriateness of accounting policies used and the reasonableness of accounting estimates and related disclosures made by Management.
- Conclude on the appropriateness of Management's use of the going concern basis of accounting in preparing the financial statements, and, based on the audit evidence obtained, whether a material uncertainty exists related to events or conditions that may cast significant doubt on the Entity's ability to continue as a going concern. If we conclude that a material uncertainty exists, we are required to draw attention in our auditor's report to the related disclosures in the financial statements or, if such disclosures are inadequate, to modify our opinion. Our conclusions are based on the audit evidence obtained up to the date of our auditor's report. However, future events or conditions may cause the Entity to cease to continue as a going concern.
- Evaluate the overall presentation, structure and content of the financial statements, including the disclosures in the notes, and whether the financial statements represent the underlying transactions and events in a manner that gives a true and fair view.

We communicate with those charged with governance regarding, among other matters, the planned scope and timing of the audit and significant audit findings, including any significant deficiencies in internal control that we identify during our audit.

### Statement on the management commentary

Management is responsible for the management commentary.

Our opinion on the financial statements does not cover the management commentary, and we do not express any form of assurance conclusion thereon.

In connection with our audit of the financial statements, our responsibility is to read the management commentary and, in doing so, consider whether the management commentary is materially inconsistent with the financial statements or our knowledge obtained in the audit or otherwise appears to be materially misstated.

Moreover, it is our responsibility to consider whether the management commentary provides the information required under the Danish Financial Statements Act.

## Independent auditor's report

Based on the work we have performed, we conclude that the management commentary is in accordance with the financial statements and has been prepared in accordance with the requirements of the Danish Financial Statements Act. We did not identify any material misstatement of the management commentary.

Copenhagen, 20.03.2020

### **Deloitte**

Statsautoriseret Revisionspartnerselskab

Central Business Registration No: 33963556

Jens Sejer Pedersen

State Authorised Public Accountant

Identification number (MNE) mne14986

## Management commentary

### Primary activities

Azanta Danmark A/S ("Azanta Danmark") is a privately-owned specialty pharmaceutical company primarily operating within obstetrics, women's healthcare, addiction medicine and oncology.

### Development in activities and finances

Revenue increased from DKK 35.9 million in 2018 to DKK 43.0 million in 2019. The growth was primarily driven by the satisfactory market-uptake of the Company's lead product, Angusta, in the Nordics and France.

In 2019 the Company generated a net profit of DKK 3.7 million compared with a net profit in 2018 of DKK 2.8 million. The net result is viewed to be satisfactory.

As at 31<sup>st</sup> December the Company shareholder capital and equity reserves amounted to DKK 65.3 million. The Company's total balance as at 31<sup>st</sup> December 2019 was DKK 73.5 million. The Company's cash balance by the end of 2019 was DKK 7.8 million.

In 2020 the Company expect to experience continued increased market uptake of Angusta in the Nordics and France. Thus, after 2 years of having invested in launching Angusta in these two markets the Company expect those two markets to be profitable in 2020 and beyond.

Based on the expected positive cash flow from operations and the Company's availability to additional funding, the management has prepared the consolidated financial statements for 2019 on the basis of going concern.

### Development Projects

#### Angusta®

Angusta® is a 25 micrograms misoprostol tablet for oral administration developed for induction of labour. Angusta® has been available on a Named Patient Use Program under special authorization in Denmark, Norway and Finland since 2013. In Q1 2017, Angusta® was granted Marketing Authorization in the Nordic countries (Denmark, Sweden, Norway, Finland and Iceland).

In December 2017, Regulatory Authorization was granted for Angusta® in France and 10 countries in Central Eastern Europe (Latvia, Estonia, Poland, Romania, Bulgaria, Czech Republic, Slovakia, Hungary, Slovenia, Croatia) via a Mutual Recognition Procedure (MRP). Market Access Authorization in France was granted in April 2018.

Marketing approval of Angusta® in other European countries as well as in North America will be pursued in 2020 and beyond.

#### Nimoral™

Nimoral™, a hypoxic radiosensitizer used in treatment of H&N cancer is in late stage development.



## Management commentary

Nimoral™ is available on Name Patient Use Program in Denmark since 2011 and in Norway since 2015.

### Outlook

In 2020, Azanta Danmark will continue the market launch of Angusta® in the Nordic countries and in France. The Company is also working on launching Angusta® Central Eastern Europe with a partner. With an increasing market take-up of Angusta®, the Company expects a continued positive development.

Further, Azanta will in 2020 be working on finding the best partner(s) with whom to launch Angusta in the remaining EU countries.

### Events after the balance sheet date

No events have occurred in the period from the balance sheet date until the presentation of the financial statements that materially affects the assessment of the Annual Report.

## Income statement for 2019

	<b>Notes</b>	<b>2019 DKK'000</b>	<b>2018 DKK'000</b>
Revenue		42.979	35.870
Cost of sales		-7.701	-7.624
Other external expenses		-25.478	-18.222
<b>Gross profit/loss</b>		<b>9.800</b>	<b>10.024</b>
Staff costs	1	-8.154	-8.975
<b>Operating profit/loss</b>		<b>1.646</b>	<b>1.049</b>
Other financial income	2	2.158	2.378
Other financial expenses	3	-108	-585
<b>Profit/loss for the year</b>		<b>3.696</b>	<b>2.842</b>
<b>Proposed distribution of profit/loss</b>			
Retained earnings		3.696	2.842
		<b>3.696</b>	<b>2.842</b>

## Balance sheet at 31.12.2019

	<u>Notes</u>	<u>2019 DKK'000</u>	<u>2018 DKK'000</u>
Receivables from group enterprises		<u>54.283</u>	<u>45.094</u>
<b>Fixed asset investments</b>	4	<u><b>54.283</b></u>	<u><b>45.094</b></u>
<b>Fixed assets</b>		<u><b>54.283</b></u>	<u><b>45.094</b></u>
Manufactured goods and goods for resale		<u>3.317</u>	<u>8.215</u>
<b>Inventories</b>		<u><b>3.317</b></u>	<u><b>8.215</b></u>
Trade receivables		7.857	7.102
Receivables from group enterprises		0	653
Prepayments		<u>230</u>	<u>335</u>
<b>Receivables</b>		<u><b>8.087</b></u>	<u><b>8.090</b></u>
<b>Cash</b>		<u><b>7.775</b></u>	<u><b>7.274</b></u>
<b>Current assets</b>		<u><b>19.179</b></u>	<u><b>23.579</b></u>
<b>Assets</b>		<u><b>73.462</b></u>	<u><b>68.673</b></u>

## Balance sheet at 31.12.2019

	<b>Notes</b>	<b>2019 DKK'000</b>	<b>2018 DKK'000</b>
Contributed capital	5	2.134	2.134
Retained earnings		63.147	59.451
<b>Equity</b>		<b>65.281</b>	<b>61.585</b>
Trade payables		1.079	0
Payables to group enterprises		3.209	4.812
Other payables		3.893	2.276
<b>Current liabilities other than provisions</b>		<b>8.181</b>	<b>7.088</b>
<b>Liabilities other than provisions</b>		<b>8.181</b>	<b>7.088</b>
<b>Equity and liabilities</b>		<b>73.462</b>	<b>68.673</b>
Contingent liabilities	6		

## Statement of changes in equity for 2019

	<b>Contributed capital DKK'000</b>	<b>Retained earnings DKK'000</b>	<b>Total DKK'000</b>
Equity beginning of year	2.134	59.451	61.585
Profit/loss for the year	0	3.696	3.696
<b>Equity end of year</b>	<b>2.134</b>	<b>63.147</b>	<b>65.281</b>

## Notes

	<b>2019</b>	<b>2018</b>
	<b>DKK'000</b>	<b>DKK'000</b>
<b>1. Staff costs</b>		
Wages and salaries	7.024	8.768
Pension costs	1.069	199
Other social security costs	7	7
Other staff costs	54	1
	<b>8.154</b>	<b>8.975</b>
 Average number of employees	 <b>6</b>	 <b>6</b>

	<b>2019</b>	<b>2018</b>
	<b>DKK'000</b>	<b>DKK'000</b>
<b>2. Other financial income</b>		
Financial income arising from group enterprises	2.105	2.378
Exchange rate adjustments	53	0
	<b>2.158</b>	<b>2.378</b>

	<b>2019</b>	<b>2018</b>
	<b>DKK'000</b>	<b>DKK'000</b>
<b>3. Other financial expenses</b>		
Interest expenses	1	95
Exchange rate adjustments	83	94
Other financial expenses	24	396
	<b>108</b>	<b>585</b>

	<b>Receivables from group enterprises DKK'000</b>
<b>4. Fixed asset investments</b>	
Cost beginning of year	45.094
Additions	25.942
Disposals	-16.753
<b>Cost end of year</b>	<b>54.283</b>
 <b>Carrying amount end of year</b>	 <b>54.283</b>

## Notes

	<b>Number</b>	<b>Par value DKK'000</b>	<b>Nominal value DKK'000</b>
<b>5. Contributed capital</b>			
Ordinary shares	2.134.051	1	2.134
	<b>2.134.051</b>		<b>2.134</b>

### 6. Contingent liabilities

The Entity participates in a Danish joint taxation arrangement in which Azanta A/S serves as the administration company. According to the joint taxation provisions of the Danish Corporation Tax Act, the Entity is therefore liable for income taxes etc. for the jointly taxed entities, and for obligations, if any, relating to the withholding of tax on interest, royalties and dividend for the jointly taxed entities. The total known net liability of the jointly taxed entities under the joint taxation arrangement is evident from the administration company's financial statements.

## Accounting policies

### Reporting class

This annual report has been presented in accordance with the provisions of the Danish Financial Statements Act governing reporting class B enterprises with addition of certain provisions for reporting class C.

The accounting policies applied to these financial statements are consistent with those applied last year.

### Recognition and measurement

Assets are recognised in the balance sheet when it is probable as a result of a prior event that future economic benefits will flow to the Entity, and the value of the asset can be measured reliably.

Liabilities are recognised in the balance sheet when the Entity has a legal or constructive obligation as a result of a prior event, and it is probable that future economic benefits will flow out of the Entity, and the value of the liability can be measured reliably.

On initial recognition, assets and liabilities are measured at cost. Measurement subsequent to initial recognition is effected as described below for each financial statement item.

Anticipated risks and losses that arise before the time of presentation of the annual report and that confirm or invalidate affairs and conditions existing at the balance sheet date are considered at recognition and measurement.

Income is recognised in the income statement when earned, whereas costs are recognised by the amounts attributable to this financial year.

### Foreign currency translation

On initial recognition, foreign currency transactions are translated applying the exchange rate at the transaction date. Receivables, payables and other monetary items denominated in foreign currencies that have not been settled at the balance sheet date are translated using the exchange rate at the balance sheet date. Exchange differences that arise between the rate at the transaction date and the rate in effect at the payment date, or the rate at the balance sheet date are recognised in the income statement as financial income or financial expenses. Property, plant and equipment, inventories and other non-monetary assets that have been purchased in foreign currencies are translated using historical rates.

### Income statement

#### Revenue

Revenue from the sale of manufactured goods and goods for resale is recognised in the income statement when delivery is made and risk has passed to the buyer.

Revenue from the sale of services is recognised in the income statement when delivery is made to the buyer. Revenue is recognised net of VAT, duties and sales discounts and is measured at fair value of the consideration fixed.



## Accounting policies

### Cost of sales

Cost of sales comprises goods consumed in the financial year measured at cost, adjusted for ordinary inventory write-downs.

### Other external expenses

Other external expenses include expenses relating to the Entity's ordinary activities, including expenses for premises, stationery and office supplies, marketing costs, etc. This item also includes write-downs of receivables recognised in current assets.

### Staff costs

Staff costs comprise salaries and wages as well as social security contributions, pension contributions, etc. for entity staff.

### Other financial income

Other financial income comprises dividends etc. received on other investments, interest income, including interest income on receivables from group enterprises, net capital gains on securities, payables and transactions in foreign currencies, amortisation of financial assets as well as tax relief under the Danish Tax Prepayment Scheme etc.

### Other financial expenses

Other financial expenses comprise interest expenses, including interest expenses on payables to group enterprises, net capital losses on securities, payables and transactions in foreign currencies, amortisation of financial liabilities as well as tax surcharge under the Danish Tax Prepayment Scheme etc.

### Balance sheet

#### Receivables

Receivables are measured at amortised cost, usually equalling nominal value less write-downs for bad and doubtful debts.

#### Inventories

Inventories are measured at the lower of cost using the FIFO method and net realisable value.

Cost consists of purchase price plus delivery costs. Cost of manufactured goods and work in progress consists of costs of raw materials, consumables, direct labour costs and indirect production costs.

The net realisable value of inventories is calculated as the estimated selling price less completion costs and costs incurred to execute sale.

#### Prepayments

Prepayments comprise incurred costs relating to subsequent financial years. Prepayments are measured at cost.

#### Cash

Cash comprises cash in hand and bank deposits.

## Accounting policies

### Other financial liabilities

Other financial liabilities are measured at amortised cost, which usually corresponds to nominal value.