

Annual report

Fiscal year 2021-01-01-2021-12-31



OnDosis AB (publ)

559113-1825

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NOTE: This is an English translation of the original version in Swedish. In case of any discrepancy, the Swedish version shall prevail.

CEO comments

In Q4 2021 the OnDosis Dosage Manager was combined with active medicines (pellets) and digital applications for the first time. Prior to this significant milestone important progress was made; final design freeze of the device, scale-up of pellet manufacturing towards clinical studies, and initialization of development of digital applications to support parents with children diagnosed with ADHD. These critical activities were executed in collaboration with Tiefenbacher group in Hamburg and are all steps on the path towards the FDA submission for the drug/device combination, followed by the market introduction in the US for this, the first treatment built on OnDosis unique device technology.

Four years after the foundation of OnDosis, at the time with a clear idea in mind on a new way to dose medicines, we are now in a position where the route to market is laid out and where the plans for next stages of development are more robust through dialogue with FDA and our partners.

With a growing portfolio of development projects together with Tiefenbacher, now totally five within three disease areas, we have a solid platform for continued expansion of our portfolio of collaborations and business opportunities. We have solidified the control over our company journey, and we have a more discussions with potential partners on the opportunity to combine the Dosage Manager with medicines than ever before. Both for medicines under development and medicines already on the market. A non-binding term sheet for a license agreement for a novel therapy with an UK based biotech was signed in December. Feasibility studies for a leading US based Pharma was initiated during the year, with several additional feasibilities in plan for 2022 with several major Pharma companies.

The OnDosis team was strengthened throughout 2021, from four to twelve employees. We transferred all development activities “in-house” and onto our Quality Management System. We will continue the path of building internal capabilities and know-how in core areas, whilst tapping into specific skill sets through a trusted network of external experts.

In 2022, we are aiming to reach several key milestones; the objective is to close a term sheet with a commercialisation partner for ADHD in US. Tiefenbacher is leading this activity on behalf of the collaboration. We aim for being ready for pivotal bioequivalence studies by year end and will deliver serial GMP manufactured devices for this study during autumn. The digital App and service will be developed and ready for first testing, with parents with children with ADHD. We will also focus on continue to grow the portfolio of collaborations, primarily with originator companies.

On a personal note 2021 was a truly inspiring year in a company that evolves and a team that strengthens. It was also a year with challenges. Society went through a tough period in general, and the impact from the pandemic for the company was manifested through supply chain challenges and scarcity of components. By acting early and turning every stone, the team has been successful in minimizing the impact as far as possible.

The progress achieved is a result of a professional team with incredible drive and passion, combined with shareholders that show strong support to the company and a board of directors that continuously balances challenge and support to the team as required to progress the business. These foundations are essential for our ambition to revolutionize in how patients take their medicines.

Mölnådal, March 2nd 2022



Martin Olovsson
CEO

Administration report

The Board of Directors and the CEO of OnDosis AB (publ), and based in Gothenburg, with corporate identity number 559113-1825 hereby present the company's Annual Report for the financial year 2021-01-01 to 2021-12-31.

General information about the business

OnDosis is a life science company focused on product development and business development. OnDosis' is currently focused on the development of a new category of device and platform, Dosage Manager. OnDosis is building patent pending dosing technologies for oral solid drugs formulated as granules, mini-tablets or powders. OnDosis' brings together expertise in pharmaceutical formulation, development of medical technology and digital health with the aim of launching an integrated "Closed Loop Disease Management" technology for a number of disease areas that require flexible and/or individualized dosing.



OnDosis is collaborating with leading pharmaceutical companies to develop combination products where OnDosis is responsible for developing the device and digital platform and the pharmaceutical companies are responsible for developing the drugs and the commercialization of the combination products.

Largest shareholders

Owners with more than 10% of the shares and votes as of 31 December 2021.

AstraZeneca AB	19.9 %
Martin Olovsson	15.8 %
Aeternum Management	12.4 %
DIG Investment Group	10.9 %

Significant events during the financial year

At the Extraordinary General Meeting, on 28 April 2021, new Articles of Association, a share issue increasing the number of shares to 100,000 and increasing the share capital to 500,000 SEK and OnDosis AB becoming a public company were all approved.

On 5 May 2021 the Board decided to issue new shares which increased the number of shares by 23,269 and raised 92.0 million SEK before issue costs. At the same time, it was decided to convert the convertible issued in the fourth quarter of 2020 amounting to SEK 32.4 million before interest. The number of shares was increased by 11,295 which increased the number of shares at the end of the year to 134,564.

At the Annual General Meeting, on 5 June 2021, new Articles of Association which converted all shares into ordinary shares were approved and Anders Tuv was elected as a board member replacing Jan Pilebjer.

The company has been affiliated with Euroclear since October 2021.

During the first quarter of 2021 a cooperation agreement was signed with Tiefenbacher group, Germany, for the development of 4 new products, in addition to the 2020 agreement for the product for the treatment of ADHD.

Pilot studies were initiated with placebo and active substance with a leading US based pharmaceutical company during the third quarter.

A non-binding agreement for the licensing of OnDosis Dosage Manager was signed during the fourth quarter with a UK biotechnology company for a new type of treatment.

OnDosis accelerated the building of its own organization, with a focus on product development, and grew from 4 to 12 employees during the year.

Agreements were reached with contract manufacturers for commercial production during the fourth quarter, and meetings were held with the FDA to confirm the company's development plan is in line with the authorities' expectations.

Significant events after the end of the period

On 25 January an Extraordinary General Meeting decided to issue new shares amounting to 75 million SEK which was oversubscribed during February.

OnDosis employed 4 more people, within product development, bringing the total number of employees to 16.

OnDosis agreed to start pilot studies with four major pharmaceutical companies during the year.

Risk factors

OnDosis is developing a device technology that is the first of its kind. The company is in dialogue with the relevant authorities and follows relevant guidelines for development work. However, there is no guarantee that the authorities will approve OnDosis' product. Requirements and wishes may be raised during the review process that may lead to a delay in market introduction.

OnDosis' business model is based on out licensing to, and partnerships with, pharmaceutical companies. It will be the pharmaceutical companies that ultimately launch products based on OnDosis' technology on to the market which means that future revenues will be linked to the success of these partners in the market.

Transactions with related parties

OnDosis has an ongoing agreement with GU Ventures AB, which handles the company's accounting and administration, as well as with AstraZeneca for renting premises at "BioVenture Hub" in Mölndal. The transactions are on market terms.

Multi-year overview

Development of the company's operations, profit/loss and position	2021-12-31	2020-12-31	2019-12-31
Net sales (kSEK)	156	854	4 540
Operating profit/loss (kSEK)	-23 666	-10 165	-7 243
Profit/loss for the year (kSEK)	-24 449	-10 581	-7 264
Earnings per share (kSEK)	-0,18	-1,06	-0,73
Equity (kSEK)	140 641	76 833	53 047
Equity/assets ratio %	94	91	93
Cash flow for the year (kSEK)	44 185	10 240	-4 732
Cash and bank balances (kSEK)	78 721	34 536	24 296
Number of shares	134 564	10 000	10 000
Number of employees	12	4	3

Statement of changes in equity

Amounts in SEK	Share capital	Development expenditure fund	Share premium fund	Retained earnings	Profit/loss for the year
Opening balance	50 000	49 196 241	32 839 902	5 328 672	-10 581 413
New share issue	622 820		92 482 860	-450 000	
Fund raising costs			-4 599 382		
Options				200 000	
Transfer of profit/loss from previous year				-10 581 413	10 581 413
Internal equity transfers		19 110 482		-19 110 482	
Profit/loss for the period					-24 448 509
Closing balance	672 820	68 306 723	120 723 380	-24 613 223	-24 448 509

Proposed appropriations of the company's profit or loss

The Board of Directors and the Chief Executive Officer of OnDosis AB propose that available profits, SEK 71 661 648, be distributed as follows:

	SEK
To be carried forward	71 661 648
Total	71 661 648

The financial result and position of the company in general is set out in the income statement and balance sheet below, together with the notes to the accounts.

Income statement

SEK	Notes	2021-01-01 2021-12-31	2020-01-01 2020-12-31
Net sales		155 997	854 311
Own work capitalised		19 110 482	19 382 038
Other operating income		29 970	86 003
Total operating income		19 296 449	20 322 352
Costs			
Other external expenses		-30 968 172	-26 650 497
Employee benefit expenses	2	-11 925 225	-3 422 389
Depreciation/amortisation and impairment of property, plant and equipment and intangible fixed assets		-	-
Other operating expenses	3	-68 746	-414 841
Total operating expenses		-42 962 143	-30 487 727
Operating profit/loss		-23 665 694	-10 165 375
Financial items			
Financial income		-	-
Finance costs		-782 815	-416 038
Total financial items		-782 815	-416 038
Profit/loss after financial items		-24 448 509	-10 581 413
Tax on profit for the period	4	-	-
Profit/loss for the period		-24 448 509	-10 581 413

Balance sheet

SEK	Notes	2021-12-31	2020-12-31
Assets			
Non-current assets			
<i>Intangible non-current assets</i>			
Capitalised expenditure for development and similar	5	68 306 723	49 196 241
Total intangible non-current assets		68 306 723	49 196 241
Financial non-current assets			
Shares in group companies	6	50 000	50 000
Total non-current assets		68 356 723	49 246 241
Current assets			
Trade receivables		46 326	-
Other receivables		2 581 272	347 807
Prepaid expenses and accrued income		67 217	112 856
		2 694 815	460 663
Cash and bank balances		78 720 551	34 535 865
Total current assets		81 415 366	34 996 528
TOTAL ASSETS		149 772 089	84 242 769

Balance sheet

SEK	Notes	2021-12-31	2020-12-31
EQUITY AND LIABILITIES			
<i>Equity</i>			
<i>Restricted equity</i>			
Share capital		672 820	50 000
Development expenditure fund		68 306 723	49 196 241
		68 979 543	49 246 241
<i>Unrestricted equity</i>			
Share premium fund		120 723 380	32 839 902
Retained earnings		-24 613 223	5 328 672
Profit/loss for the period		-24 448 509	-10 581 413
		71 661 648	27 587 161
Total equity		140 641 191	76 833 402
<i>Non-current liabilities</i>			
	7		
Liabilities to credit institution		1 285 714	2 142 857
Total non-current liabilities		1 285 714	2 142 857
<i>Current liabilities</i>			
Liabilities to credit institution		857 143	857 143
Trade payables		4 151 069	860 241
Other current liabilities		696 673	220 236
Accrued expenses and deferred income		2 140 299	3 328 890
Total current liabilities		7 845 184	5 266 510
TOTAL EQUITY AND LIABILITIES		149 772 089	84 242 769

Statement of cash flows

SEK	2021-01-01	2020-01-01
	2021-12-31	2020-12-31
Cash flow from operating activities		
Operating profit/loss after financial items	-24 448 509	-10 581 413
<i>Adjustment for non-cash items</i>		
Depreciation/amortisation and impairments	-	-
Cash flow from operating activities before changes in working capital	-24 448 509	-10 581 413
<i>Cash flow from changes in working capital</i>		
Increase (-)/decrease (+) in operating receivables	-2 234 152	2 754 760
Increase (+)/decrease (-) in operating liabilities	2 578 674	80 215
Cash flow from operating activities	-24 103 987	-7 746 438
Cash flow from investing activities		
Investments in intangible non-current assets	-19 110 482	-19 382 037
Cash flow from investing activities	-19 110 482	-19 382 037
Cash flow from financing activities		
New share issue	92 655 680	32 839 902
Options	200 000	200 000
Costs for new share issue	-4 599 382	-1 500 000
Shareholders' contribution received	-	2 828 385
Borrowings (+)/repayment of debt (-)	-857 143	3 000 000
Cash flow from financing activities	87 399 155	37 368 287
Cash flow for the period	44 184 686	10 239 812
Cash and cash equivalents at beginning of period	34 535 865	24 296 053
Cash and cash equivalents at end of period	78 720 551	34 535 865

Notes

Note 1 Accounting policies

All amounts in SEK unless otherwise specified.

General accounting policies

This annual report is prepared in accordance with the Swedish Annual Accounts Act and pursuant to the general recommendations of the Swedish Accounting Standards board BFNAR 2012:1 Annual accounts and consolidated financial statements (K3).

Consolidated financial statements

OnDosis AB is the parent company of OnDosis Options AB. The company does not prepare consolidated accounts as the subsidiary is of minor importance according to 7 kap. 3§ ÅRL.

Valuation policies, etc.

Assets, provisions and liabilities are measured at cost unless otherwise specified below.

Research and development costs

Development costs are recognized according to the capitalization model. That means expenditures arising during the development phase are reported as assets when all the following prerequisites are met:

- It is technically possible to complete the intangible fixed asset for use or sale.
- The intention is to complete the intangible fixed asset and to use it or sell it.
- There are prerequisites for using or selling the intangible fixed asset.
- It is likely that the intangible fixed asset will generate future economic benefits.
- Sufficient and adequate technological financial and other resources are available to complete the development and use or sell the intangible asset.
- The costs that are attributable to the intangible asset can be calculated reliably.

Other intangible fixed assets

Other intangible fixed assets acquired by the Company are recognized at cost less accumulated amortization and impairment losses.

Expenses for internally generated goodwill and brands are reported in the income statement as an expense when they arise.

Amortization

Amortization is recognized on a straight-line basis over the asset's estimated useful life, and as an expense in the income statement. No amortizations have been recorded during the year. Amortization will be recognized when the products are commercialized.

Depreciation – intangible assets

At each balance sheet date, an assessment is made as to whether there is any indication that an asset value is lower than its carrying amount. If such an indication exists, the asset's recoverable amount is calculated.

The recoverable amount is the highest of the fair value less costs to sell and the value in use. The value in use is calculated as the present value of future cash flows that the asset is expected to generate in the operating activities as well as when it is sold or scrapped. The discount rate applied is before tax and reflects assessments, based on market conditions, of the time value of money and the risks associated with the asset. An impairment loss recognized in prior periods is only reversed if there has been a change

in the estimates used to determine the asset's recoverable amount since the last recognition of impairment loss.

Revenue

The inflow of financial benefits that the company has received or will receive for its own account is reported as income. Revenue is valued at the fair value of what has been received. Sub-invoiced development expenses are reported as a reduction in the asset's acquisition value.

Note 2 Employees

Average number of employees

	2021-01-01- 2021-12-31	2020-01-01- 2020-12-31
Total	9	4
	9	4

Note 3 Other operating expenses

	2021-01-01- 2021-12-31	2020-01-01- 2020-12-31
Exchange rate losses	68 746	414 841

Note 4 Tax on profit for the period

	2021-01-01- 2021-12-31	2020-01-01- 2020-12-31
Current tax for the year	-	-

Total unutilized tax deficits amount to SEK 48,523,840.

Note 5 Capitalized expenditure for development work

	2021-12-31	2020-12-31
<i>Accumulated acquisition values</i>		
- Beginning of the year	59 504 874	39 725 135
- Capitalized during the year	19 349 088	19 779 739
At the end of the year	78 853 962	59 504 874
<i>Accumulated contributions</i>		
- Beginning of the year	-10 308 633	-9 910 931
- Contribution against the capitalised expenditure	-238 606	-397 702
At the end of the year	-10 547 239	-10 308 633
Accounted values at end of the year	68 306 723	49 196 241

Note 6 Shares in group companies

	2021-12-31	2020-12-31
<i>Accumulated acquisition values</i>		
- Beginning of the year	50 000	50 000
Accounted values at end of the year	50 000	50 000

Specification of the parent company's holdings of shares and participations in group companies

The ownership share of the capital is referred to, which also corresponds to the share of the votes for total.

<i>Subsidiary/Org.numbeerr/Residence</i>	<i>Number of shares</i>	<i>Ownership in %</i>
OnDosis Options AB, 559201-2131, Gothenburg	50 000	100

Note 7 Non-current liabilities

	2021-12-31	2020-12-31
Liabilities that fall due later than five years from the balance sheet date	-	-

Note 8 Pledged assets and contingent liabilities

	2021-12-31	2020-12-31
Pledged assets	3 000 000	3 000 000
Contingent liabilities	None	None

Note 9 Significant events after the balance sheet date

Apart from what appears from the administration report, there are no significant events after the end of the financial year.

Note 10 Definitions of key figures

Solidity: Total equity including equity part of untaxed reserves divided with total assets



Signatures

Gothenburg 2022-03-08

Staffan Ternström
Chair of the board

Martin Olovsson
CEO

Kay Brickmann
Board member

Adina Symreng
Board member

Anders Tuv
Board member

Johan Öberg
Board member

Klementina Österberg
Board member

Our auditor's report was submitted on 2022-03-08

Frejs Revisorer AB

Mikael Glimstedt
Authorized Public Accountant

Auditor's report

To the general meeting of the shareholders of OnDosis AB

Corporate identity number 559113-1825

Report on the annual accounts

Opinions

We have audited the annual accounts of OnDosis AB for the financial year 2021.

In our opinion, the annual accounts have been prepared in accordance with the Annual Accounts Act and present fairly, in all material respects, the financial position of OnDosis AB as of 31 December 2021 and its financial performance and cash flow for the year then ended in accordance with the Annual Accounts Act. The statutory administration report is consistent with the other parts of the annual accounts.

We therefore recommend that the general meeting of shareholders adopt the income statement and balance sheet.

Basis for Opinions

We conducted our audit in accordance with International Standards on Auditing (ISA) and generally accepted auditing standards in Sweden. Our responsibilities under those standards are further described in the *Auditor's Responsibilities* section. We are independent of OnDosis AB in accordance with professional ethics for accountants in Sweden and have otherwise fulfilled our ethical responsibilities in accordance with these requirements.

We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis

Responsibilities of the Board of Directors and the Managing Director

The Board of Directors and the Managing Director are responsible for the preparation of the annual accounts and that they give a fair presentation in accordance with the Annual Accounts Act. The Board of Directors and the Managing Director are also responsible for such internal control as they determine necessary to enable the preparation of annual accounts that are free from material misstatement, whether due to fraud or error.

In preparing the annual accounts, The Board of Directors and the Managing Director are responsible for the assessment of the company's ability to continue as a going concern. They disclose, as applicable, matters related to going concern and using the going concern basis of accounting. The going concern basis of accounting is however not applied if the Board of Directors and the Managing Director intend to liquidate the company, to cease operations, or has no realistic alternative but to do so.

Auditor's responsibility

Our objectives are to obtain reasonable assurance about whether the annual accounts as a whole are free from material misstatement, whether due to fraud or error, and to issue an auditor's report that includes our opinions. Reasonable assurance is a high level of assurance, but is not a guarantee that an audit conducted in accordance with ISAs and generally accepted auditing standards in Sweden 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 annual accounts.

As part of an audit in accordance with ISAs, We exercise professional judgment and maintain professional scepticism throughout the audit. We also:

- Identify and assess the risks of material misstatement of the annual accounts, 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 opinions. 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 the company’s internal control relevant to our 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 company’s internal control.
- Evaluate the appropriateness of accounting policies used and the reasonableness of accounting estimates and related disclosures made by the Board of Directors and the Managing Director.
- Conclude on the appropriateness of the Board of Directors’ and the Managing Director’s use of the going concern basis of accounting in preparing the annual accounts. We also draw a conclusion, based on the audit evidence obtained, as to whether any material uncertainty exists related to events or conditions that may cast significant doubt on the company’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 annual accounts or, if such disclosures are inadequate, to modify our opinion about the annual accounts. 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 company to cease to continue as a going concern.
- Evaluate the overall presentation, structure and content of the annual accounts, including the disclosures, and whether the annual accounts represent the underlying transactions and events in a manner that achieves fair presentation.

We must inform the Board of Directors of, among other matters, the planned scope and timing of the audit. We must also inform of significant audit findings during our audit, including any significant deficiencies in internal control that we identified.

Report on other legal and regulatory requirements

Opinions

In addition to our audit of the annual accounts, we have also audited the administration of the Board of Directors and the Managing Director of OnDosis AB for the financial year 2021 and the proposed appropriations of the company's profit or loss.

We recommend to the general meeting of shareholders that the profit be appropriated in accordance with the proposal in the statutory administration report and that the members of the Board of Directors and the Managing Director be discharged from liability for the financial year.

Basis for Opinions

We conducted the audit in accordance with generally accepted auditing standards in Sweden. Our responsibilities under those standards are further described in the *Auditor's Responsibilities* section. We are independent of OnDosis AB in accordance with professional ethics for accountants in Sweden and have otherwise fulfilled our 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 opinions.

Responsibilities of the Board of Directors and the Managing Director

The Board of Directors is responsible for the proposal for appropriations of the company's profit or loss. At the proposal of a dividend, this includes an assessment of whether the dividend is justifiable considering the requirements which the company's type of operations, size and risks place on the size of the company's equity, consolidation requirements, liquidity and position in general.

The Board of Directors is responsible for the company's organization and the administration of the company's affairs. This includes among other things continuous assessment of the company's financial situation and ensuring that the company's organization is designed so that the accounting, management of assets and the company's financial affairs otherwise are controlled in a reassuring manner. The Managing Director shall manage the ongoing administration according to the Board of Directors' guidelines and instructions and among other matters take measures that are necessary to fulfill the company's accounting in accordance with law and handle the management of assets in a reassuring manner.

Auditor's responsibility

Our objective concerning the audit of the administration, and thereby our opinion about discharge from liability, is to obtain audit evidence to assess with a reasonable degree of assurance whether any member of the Board of Directors or the Managing Director in any material respect:

- has undertaken any action or been guilty of any omission which can give rise to liability to the company, or
- in any other way has acted in contravention of the Companies Act, the Annual Accounts Act or the Articles of Association.

Our objective concerning the audit of the proposed appropriations of the company's profit or loss, and thereby our opinion about this, is to assess with reasonable degree of assurance whether the proposal is in accordance with the Companies Act.

Reasonable assurance is a high level of assurance, but is not a guarantee that an audit conducted in accordance with generally accepted auditing standards in Sweden will always detect actions or omissions that can give rise to liability to the company, or that the proposed appropriations of the company's profit or loss are not in accordance with the Companies Act.

This Auditor's report is translated for convenience purposes only



As part of an audit in accordance with generally accepted auditing standards in Sweden, we exercise professional judgment and maintain professional skepticism throughout the audit. The examination of the administration and the proposed appropriations of the company's profit or loss is based primarily on the audit of the accounts. Additional audit procedures performed are based on our professional judgment with starting point in risk and materiality. This means that we focus the examination on such actions, areas and relationships that are material for the operations and where deviations and violations would have particular importance for the company's situation. We examine and test decisions undertaken, support for decisions, actions taken and other circumstances that are relevant to our opinion concerning discharge from liability. As a basis for our opinion on the Board of Directors' proposed appropriations of the company's profit or loss we examined whether the proposal is in accordance with the Companies Act.

Gothenburg, March 8 2022

Frejs Revisorer AB

Mikael Glimstedt
Authorized Public Accountant