

Vivesto AB (publ)

Interim report for the period January 1, 2022 – September 30, 2022

SIGNIFICANT EVENTS DURING THE THIRD QUARTER

- In July Christer Nordstedt was appointed acting CEO.
- In July Vivesto announced that the company has decided to wind down its activities in Russia following the Russian invasion of Ukraine, ongoing hostilities and international sanctions. The wind down of Vivesto's activities in Russia means that a write down of SEK 44.6 million is carried out during the third quarter of 2022, equal to the net book value of the capitalized development costs for Paclical® after amortization as of June 30, 2022.
- In August, Vivesto's and Elevar's partner Inceptua began the commercial launch of Apealea® in Germany.

SIGNIFICANT EVENTS AFTER THE REPORTING PERIOD

- In November Vivesto announced that the acting CEO Christer Nordstedt had resigned from his position in order to assume a new role outside of the company. Christer Nordstedt will remain as senior advisor to Vivesto on a consultancy basis within R&D.

THIRD QUARTER: JULY 1, 2022 – SEPTEMBER 30, 2022

- Consolidated net sales amounted to TSEK 1,015 (11,920)
- Operating profit/loss was TSEK 71,318 (-29,572)
- Write-down of development costs attributable to Russia TSEK -44,624 (0)
- Operating profit/loss adjusted for write-down of development costs attributable to Russia TSEK -26,694 (-29,572), a decrease of SEK 2,878
- Net profit/loss after tax amounted to TSEK -71,682 (-30,987)
- Earnings per share amounted to SEK -0.14 (-0.07)

THE PERIOD: JANUARY 1, 2022 – SEPTEMBER 30, 2022

- Consolidated net sales amounted to TSEK 1,015 (16,553)
- Operating profit/loss was TSEK -133,970 (-126,579)
- Write-down of development costs attributable to Russia TSEK -44,624 (0)
- Operating profit/loss adjusted for write-down of development costs attributable to Russia TSEK -89,346 (-126 579), a decrease of SEK 37,233
- Net profit/loss after tax amounted to TSEK -136,653 (-129,873)
- Earnings per share amounted to SEK -0.28 (-0.29)
- Short-term investments, cash and cash equivalents amounted to TSEK 164,241 (149,677)
- Equity/assets ratio was 95% (80%)

ACTING CEO REVIEW

Immediately after I took over as acting CEO at Vivesto in July, I began a thorough review of the entire business. All of Vivesto's assets and projects have been reviewed and evaluated from both a scientific and financial perspective. Our work is currently focused on three main areas: to further strengthen the research portfolio, to increase the value of existing projects and technology platforms, and to further trim our costs in order to be able to use a greater part of our resources to build and run our research portfolio.



After the initial review, it is clear that, just as previously assumed, our formulation technology should be able to be used with significantly more drugs than just paclitaxel. As part of the work to strengthen Vivesto's research portfolio, we have identified a number of different substances, with patent protection, or without patent protection, so-called generic substances, which could be formulated with our technology and offer patients important treatment benefits.

Within modern pharmaceutical chemistry, a strong trend has been seen for several years towards new molecules becoming larger and more difficult to dissolve than before. These molecules often have higher specificity and effect, that is, they are more effective than previous generations of drug substances. In addition, they often address a new category of targets previously unknown to science, or previously not considered possible to develop into useful drugs. I am convinced that Vivesto's formulation technology can be valuable for numerous molecules that today cannot be used due to lack of solubility, including molecules with remaining patent protection. We will therefore systematically, with the help of artificial intelligence, neural networks and other applicable technology, search for such opportunities with the aim of establishing collaborations with other pharma companies. In this way, we could grow our portfolio with more value-generating projects and strengthen Vivesto's position as a drug developer.

Our existing development projects and products form the basis of Vivesto, and we work intensively to increase the value of existing assets. There are several ways to increase the value of a project/molecule. The clinical plan is reviewed continuously with the aim of finding out whether it is possible to make minor changes in study setup or study design to strengthen the chances of success or shorten the time to market-approved drug. Another way is to evaluate the substance within other indications in order to broaden the target group and increase the future market potential. We are currently working on both of these strategies for our clinical cancer program Cantrixil and hope to strengthen the value of the project in this way.

Another high-priority area for Vivesto is to build a larger and stronger IP portfolio around our proprietary formulation technology. It was therefore very satisfying that we in September were able to submit a patent application for the XR-18 to the Swedish Patent and Registration Office.

As previously announced, our market-approved product Apealea was launched in Germany in August this year. The launch took place through our partner Elevar and its European partner Inceptua. This is an important milestone as it is the first time that Apealea has been launched commercially in a larger market. We are in close contact with Elevar to follow how sales develop in Germany and how the launch plans progress in other markets. We cannot provide any sales figures at this time, but we hope to be able to do so during the first half of 2023.

In addition, we can also report that the investigator-initiated phase 1b study evaluating Docetaxel micellar in patients with metastatic prostate cancer, conducted in Switzerland by the Swiss Group for Clinical Cancer Research (SAKK), continues to enroll patients. More than half of the patients are included and according to SAKK's assessment the recruitment can be completed during the next year. Results are expected in 2024.

Vivesto has previously received a conditional approval in the USA for the veterinary drug Paccal Vet, our formulation of paclitaxel for the treatment of cancer in dogs. For strategic reasons, the process was not completed, and the drug was therefore withdrawn from the market. The market for companion animals is now facing rapid growth, while there are currently very few approved drugs for cancer in dogs. With a solid research foundation and significant in-house expertise in the field, we are reviewing the possibilities of continuing development in veterinary medicine and, if deemed appropriate, preparing for further studies in selected indications.

During the roughly four months I have been acting CEO at Vivesto, I have gained a very good insight into the company's operations. I am impressed by the development work that is being carried out and I see significant potential in both the company's assets and its dedicated employees. The role as acting CEO has always been intended to be of a temporary nature and at the end of November I will move on to a new position outside of the company. I now look forward to continuing to contribute to Vivesto's development as a senior advisor within R&D on a consulting basis.

Christer Nordstedt, acting CEO of Vivesto

ABOUT VIVESTO

Vivesto is an oncology-focused specialty pharmaceutical company that develops new treatment options for patients suffering from difficult-to-treat cancer. The company has a portfolio of projects targeting innovative cancer treatments and the capacity to develop drugs from early research to regulatory approval. Late clinical-phase and commercial development is carried out individually or in partnership with other pharmaceutical companies.

Apealea® (paclitaxel micellar) is being made available to ovarian cancer patients through a partnership with Elevar Therapeutics, Inc. Development programs include Cantrixil, in clinical development for late-stage ovarian cancer, and docetaxel micellar, in development for advanced prostate cancer. Vivesto has developed proprietary drug delivery technologies designed to improve solubility of various active pharmaceutical ingredients.

Vivesto's shares are traded on Nasdaq Stockholm (VIVE). To find out more about Vivesto please visit www.vivesto.com.

TECHNOLOGY PLATFORMS

The foundation for Vivesto is the proprietary drug delivery technology XR-17™, a technology platform that can improve aqueous solubility for intravenous active pharmaceutical ingredients to improve their efficacy and safety. The technology has been successfully applied when developing Vivesto's most advanced product, Apealea. Development is currently ongoing for developing the next-generation drug delivery platform, XR-18.

XR-17™ Technology

XR-17 is Vivesto's proprietary drug delivery technology and is based on a blend of two isomers of a synthetic derivative of vitamin-A acid (XMeNa and 13XMeNa), which can solubilize compounds with poor aqueous solubility, such as paclitaxel. XR-17 demonstrates amphiphile properties since its molecules contain both hydrophilic and hydrophobic structural regions. As a result, XR-17 molecules can spontaneously form nanosized structures, known as micelles, within aqueous environments. During the process hydrophobic substances are dissolved in the XR-17 micelles.

XR-18 Technology

When developing Apealea and other projects using the XR-17 technology platform, Vivesto has built up valuable knowledge and understanding of how solubility and drug delivery can be improved in pharmaceutical molecules with solubility and delivery challenges. Based on this experience, Vivesto is developing the next generation of drug delivery technology, XR-18, which is an expanded and improved version of the XR-17 technology.

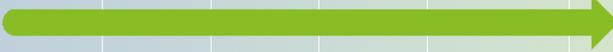
XR-18 is currently in an early development phase and has delivered promising results so far in terms of formulations employing new APIs. In early 2022, Vivesto announced that progress had been made in the internal development of XR-18 and that the company had identified and formulated promising compounds for further development. A patent application is filed for XR-18.

Exploratory Research

Vivesto is engaged in a project to investigate the biologic effects of its product candidates and technology platform variants, XR-17 and XR-18, leading to the quantification of cellular effects on target cells, initially in cancer indications, to create a screening tool for future development. This project is currently carried out with Visikol, Inc. in the USA and Vivesto hope to report new developments in the future.

PRODUCTS & PROJECT PORTFOLIO

Vivesto has a portfolio of projects in clinical and commercial phases that are intended to treat late-stage, hard-to-treat cancer. The drug Apealea was developed for patients with ovarian cancer and is scheduled to be launched in selected European markets under Inceptua's responsibility. Vivesto's development program includes Cantrixil, a clinical cancer program, and Docetaxel micellar for metastatic prostate cancer.

Product	Indication	Pre-clinical	Phase I	Phase II	Phase III	Registration/ approval	Commercial launch	Geography	
Apealea (paclitaxel micellar)	Ovarian cancer								EU/EEA
Apealea (paclitaxel micellar)	Ovarian cancer								USA
Cantrixil IP	Ovarian cancer								Global
Docetaxel micellar	Prostate cancer								EU/EEA
Cantrixil IV	Ovarian cancer								Global

Apealea

Apealea (paclitaxel micellar) is a patented solvent-free formulation: it applies paclitaxel – a cornerstone within chemotherapy for many different forms of cancer – through Vivesto's XR-17 technology platform. Apealea is approved by the European regulatory authority, the EMA, for use in combination with carboplatin for the treatment of adult patients with first relapse of platinum-sensitive epithelial ovarian cancer, primary peritoneal cancer and fallopian tube cancer. Apealea has also received orphan drug designation from the US regulatory authority FDA for the treatment of epithelial ovarian cancer, which could entail several potential benefits, including seven years of market exclusivity.

Status of partnerships

Elevar

Vivesto signed a global strategic partnership with US-based Elevar Therapeutics for the commercialization of Apealea in March 2020. Elevar has signed a license agreement with Inceptua Group for the commercialization of Apealea in Europe.

In December 2021 the transfer of the marketing authorization for Apealea from Vivesto to Inceptua was approved by from the European Commission and the UK Medicines and Healthcare products Regulatory Agency (MHRA).

In August 2022 Inceptua announced that they had launched Apealea in Germany.

FarmaMondo

In September 2021, Vivesto entered into an agreement with the Swiss FarmaMondo for commercialization purposes of Paclical (Apealea) in Russia and CIS countries. Following the Russian invasion of Ukraine, ongoing hostilities and international sanctions, Vivesto has decided to wind down its activities in Russia. This means that the distribution activities for Paclical (Apealea) in Russia and CIS countries are paused until further notice.

Cantrixil

Cantrixil is a clinical-stage product that consists of the active molecule, a potent and selective third generation benzopyran SMETI inhibitor named TRXE-002-01, encapsulated in a cyclodextrin. It is believed to target a wide spectrum of cancer cells, including chemotherapy-resistant tumor-initiating cells that are thought to be responsible for disease relapse.

Status

An upcoming clinical trial with Cantrixil is being prepared and Vivesto is currently working with clinical and regulatory experts to design the trial. The first part of this work was developing testing

material for the coming clinical trials. In March, Vivesto announced that the company had signed a large-scale manufacturing agreement with Lonza, a global development and manufacturing partner to the pharma, biotech and nutrition industries, for the main drug intermediate in the supply of clinical material for Cantrixil.

Docetaxel micellar

Docetaxel micellar is a product candidate in early clinical development and is a novel formulation that combines XR-17 with docetaxel – a well-established cytotoxin, currently administered intravenously and containing ethanol. In June 2020, Vivesto partnered with the Swiss Group for Clinical Cancer Research (SAKK) with the aim of conducting the first clinical study on the treatment of metastasized prostate cancer with Vivesto's Docetaxel micellar formulation.

Status

Docetaxel micellar is being evaluated in an instigator-initiated Phase 1b trial in patients with metastasized prostate cancer. In February Vivesto announced that the first patient had fully completed the study. About half of the patients are now recruited to the study and recruitment is expected to be completed in H1 2023.

VETERINARY MEDICINE

Vivesto's product candidates within veterinary medicine use the XR-17 technology platform to facilitate the administration of intravenously delivered solvent-free active pharmaceutical ingredients. Vivesto is currently evaluating strategic/commercial alternatives for the company's assets within veterinary medicine operations.

Paccal Vet

Paccal Vet utilizes Vivesto's formulation of paclitaxel with its XR-17 encapsulation technology for the treatment of canine mastocytoma. Vivesto intends to carry out a study together with reputable experts in the field in order to evaluate the possibilities for further development of Paccal Vet.

Doxophos Vet

Doxophos Vet is a patented formulation of doxorubicin, one of the most efficacious and widely used chemotherapeutic substances for the treatment of cancer. Vivesto has developed Doxophos Vet for the treatment of lymphoma, one of the most frequent forms of canine cancer. Pre-clinical and earlier clinical studies have been conducted on dogs with cancer. In the first attempt, Doxophos Vet showed promising efficacy against hematological tumors. The development program is currently on hold, awaiting further strategic decisions.

FINANCIAL INFORMATION

Condensed consolidated income statement

TSEK	2022 Jul–Sep	2021 Jul–Sep	2022 Jan–Sep	2021 Jan–Sep	2021 Jan–Dec
Net sales	1,015	11,920	1,015	16,553	26,192
Operating profit/loss	-71,318	-29,572	-133,970	-126,579	-128,647
Profit/loss for the period	-71,682	-30,987	-136,653	-129,873	-132,722
Earnings per share before and after dilution, SEK	-0.14	-0.07	-0.28	-0.29	-0.30

THIRD QUARTER

July 1 – September 30, 2022

Net sales

Net sales amounted to TSEK 1,015 (11,920) and comprised sales of goods for TSEK 1,015 (11,883) and licensing revenues of TSEK 0 (37).

Other operating income

Other operating income amounted to TSEK 113 (4,354) and comprised other operating income of TSEK 60 (-322), foreign exchange gains of TSEK 53 (125) and the proceeds of last year's liquidation of the subsidiary AdvaVet of TSEK 0 (4,551).

Operating profit/loss for the quarter

The operating loss for the quarter amounted to TSEK -71,318 (-29,572). The year-on-year difference in operating profit/loss was largely attributable to the write-down of the company's operations in Russia, which amounted to TSEK -44,624. Operating profit/loss for the quarter after adjustment for this write-down was TSEK -26,694, a year-on-year improvement of TSEK 2,878. The difference pertained primarily to lower employee benefit expenses.

The change in inventories of products in progress and finished goods amounted to TSEK -886 (-12,237).

Raw materials and consumables TSEK 0 (69).

Other external expenses amounted to TSEK -14,079 (-15,998).

Employee benefit expenses amounted to TSEK -6,624 (-10,396). The number of employees at the end of the quarter was 17 (26).

Depreciation, amortization and impairment amounted to TSEK -50,857 (-7,284), of which the increase is attributable to the write-down of operations in Russia.

Net financial items for the quarter

Net financial items for the quarter of TSEK -364 (-1,415) consisted of financial income amounting to TSEK 26 (459) and financial expenses of TSEK -390 (-1,874).

The financial income comprised capital gains on short-term investments of TSEK 26 (109) and interest income from current financial receivables of TSEK 0 (350).

Financial expenses consisted of value changes in short-term investments of TSEK -275 (0), interest expenses attributable to other borrowings and credits of TSEK 0 (-1,728), exchange losses on cash and cash equivalents of TSEK -20 (-3) and interest expenses from leases of TSEK -95 (-143).

Profit/loss before tax for the quarter

Profit/loss before tax amounted to TSEK -71,682 (-30,987). The year-on-year decrease was largely attributable to the write-down of the company's operations in Russia of TSEK -44,624, see above.

Income tax

Reported income tax for the quarter was TSEK 0 (0).

Profit/loss for the quarter

The net loss after tax was TSEK -71,682 (-30,987).

Cash flow and capital expenditure

Net cash flow for the quarter was TSEK 688 (3,264) and consisted of Cash flow from operating activities of TSEK -22,591 (-25,328), Cash flow from investing activities of TSEK 24,752 (29,990) and Cash flow from financing activities of TSEK -1,473 (-1,398).

Cash flow from operating activities

The cash flow from operating activities for the quarter was TSEK -22,591 (-25,328). The improvement in cash flow was attributable to improved earnings and a net improvement in working capital of TSEK -1,443.

Cash flow from investing activities

Cash flow from investing activities for the quarter was TSEK 24,752 (29,990).

Investments in property, plant and equipment and in intangible assets

Capital expenditure during the quarter consisted of investments in property, plant and equipment of TSEK 248 (10).

Divestment of short-term investments

During the quarter, short-term fixed-income funds amounting to TSEK 25,000 (30,000) were divested. These flows are reported in the cash flow statement as divestment of short-term investments.

Cash flow from financing activities

The cash flow from financing activities amounted to TSEK -1,473 (-1,398) and comprised amortization of lease liabilities of TSEK 1,473 (1,398). Amortization of lease liabilities primarily comprised rental payments which were recognized as amortization pursuant to IFRS 16.

THE PERIOD

January 1 – September 30, 2022

Net sales

Net sales amounted to TSEK 1,015 (16,553) and comprised sales of goods for TSEK 1,015 (16,442) and licensing revenues of TSEK 0 (111).

Other operating income

Other operating income amounted to TSEK 2,284 (6,631) and comprised insurance compensation of TSEK 1,125 (0), disposal of equipment of TSEK 384 (20), recharged costs of TSEK 0 (1,863), other operating income of TSEK 453 (0) and foreign exchange gains of TSEK 322 (197). The year-on-year difference was attributable to proceeds TSEK 0 (4,551) from the liquidation of the subsidiary AdvaVet in 2021.

Operating profit/loss for the period

The operating loss for the period amounted to TSEK -133,970 (-126,579). The year-on-year difference in operating profit/loss was largely attributable to the write-down of the company's operations in Russia, which amounted to TSEK -44,624. Operating profit/loss for the period after adjustment for this write-down was TSEK -89,346, a year-on-year improvement of TSEK 37,233. The difference largely comprised last year's write-down of goods in an amount of TSEK 17,448 as a result of expired shelf lives as well as lower other external expenses and lower employee benefit expenses.

The change in inventories of products in progress and finished goods amounted to TSEK -1,879 (-34,970).

Other external expenses of TSEK -43,587 (-59,940) decreased TSEK 16,353, mainly due to lower consultancy fees and legal fees, the latter stemming from concluded legal proceedings.

Employee benefit expenses amounted to TSEK -26,424 (-33,008). The number of employees at the end of the quarter was 17 (26).

Depreciation, amortization and impairment amounted to TSEK -65,378 (-21,603), which included the write-down of capitalized development costs in Russia of TSEK -44,624.

Net financial items for the period

Net financial items for the period of TSEK -2,683 (-3,294) consisted of financial income amounting to TSEK 234 (2,453) and financial expenses of TSEK -2,917 (-5,747). The financial income comprised capital gains on short-term investments of TSEK 234 (1,405) and interest income from current financial receivables of TSEK 0 (1,048). Financial expenses consisted of value changes in short-term investments of TSEK -2,516 (0), interest expenses attributable to other borrowings and credits of TSEK 39 (5,086), exchange losses on cash and cash equivalents of TSEK 38 (286) and interest expenses from leases of TSEK 324 (375).

Profit/loss before tax for the period

Profit/loss before tax amounted to TSEK -136,653 (-129,873). The year-on-year decrease was largely attributable to the write-down of the company's operations in Russia of TSEK -44,624, see above.

Income tax

Reported income tax for the period amounted to TSEK 0 (0).

Profit/loss for the period

The net loss after tax was TSEK -136,653 (-129,873).

Cash flow and capital expenditure

Net cash flow for the period was TSEK -4,165 (-33,920) and consisted of Cash flow from operating activities of TSEK -59,101 (-100,429), Cash flow from investing activities of TSEK -75,277 (70,891) and Cash flow from financing activities of TSEK 130,213 (-4,382).

Cash flow from operating activities

Cash flow from operating activities for the period was TSEK -59,101 (-100,429). The TSEK 41,328 improvement in cash flow was primarily attributable to the improved operating profit/loss after adjustment for the write-down of capitalized development costs in Russia of TSEK -44,624.

Cash flow from investing activities

Cash flow from investing activities for the period was TSEK -75,277 (70,891) and pertained to investments in short-term fixed-income funds of TSEK -120,000 (0) from the funds raised in this year's new share issue of TSEK 134,258 and to the divestment of TSEK 45,000 (105,000) in the period. The fund shares can be converted into cash within a few banking days.

Investments in property, plant and equipment and in intangible assets

Capital expenditure during the period consisted of investments in property, plant and equipment of TSEK -277 (-873) and investments in intangible assets of TSEK 0 (-33,236).

The preceding year's investments in intangible assets consisted of license rights pertaining to the global development and commercialization for Cantrixil – a clinical-stage ovarian cancer program. The agreement was the first step in Vivesto's strategy to reach critical mass in its oncology portfolio.

Short-term investments

During the period, short-term fixed-income funds amounting to TSEK 45,000 (105,000) were divested. These flows are reported in the cash flow statement as divestment of short-term investments.

Cash flow from financing activities

The cash flow from financing activities amounted to TSEK 130,213 (-4,382) and comprised new share issues of TSEK 150,652 (0) gross, issue expenses of TSEK -16,394 (0) and amortization of lease liabilities of TSEK -4,045 (-4,382). Amortization of lease liabilities primarily comprised rental payments which were recognized as amortization pursuant to IFRS 16.

Financing and financial position

Cash and cash equivalents

The Group's cash and cash equivalents at the end of the period amounted to TSEK 2,400 (7,185).

Short-term investments

The company's liquidity surplus was invested in short-term fixed-income funds. The fund shares can be converted into cash within a few banking days. As of September 30, 2022, the value of the funds was TSEK 161,841 (142,492).

Other borrowings

In accordance with IFRS 16 Leases, the Group recognizes the present value of future lease payments as interest-bearing liabilities. At the end of the period, the reported lease liabilities amounted to TSEK 5,879 (12,117), of which long-term liabilities were TSEK 3,442 (5,988).

Bank overdraft facility

The Parent Company has an unutilized bank overdraft facility amounting to TSEK 5,000 (5,000).

Equity

At the end of the period, equity amounted to TSEK 545,495 (552,069), the equity/assets ratio was 95% (80), and the debt/equity ratio was negative (negative). The reason that the debt/equity ratio is negative is that net debt is negative, meaning that the sum of cash and cash equivalents and short-term investments is greater than borrowing.

On March 25, Vivesto announced the final result of the company's fully underwritten rights issue. 48,367,120 shares, corresponding to approximately 53.9% of the shares offered, were subscribed for by the exercise of subscription rights. 1,519,430 shares, corresponding to approximately 1.7% of the shares offered, were subscribed for without the use of subscription rights. The remaining 39,787,359 shares offered, corresponding to approximately 44.4%, have been allotted to underwriters. The rights issue raised proceeds of approximately TSEK 150,652 for the company before issue expenses of TSEK 16,394, resulting in net additional capital of TSEK 134,258. As of March 31, the additional capital strengthened Equity as follows: Share capital TSEK 8,968 and Other capital provided TSEK 125,291. The issue proceeds and the majority of the issue expenses were settled during the period.

Warrants and other instruments outstanding that can increase the number of shares in Vivesto

	No. of options	Max. No. of shares	Subscription price, interval	
Warrants which can be converted to three shares	1,280,250	3,840,750	4.06	USD
Employee stock options which can be converted to one share	450,000	450,000	1.45	SEK
Max. No. of shares		450,000		

Warrants which can be converted to three shares refer to warrants issued in 2015 with a maturity date of October 28, 2025. One warrant gives one right to subscribe for three shares at the subscription price of USD 4.06.

The Extraordinary General Meeting on May 25, 2022, approved an employee stock option program directed to senior executives. The program encompasses not more than 2,700,000 options, of which 450,000 have been issued to individuals in senior positions. These options entitle, after vesting in accordance with the terms and conditions, the participant to subscribe for an equal number of shares at an exercise price of SEK 1.45 during the period from and including July 1, 2024 until and including

September 30, 2025 subject to the precondition that the holder remains in the company's employ for three years.

During the period, the individuals in senior positions who received options pursuant to the previous option program announced that their employment at the company had ceased, forfeiting their options and terminating the program. This entailed a negative impact of TSEK 1,798 on equity.

Legal information and additional information

As regards the company's legal proceedings, nothing of material import has taken place during the period.

War in Ukraine

On February 24, 2022, Russia launched a military invasion of Ukraine. The situation in Eastern Europe has led to a great deal of volatility in the global economy and the global credit markets, which can have a negative impact on Vivesto in both the short and long term. On July 5, 2022, Vivesto announced that the company had decided to wind down its activities in Russia following the Russian invasion of Ukraine, ongoing hostilities and international sanctions. This means that the distribution activities for Paclical® (Apealea®) in Russia and the Commonwealth of Independent States (CIS) will be paused until further notice (for more information, refer to Other customer contracts on page 64 of the 2021 Annual Report). It is unclear if, and if so when, commercialization for Paclical® (Apealea) can begin again in these markets. There is also a risk that the situation in Eastern Europe will affect other markets where Vivesto is active, particularly if the conflict escalates further, continues for a long period of time or spreads to other countries. However, the business impact is difficult to predict due to uncertain market conditions. The wind down of Vivesto's activities in Russia means that a write down of MSEK 44.6 has been carried out in the third quarter (July 2022), equal to the net book value of the capitalized development costs for Paclical® after amortization as of June 30, 2022.

Parent Company

The Parent Company's net sales for the period amounted to TSEK 1,015 (16,553) and profit/loss before tax was TSEK -136,602 (-134,274). As of September 30, 2022, the Parent Company's cash and cash equivalents amounted to TSEK 2,400 (7,185) and short-term investments, which within a few banking days can be converted into cash, amounted to TSEK 161,841 (142,492).

Key metrics and other information

	2022	2021	2022	2021	2021
	Jul–Sep	Jul–Sep	Jan–Sep	Jan–Sep	Jan–Dec
No. of shares at end of period, before and after dilution, thousand	538,043	448,370	538,043	448,370	448,370
Weighted average No. of shares, before and after dilution, thousand	517,390	448,370	493,207	448,370	448,370
Earnings per share before and after dilution, SEK	-0.14	-0.07	-0.28	-0.29	-0.30
Equity per share, SEK	1.01	1.23	1.01	1.23	1.23
Equity/assets ratio, %	95	80	95	80	92
Net liability, TSEK	-164,241	-69,677	-164,241	-69,677	-97,268
Debt/equity ratio, %	neg.	neg.	neg.	neg.	neg.
Return on total assets, %	neg.	neg.	neg.	neg.	neg.
Return on equity, %	neg.	neg.	neg.	neg.	neg.
Number of employees at period end	17	26	17	26	22

Definitions

Earnings per share: Income for the period attributable to the Parent Company shareholders in relation to the weighted average number of shares, before and after dilution, in the period.

Equity per share: Equity attributable to Parent Company shareholders as a ratio of the number of shares at the end of the period.

Equity/assets ratio: Equity as a ratio of total assets.

Net liability: Total borrowings (including the balance-sheet items: liabilities to credit institutions, convertible debt instruments and other borrowings) with deduction of cash and cash equivalents and short-term investments. Lease liabilities calculated in accordance with IFRS 16 are not included in net liability.

Debt/equity ratio: Net liability as a ratio of equity.

Return on total assets: Income before deduction of interest expenses as a ratio of average total assets.

Return on equity: Earnings before taxes as a ratio of average equity.

The key definitions found above are generic definitions often used in analyses and comparisons between different companies. They are therefore given to enable the reader to rapidly and summarily evaluate Vivesto's financial situation and possibly compare with other companies. These have been calculated as follows:

	2022 Jul-Sep	2021 Jul-Sep	2022 Jan-Sep	2021 Jan-Sep	2021 Jan-Dec
Equity per share					
Equity attributable to Parent Company shareholders at the end of the period, TSEK	545,494	552,069	545,494	552,069	549,713
No. of shares at end of period, thousand	538,043	448,370	538,043	448,370	448,370
Equity per share, SEK	1.01	1.23	1.01	1.23	1.23
Equity/assets ratio					
Equity at end of period, TSEK	545,494	552,069	545,494	552,069	549,713
Total assets at end of period, TSEK	573,236	693,303	573,236	693,303	594,308
Equity/assets ratio	95%	80%	95%	80%	92%
Net liability, TSEK					
Other borrowings	–	80,000	–	80,000	–
Total borrowings	–	80,000	–	80,000	–
Short-term investments	161,841	142,492	161,841	142,492	89,357
Cash and cash equivalents	2,400	7,185	2,400	7,185	7,912
Total short-term investments, and cash and cash equivalents	164,241	149,677	164,241	149,677	97,269
Net liability	-164,241	-69,677	-164,241	-69,677	-97,269
Debt/equity ratio					
Net liability, TSEK	-164,241	-69,677	-164,241	-69,677	-97,269
Equity, TSEK	545,494	552,069	545,494	552,069	549,713
Debt/equity ratio	-30%	-13%	-30%	-13%	-18%
Return on total assets					
Income before deduction of interest expenses	-71,292	-29,113	-133,736	-124,126	-126,188
Average total assets	633,270	792,525	583,772	778,422	728,925
Return on total assets	-11%	-4%	-23%	-16%	-17%
Return on equity					
Profit/loss before tax	-71,682	-30,987	-136,653	-129,873	-132,722
Average equity	548,782	567,371	547,603	616,133	614,955
Return on equity	-13%	-5%	-25%	-21%	-22%

Consolidated income statement

TSEK	Note	2022 Jul–Sep	2021 Jul–Sep	2022 Jan–Sep	2021 Jan–Sep	2021 Jan–Dec
Net sales		1,015	11,920	1,015	16,553	26,192
Other operating income		113	4,354	2,284	6,631	42,481
Change in inventories of products in progress and finished goods		-886	-12,237	-1,879	-34,970	-42,258
Raw materials and consumables		–	69	-1	-242	-1,864
Other external expenses		-14,079	-15,998	-43,587	-59,940	-79,438
Employee benefit expenses		-6,624	-10,396	-26,424	-33,008	-44,883
Depreciation, amortization and impairment		-50,857	-7,284	-65,378	-21,603	-28,877
Operating profit/loss		-71,318	-29,572	-133,970	-126,579	-128,647
Financial income		26	459	234	2,453	2,460
Financial expenses		-390	-1,874	-2,917	-5,747	-6,534
Financial income and expenses – net		-364	-1,415	-2,683	-3,294	-4,075
Profit/loss before tax		-71,682	-30,987	-136,653	-129,873	-132,722
Income tax		–	–	–	–	–
Profit/loss for the period		-71,682	-30,987	-136,653	-129,873	-132,722
Profit/loss for the period attributable to:						
Parent Company shareholders		-71,682	-30,987	-136,653	-129,873	-132,722
Earnings per share before and after dilution, SEK		-0.14	-0.07	-0.28	-0.29	-0.30

Consolidated statement of comprehensive income

TSEK	Note	2022 Jul–Sep	2021 Jul–Sep	2022 Jan–Sep	2021 Jan–Sep	2021 Jan–Dec
Profit/loss for the period		-71,682	-30,987	-136,653	-129,873	-132,722
Other comprehensive income						
Items that may subsequently be transferred to the income statement:						
Translation differences		71	9	360	743	–
Total other comprehensive income		71	9	360	743	–
Comprehensive income for the period		-71,611	-30,978	-136,293	-129,130	-132,722
Comprehensive income attributable to:						
Parent Company shareholders		-71,611	-30,978	-136,293	-129,130	-132,722

Consolidated statement of financial position

TSEK	Note	Sep 30, 2022	Sep 30, 2021	Dec 31, 2021
ASSETS				
Non-current assets				
Property, plant and equipment		12,998	18,593	17,108
Capitalized development costs	2	342,550	405,683	400,799
Other intangible assets		37,210	40,404	39,605
Financial assets		301	301	301
Total non-current assets		393,059	464,981	457,813
Current assets				
Inventories	3	8,027	16,196	9,897
Accounts receivable		1,322	5,037	10,101
Other current receivables		1,762	44,752	8,680
Prepaid expenses and accrued income		4,825	12,660	10,549
Short-term investments		161,841	142,492	89,357
Cash and cash equivalents		2,400	7,185	7,912
Total current assets		180,177	228,322	136,495
TOTAL ASSETS		573,236	693,303	594,308
EQUITY				
Equity and reserves attributable to Parent Company shareholders				
Share capital		53,804	44,837	44,837
Other capital provided		2,029,327	1,905,762	1,905,828
Reserves		395	–	427
Retained earnings, including income for the period		-1,538,032	-1,398,530	-1,401,379
Equity attributable to Parent Company shareholders		545,495	552,069	549,713
Total equity		545,495	552,069	549,713
LIABILITIES				
Long-term liabilities				
Lease liabilities, long-term		3,442	5,988	5,141
Total long-term liabilities		3,442	5,988	5,141
Current liabilities				
Other borrowings		–	80,000	–
Accounts payable		6,547	6,186	13,590
Lease liabilities, short-term		2,802	6,129	5,287
Other current liabilities		2,517	4,942	3,307
Accrued expenses and deferred income		12,434	37,989	17,270
Total current liabilities		24,299	135,246	39,454
Total liabilities		27,741	141,234	44,595
TOTAL EQUITY AND LIABILITIES		573,236	693,303	594,308

Consolidated statement of changes in equity

TSEK	Attributable to Parent Company shareholders					Total equity
	Share capital	Other capital provided	Reserves	Retained earnings, including profit/loss for the period	Total equity attributable to Parent Company shareholders	
Opening balance, January 1, 2021	44,837	1,904,760	-743	-1,268,657	680,197	680,197
Profit/loss for the period	–	–	–	-129,873	-129,873	-129,873
Other comprehensive income	–	–	743	–	743	743
Comprehensive income for the period	–	–	743	-129,873	-129,130	-129,130
Employee stock options		1,002			1,002	1,002
Closing balance, September 30, 2021	44,837	1,905,761	–	-1,398,530	552,069	552,069
Opening balance, January 1, 2021	44,837	1,904,760	-743	-1,268,657	680,197	680,197
Profit/loss for the period	–	–	–	-132,722	-132,722	-132,722
Other comprehensive income	–	–	1,170	–	1,170	1,170
Comprehensive income for the period	–	–	1,170	-132,722	-131,552	-131,552
Employee stock options		1,068			1,068	1,068
Closing balance, December 31, 2021	44,837	1,905,828	427	-1,401,379	549,713	549,713
Opening balance, January 1, 2022	44,837	1,905,828	427	-1,401,379	549,713	549,713
Profit/loss for the period	–	–	–	-136,653	-136,653	-136,653
Other comprehensive income	–	–	-32	–	-32	-32
Comprehensive income for the period	-	-	-32	-136,653	-136,685	-136,685
Employee stock options	–	-1,792	–	–	-1,792	-1,792
Share issues	8,968	141,685	–	–	150,652	150,652
Issue expenses	–	-16,394	–	–	-16,394	-16,394
Closing balance, September 30, 2022	53,804	2,029,327	395	-1,538,032	545,494	545,494

Consolidated statement of cash flows

	2022	2021	2022	2021	2021
TSEK	Jul–Sep	Jul–Sep	Jan–Sep	Jan–Sep	Jan–Dec
Operating activities					
Operating profit/loss	-71,318	-29,572	-133,970	-126,579	-128,647
Adjustments for non-cash items	50,857	3,836	65,378	17,057	28,877
Interest paid	863	232	-1,130	-38	-552
Cash flow from operating activities before changes in working capital	-21,324	-25,504	-69,722	-109,560	-100,322
Changes in working capital					
Change in inventories	887	11,752	1,870	35,300	41,599
Change in accounts receivable	-340	-3,095	8,779	-3,548	-8,612
Change in other current receivables	2,548	25,469	12,642	18,279	57,462
Change in accounts payable	-1,518	-3,340	-7,043	-4,530	2,874
Change in other current liabilities	-2,844	-30,610	-5,627	-36,370	-138,566
Cash flow from operating activities	-22,591	-25,328	-59,101	-100,429	-145,565
Investing activities					
Investments in intangible assets	–	–	–	-33,236	-33,236
Investments in property, plant and equipment	-248	-10	-277	-873	-1,113
Short-term investments	–	–	-120,000	–	–
Divestment of short-term investments	25,000	30,000	45,000	105,000	153,000
Cash flow from investing activities	24,752	29,990	-75,277	70,891	118,651
Financing activities					
Amortization of lease liability	-1,473	-1,398	-4,045	-4,382	-5,809
New share issues	–	–	150,652	–	–
Issue expenses	–	–	-16,394	–	–
Cash flow from financing activities	-1,473	-1,398	130,213	-4,382	-5,809
Cash flow for the period	688	3,264	-4,165	-33,920	-32,723
Effects of exchange rate changes on cash and cash equivalents	1	28	-1,347	977	507
Cash and cash equivalents at the beginning of the period	1,711	3,893	7,912	40,128	40,128
Cash and cash equivalents at the end of the period	2,400	7,185	2,400	7,185	7,912

Parent Company income statement

TSEK	Note	2022 Jul–Sep	2021 Jul–Sep	2022 Jan–Sep	2021 Jan–Sep	2021 Jan–Dec
Net sales		1,015	11,920	1,015	16,553	26,192
Change in inventories of products in progress and finished goods		-886	-12,237	-1,879	-34,970	-42,258
Other operating income		113	-197	2,284	2,080	37,930
Raw materials and consumables		–	69	-1	-242	-1,864
Other external expenses		-15,116	-17,336	-46,700	-63,287	-83,770
Employee benefit expenses		-6,627	-10,396	-26,424	-33,008	-44,826
Depreciation, amortization and impairment of PPE and intangible assets		-49,911	-6,322	-62,538	-18,481	-24,800
Operating profit/loss		-71,413	-34,499	-134,243	-131,355	-133,396
Profit/loss from participations in Group companies		–	330	–	–	–
Other interest income and similar income		25	459	234	2,453	2,460
Interest expenses and similar expenses		-295	-1,729	-2,592	-5,372	-6,027
Financial income and expenses – net		-270	-940	-2,359	-2,919	-3,567
Profit/loss before tax		-71,683	-35,439	-136,602	-134,274	-136,963
Income tax on profit/loss for the period		–	–	–	–	–
Profit/loss for the period		-71,683	-35,439	-136,602	-134,274	-136,963

Parent Company balance sheet

TSEK	Note	Sep 30, 2022	Sep 30, 2021	Dec 31, 2021
ASSETS				
Non-current assets				
Intangible non-current assets				
Capitalized development costs	2	342,550	405,682	400,799
Concessions, patents, licenses, trademarks and similar rights		37,210	40,404	39,605
Property, plant and equipment				
Equipment, tools and fixtures and fittings		6,283	8,419	7,890
Construction in progress and advance payments for property, plant and equipment		648	648	648
Financial assets				
Other securities held as non-current assets		301	301	301
Total non-current assets		386,991	455,454	449,243
Current assets				
Inventories, etc.				
Raw materials and consumables	3	5,944	6,971	7,848
Products in progress		2,083	8,678	2,049
Finished goods		–	547	–
		8,027	16,196	9,897
Current receivables				
Accounts receivable		1,322	5,037	10,101
Other current receivables		1,762	44,751	8,680
Prepaid expenses and accrued income		5,677	13,027	10,920
		8,761	62,815	29,701
Short-term investments				
		161,841	142,492	89,357
Cash and bank balances				
		2,400	7,185	7,898
Total current assets		181,029	228,688	136,853
TOTAL ASSETS		568,021	684,142	586,096
EQUITY AND LIABILITIES				
Equity				
Restricted equity				
Share capital		53,804	44,837	44,837
Statutory reserve		4,620	4,620	4,620
Reserve for development costs		20,927	25,819	25,394
		79,351	75,276	74,851
Non-restricted equity				
Share premium reserve		2,029,640	1,905,762	1,906,141
Retained earnings		-1,426,231	-1,294,160	-1,293,735
Profit/loss for the period		-136,602	-134,274	-136,964
		466,807	477,328	475,442
Total equity¹		546,159	552,604	550,293
Current liabilities				
Other borrowings				
		–	80,000	–
Accounts payable				
		6,547	6,185	13,590
Liabilities to Group companies				
		–	–	–
Other current liabilities				
		2,517	4,941	3,307
Accrued expenses and deferred income				
		12,799	40,412	18,906
Total current liabilities		21,862	131,538	35,803
TOTAL EQUITY AND LIABILITIES		568,021	684,142	586,096

Parent Company statement of changes in equity

TSEK	Restricted equity			Non-restricted equity		Total equity
	Share capital	Statutory reserve	Reserve for development costs	Share premium reserve	Retained earnings, including profit/loss for the year	
Opening balance, January 1, 2021	44,837	4,620	27,096	1,905,073	-1,296,837	684,789
Profit/loss for the period	–	–	–	–	-134,274	-134,274
Reversal of Reserve for development costs	–	–	-1,277	–	1,277	–
Results from fusion	–	–	–	–	1,400	1,400
Employee stock options	–	–	–	689	–	689
Closing balance, September 30, 2021	44,837	4,620	25,819	1,905,762	-1,428,434	552,604
Opening balance, January 1, 2021	44,837	4,620	27,096	1,905,073	-1,296,837	684,789
Profit/loss for the year	–	–	–	–	-136,963	-136,963
Reversal of Reserve for development costs	–	–	-1,702	–	1,702	–
Results from fusion	–	–	–	–	1,400	1,400
Employee stock options	–	–	–	1,068	–	1,068
Closing balance, December 31, 2021	44,837	4,620	25,394	1,906,141	-1,430,699	550,293
Opening balance, January 1, 2022	44,837	4,620	25,394	1,906,141	-1,430,699	550,293
Profit/loss for the period	–	–	–	–	-136,602	-136,602
Reversal of Reserve for development costs	–	–	-4,467	–	4,467	–
Employee stock options	–	–	–	-1,792	–	-1,792
Share issues	8,968	–	–	141,685	–	150,652
Issue expenses	–	–	–	-16,394	–	-16,394
Closing balance, September 30, 2022	53,804	4,620	20,927	2,029,640	-1,562,833	546,159

Note 1 Accounting policies, etc.

This condensed interim report for the Group has been prepared in accordance with IAS 34 Interim Financial Reporting and applicable regulations in the Annual Accounts Act.

The interim report for the Parent Company has been prepared in accordance with Chapter 9 of the Annual Accounts Act, Interim Report.

The Group's and the Parent Company's accounting policies and calculation methods are consistent with those used in the Annual Report for the fiscal year from January 1, 2021 to December 31, 2021.

No new or amended IFRS standards or IFRIC interpretations have entered force since January 1, 2022 that have had any impact on Vivesto's financial statements.

The carrying amounts for loan receivables, other receivables, cash and cash equivalents, accounts payable and other liabilities comprise reasonable approximations of fair value.

The Group currently has only one operating segment and does not therefore report any information by segment.

Note 2 Capitalized development costs

Vivesto has capitalized development costs consisting of the company's work on clinical trials in Phase III for the product candidates Paclical/Apealea® and Paccal Vet. The accumulated assets by product candidate are shown below.

TSEK	Sep 30, 2022	Sep 30, 2021	Dec 31, 2021
Paclical	233,142	296,275	291,392
Paclical Vet	109,408	109,408	109,408
Total	342,550	405,683	400,800

Amortization in the period amounted to TSEK 20,754 (21,603). In July, Vivesto decided to wind down its activities in Russia following the Russian invasion of Ukraine, ongoing hostilities and international sanctions. Accordingly, capitalized costs of TSEK 44,624 for Paclical in Russia were written down after amortization in June.

Note 3 Inventories

TSEK	Sep 30, 2022	Sep 30, 2021	Dec 31, 2021
Measured at cost			
Raw materials and consumables	5,944	6,971	7,848
Products in progress	2,083	8,678	2,049
Finished goods	0	547	0
Total	8,027	16,196	9,897

Goods have been expensed and written down as follows:

TSEK	2022 Jan-Sep	2021 Jan-Sep	2021 Jan-Dec
Expensed goods	886	17,330	24,263
Written down goods	993	17,448	17,995

Note 4 Transactions with related parties

During the period, expenses in the form of consultancy fees to members of the Board or management were recognized in an amount of TSEK 1,976 (1,680). Otherwise, no material transactions with related parties were conducted during the period other than the remuneration disbursed to Board members and employees.

Note 5 Contingent liabilities, pledged assets and contingent assets

The Parent Company has taken out a chattel mortgage of TSEK 8,000 with a bank as collateral for an overdraft facility of TSEK 5,000 (and as the limit for a foreign currency derivative of TSEK 3,000).

Note 6 Risk factors

The Group is exposed to various types of risk through its operations. Through creating awareness of the risks inherent to operations, these risks can be limited, controlled and managed at the same time as business opportunities can be leveraged to increase earnings. The risks pertaining to the Company's operations are detailed in the Annual Report for the fiscal year from January 1, 2021 to December 31, 2021.

The Board of Directors and the acting CEO of Vivesto AB certify that this Interim report gives a fair view of the Parent Company's and the Group's activities, position and results, and describes essential risks and uncertainty factors that the Parent Company and the companies that are part of the Group face.

Uppsala, November 17, 2022

Peter Zonabend, Chairman of the Board

Hege Hellström, Member of the Board

Pål Ryfors, Member of the Board

Roger Tell, Member of the Board

Christer Nordstedt, acting CEO

This report contains forward-looking statements including valuations of intangible assets which are based on assessments of future economic conditions, the impact from competing products and pricing, currency effects and other risks. These forward-looking statements reflect Vivesto management's view of future events at the time these statements are made but are events. When words such as "foresees," "believes," "estimates," "expects," "intends," "plans" and "projects" occur in this report, they represent forward-looking statements. These statements may include risks and uncertainties concerning, for example, product demand, market acceptance, effects of made subject to different risks and uncertainties. All these forward-looking statements are based on Vivesto management's estimates and assumptions and are assessed to be reasonable but are by their very nature uncertain and difficult to foresee. Actual outcomes and experiences may deviate considerably from the forward-looking statements. Vivesto does not intend, and does not undertake, to update these forward-looking statements.

This information is information that Vivesto AB (publ) is obliged to make public pursuant to the EU Market Abuse Regulation and the Securities Markets Act. The information was submitted for publication, through the agency of the contact person set out below, at 08:00 CET on November 17, 2022.

This report has been prepared in both Swedish and English. In the event of any discrepancy in the content of the two versions, the Swedish version shall take precedence.

This report has been subject to review by the company's auditors.



Translation from the Swedish original

Review report

Vivesto AB (publ)

Corp. id. 556332-6676

Introduction

We have reviewed the condensed interim financial information (interim report) of Vivesto AB (publ) as of 30 September 2022 and the nine-month period then ended. The Board of Directors and the Managing Director are responsible for the preparation and presentation of this interim report in accordance with IAS 34 and the Annual Accounts Act. Our responsibility is to express a conclusion on this interim report based on our review.

Scope of review

We conducted our review in accordance with International Standard on Review Engagements ISRE 2410 *Review of Interim Financial Information Performed by the Independent Auditor of the Entity*. A review of interim financial information consists of making inquiries, primarily of persons responsible for financial and accounting matters, and applying analytical and other review procedures. A review is substantially less in scope than an audit conducted in accordance with International Standards on Auditing and other generally accepted auditing practices and consequently does not enable us to obtain assurance that we would become aware of all significant matters that might be identified in an audit. Accordingly, we do not express an audit opinion.

Conclusion

Based on our review, nothing has come to our attention that causes us to believe that the interim report is not prepared, in all material respects, for the Group in accordance with IAS 34 and the Annual Accounts Act, and for the Parent Company in accordance with the Annual Accounts Act.

Stockholm 17 November 2022

KPMG AB

Duane Swanson

Authorized Public Accountant

Auditor in charge

Henrik Lind

Authorized Public Accountant

COMPANY INFORMATION

Vivesto Pharmaceutical AB (publ)
Corp. reg. no. 556332-6676
Domicile: Stockholm

Contact

Vivesto Pharmaceutical AB
Vallongatan 1
752 28 Uppsala, Sweden

Head Office:

Vivesto Pharmaceutical AB
Gustav III:s Boulevard 46, 5th floor
169 73 Solna, Sweden

Phone: +46 18-50 54 40
Website: www.vivesto.com
E-mail: info@vivesto.com

For more information

Christer Nordstedt, acting Chief Executive Officer
Phone: +46 18-50 54 40
E-mail: IR@vivesto.com

Robert Maiorana, acting Chief Financial Officer
Phone: +46 18-50 54 40
E-mail: IR@vivesto.com

Financial calendar

Year-end report (Jan-Dec 2022)	February 23, 2023
Annual Report publication	Week 17, 2023
Interim report Q1 (Jan-Mar 2023)	May 25, 2023
Annual General Meeting 2023	May 25, 2023
Interim report Q2 (Jan-Jun 2023)	August 24, 2023
Interim report Q3 (Jan-Sep 2023)	November 16, 2023
Year-end report (Jan-Dec 2023)	February 23, 2024