



circio

First half year report 2024

29 August 2024

RNA therapeutics and gene therapy are highly promising fields in medicine

RNA therapeutics and gene therapy are on a trajectory to change medical practice and provide benefits to many patients which have no other or insufficient treatment options. The first globally successful mRNA therapeutics were the vaccines approved and broadly used for COVID-19 since 2021. mRNA vaccines are just the tip of the iceberg of the overall therapeutic potential of RNA medicines in new disease areas. Circular RNA (circRNA) is emerging as one of the most promising RNA formats, and Circio's powerful and differentiated circVec platform is uniquely positioned to unlock the potential of circRNA in gene therapy and other areas.

About Circio

Circio Holding ASA (OSE: CRNA) is a biotechnology company developing novel circular RNA and immunotherapy medicines.

Circio has established a unique circular RNA (circRNA) platform for genetic medicine. The proprietary circVec technology is based on a modular genetic cassette design for efficient biogenesis of multifunctional circRNA from DNA and viral vectors, which can be deployed in multiple disease settings. The circVec platform has demonstrated enhanced and more durable protein expression than classic mRNA vector systems, and has the potential to become the new gold-standard for DNA and virus-based therapeutics in the future. The circRNA R&D activities are being conducted by the wholly owned subsidiary Circio AB based at the Karolinska Institute in Stockholm, Sweden.

In addition, Circio is continuing to develop its legacy oncology program, TG01, targeting KRAS driver mutations. TG01 is currently being tested in clinical trials which are being run through academic collaborative networks, supported by prestigious research grants from Innovation Norway and the Norwegian Research Council.

First half year presentation

Management will hold an online presentation on 29 August 2024 at 10:00 CET.

The presentation will be webcast live and can be accessed [here](#) and at www.circio.com.

Upcoming conferences / events

- 4-5 September: RNA Leaders, LSX conference, San Diego, USA
- 22-25 October: European Society of Cell and Gene Therapy (ESGCT) Annual Meeting, Rome
- 25-27 October: Biotech on Tap, BD & Finance Meeting, Munich
- 4-6 November: Bio-Europe, partnering conference, Stockholm
- 4-18 December: Warrants exercise period

Upcoming data and milestones

- 2H24: Circular RNA program
 - circVec *in vivo* testing of new delivery formats
 - circVec 2.2 *in vivo* expression and durability
 - circVec 3.0 generation design and testing
- 2H24: KRAS cancer vaccine program
 - TG01 clinical safety and immune response data

First half year highlights

Corporate

- In January, Business Finland approved Circio's application for a waiver of the three R&D loans totaling a EUR 6.2 million savings.
- In March, the Chinese National Medical Products Administration (NMPA) approved the investigational new drug (IND) application of TG01
- In May, announced financing to secure cash runway for 12 months through a rights issue and commitments from Atlas Capital Markets
- Cash burn of NOK 19 million, representing a 68% reduction versus 1H 23

Circular RNA

- In April, announced technical in vivo proof-of-concept for its proprietary circVec circular RNA platform with >4 month expression durability
- In May, presented two circVec posters at the American Society of Gene & Cell Therapy (ASGCT) 2024 annual meeting in Baltimore, USA
- In June, announced a new generation circVec 2.2, achieving 2-4-fold higher expression than v2.1 and up to 15x improvement over mRNA expression

Mutant KRAS

- In February, announced that the first patient was dosed in the Georgetown University Phase 2 study, testing TG01 in a triple combination in collaboration with Janssen and BMS

Key figures

<i>Amounts in NOK thousands</i>	1H 2024	1H 2023	FY 2023
Total operating revenues	-	-	123
Total operating expenses	-22 891	-72 519	-100 626
Operating profit/loss	-22 891	-72 519	-100 503
Net financial items	67 173 ¹⁾	-3 443	-10 233
Income tax		-	-
Net profit/loss	44 282	-75 962	-110 736
Basic and diluted EPS (NOK/share)	5.33	-0.40	-16.33
Net change in cash	-19 411	-34 652	-43 765
Cash and cash equivalents start of period	22 250	66 015	66 015
Cash and cash equivalents end of period	2 839	31 363	22 250

The interim financial information has not been subject to audit

1) Derecognition of the EUR 6.2m debt to Business Finland, the debt was waived in full in the first half of 2024

CEO statement

We are starting to establish Circio as a leader in the emerging circular RNA space, highlighted by recent coverage of Circio and our circVec technology in various well-known international industry media. The latest circVec 2.2 generation has new features that further boost the advantage over conventional mRNA-based expression. We are committed to driving this unique and powerful technology forward and establish circVec as the new gold-standard expression system for gene therapy and beyond.

Leading with 'CIRC' in Circio

Under the leadership of CTO and circRNA discoverer Dr Thomas Hansen and CSO Dr Victor Levitsky, we are continuing to advance our circVec platform. Using machine learning to optimize the genetic sequence, we have established circVec generation 2.2. This feature further enhances protein expression by 2-4 -fold vs. circVec 2.1 and increases the advantage vs. conventional mRNA-expression up to at least 15-fold in vitro. The novel 2.2 design is now being implemented across our circVec expression vectors to test its performance in multiple settings.

The circVec 2.1 in vivo data package also continues to strengthen as the results of ongoing experiments mature. We have now demonstrated statistically significant enhanced durability and >3x expression level in vivo vs. mRNA-based expression for up to six months. This feature is particularly important in gene therapy where low expression is a substantial hurdle for current approaches, and we are therefore selecting genetic medicine as the lead application for our initial circVec therapeutic candidates.

Still progressing in 'IO'

The TG01 KRAS program is being tested in clinical studies armed with a more powerful adjuvant and multiple new combination therapies. During 2023, three collaborative studies with internationally renowned experts were started, two in the USA and one in Norway. One of the USA-based studies was unfortunately closed for further enrollment in July 2024 due to slow recruitment of patients, but the other two remain active. Consistent with our strategy of advancing TG01 through collaborations at low cost to Circio, these studies are externally sponsored and involve multiple high-profile industry and academic partners.

Financing secured

Following the presentation of strong pre-clinical circVec data in April 2024, Circio launched a rights issue supported by existing shareholders and financing partner Atlas Capital Markets, raising apx. NOK 19.6m in gross proceeds. In addition, Atlas has committed to fund Circio's operations until the end of June 2025 under the existing convertible bond facility. As such, Circio now has the financial security to enable us to deliver important pre-clinical milestones for our novel circVec gene therapy formats, further enhancing the platform towards circVec generation 3.0, and expand the intellectual property portfolio to protect both the technology and its applications.

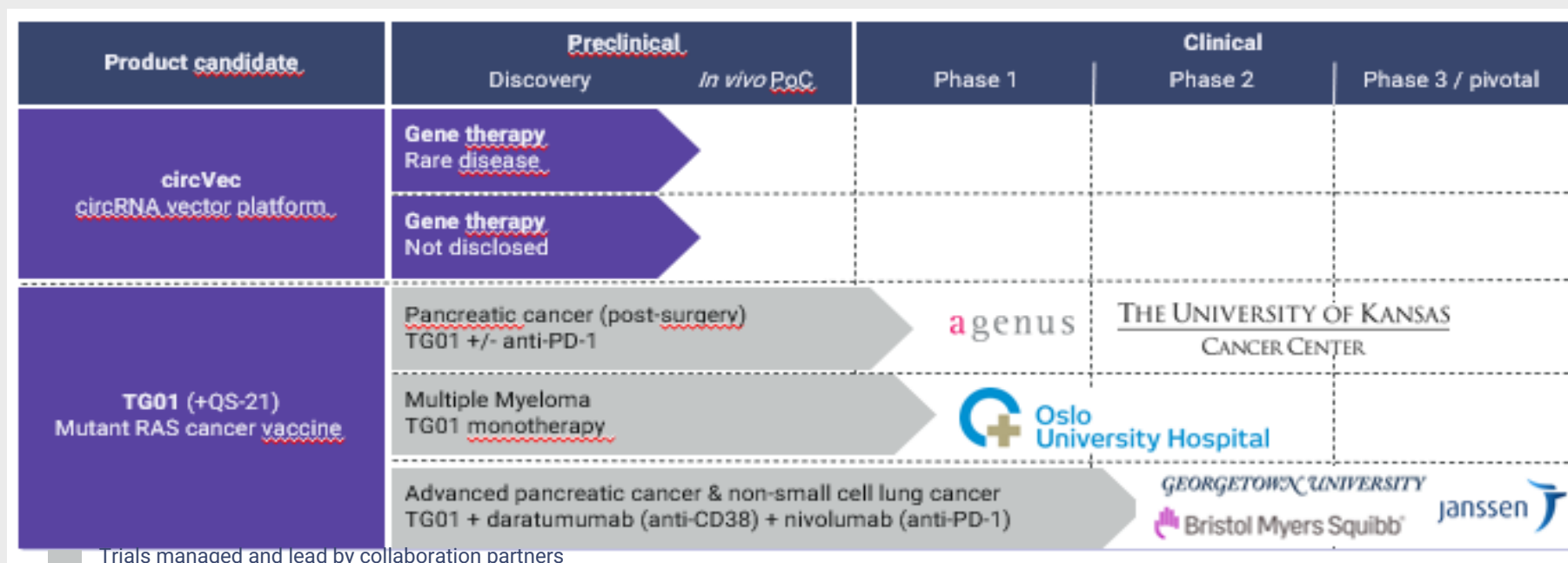
Looking ahead to strategic partnerships

The circVec platform can be deployed for a variety of applications, and as we demonstrate this through our ongoing experimental program, we believe multiple avenues to partnerships will become available. Based on our current data, plans and estimates, we aim to enter our first strategic partnership during 2025.

The team and I are very excited to lead Circio forward to build this groundbreaking technology and execute on the opportunities that lie ahead.

Erik Digman Wiklund
CEO, Circio Group

Pipeline and newsflow



Business and technology platforms

The Circio Group develops novel circular RNA ("circRNA") and cancer immunotherapy medicines. The Group's mission is to create novel targeted, multi-functional circRNA therapeutics. Circio has developed a differentiated, proprietary circRNA delivery platform named circVec. circVec is a DNA-based vector system designed and optimized for efficient intra-cellular circRNA biogenesis to drive robust and durable protein expression in patients. circVec has demonstrated statistically significant enhanced protein expression vs conventional mRNA-based systems both *in vitro* and *in vivo*. Circio is focusing on gene

therapy as the primary application of the circVec technology but is also exploring expansion of the circVec platform into oncology and cell therapy applications.

circRNA Platform

Circio is a leader in circRNA, a promising emerging class of novel RNA therapeutics. circRNA offers several advantages over mRNA, including substantially prolonged half-life and enhanced protein expression. circRNA co-discoverer and pioneer Dr Thomas B Hansen, CTO at Circio, is building the circVec platform technology together with our experienced scientific team on the campus of the Karolinska Institute in Stockholm, Sweden.

Circio has a unique, proprietary platform technology for circRNA delivery, circVec. circVec is a vector system designed for efficient circRNA expression which has potential use in many different disease areas. circVec offers several advantages over synthetic circRNA approaches, including durability, scalability and expression level, and has the potential to boost the potency of current gold-standard gene therapy approaches. To date, technical

proof-of-concept (PoC) has been established for the circVec approach in multiple vector formats, demonstrating clear advantages over traditional mRNA-based expression systems. Key design features for optimal circRNA biogenesis and high level of protein expression have been identified and validated, and several patent applications covering the core elements of the circVec concept have been filed to protect this powerful platform technology.

Circio is aiming to further expand and enhance the circVec platform, and to demonstrate its benefit and versatility during 2024. Following robust technical results, Circio is now exploring the design of different circVec in relevant disease areas. The aim is to generate *in vivo* proof-of-concept in disease models within the next twelve months, and subsequently proceed towards selecting a lead candidate to bring forward towards clinical entry. Circio plans to develop future therapeutic circVec candidates both in house and through partnering with pharmaceutical companies.

Mutant KRAS platform

Oncogenic KRAS mutations drive around 30% of all cancers and are considered highly attractive targets in cancer drug development. In the past, TG01 has shown promising efficacy in clinical trials, and has attained Orphan Drug Designation in pancreatic cancer in both the USA and Europe.

TG01 is currently being tested in two externally sponsored clinical trials in RAS-mutated pancreatic cancer, lung cancer and multiple myeloma in the USA and Norway. These studies are being run through academic and industry collaborative networks, supported by prestigious research grants from Innovation Norway and the Norwegian Research Council, creating future optionality for the program at low cost to Circio.

Multiple Myeloma

Our novel TG01 vaccine adjuvant combo is in a phase 1 trial at Oslo University Hospital (OUS) evaluating TG01/QS-21 in RAS-mutated multiple myeloma (MM). Although 15-20% of multiple myeloma patients harbor RAS driver mutations, there are currently no available RAS-targeted treatment alternatives for this cancer indication. The study is led by multiple myeloma expert Dr. Fredrik Schjesvold from the OUS and supported by the research grants from Innovation Norway and the Norwegian Research Council.

Lung and Pancreatic Cancer

In early 2024, the first patient was dosed in a new study led by Georgetown University (GU) in Washington D.C., USA, in a collaboration with Circio, Janssen and Bristol Myers Squibb (BMS) to test TG01 in a triple combination regimen with daratumumab (anti-CD38) and nivolumab (anti-PD1) in patients with RAS-mutated pancreatic and lung cancers who have progressed on prior PD-1 therapy. The study will be the first time TG01 is tested in a broader immunotherapy regimen designed to overcome resistance to anti-PD-1 checkpoint blockade.

IPR / Market exclusivity

Circio's patent portfolio is designed to protect the technological platform and specific drug candidates and their therapeutic applications and includes patents and patent. Following successful pre-clinical research with circVec, patent applications covering critical aspects of the circVec platform and applications have been filed. Further development and optimization are continuously ongoing and new patent applications will be filed to broaden and strengthen the IP protection of our unique circVec platform.

Highlights during first half 2024

- In January, announced that Business Finland had approved Circio's application for a waiver in full of three R&D loans totaling EUR 6.2m granted towards the development of the discontinued ONCOS-102 program
- In February, announced that the first patient had been dosed in the collaborative phase 2 trial sponsored by Georgetown University with financing from J&J (Janssen). In this study, TG01 is being tested in combination with daratumumab (anti-CD38, Janssen) and nivolumab (anti-PD1, BMS) in patients with RAS-mutated pancreatic and lung cancer.
- In March, announced that the IND application filed by partner IOVaxis Therapeutics to initiate TG01 clinical development in China was approved by the Chinese NMPA. The license option agreement with IOVaxis was subsequently terminated in April due to non-payment of the agreed USD 3m IND milestone.

- In April, presented results demonstrating significantly enhanced circVec protein expression and durability vs. conventional mRNA-based expression with DNA vectors *in vivo*.
- In May, published pre-clinical circVec POC data in two poster presentations at the American Society of Gene & Cell Therapy (ASGCT) 2024 annual meeting in Baltimore, USA
- In May, announced a proposed transaction structure combining the intended rights issue with a financing commitment from Atlas, securing the required capital to fund the company's operations until 30 June 2025. The proposed transaction structure was approved by the company's Annual General Meeting held on 19 June 2024.
- In June, presented a new circVec 2.2 design and strengthened *in vivo* data demonstrating enhanced expression vs. conventional mRNA-based vectors *in vivo* for up to five months
- In June, announced that Circio's leading position in circular RNA therapeutics had been highlighted by recent coverage in international industry media, including five articles and interviews in widely read EU and US life science publications with a combined readership of over 3 million.

Important events after balance sheet date

- In July, announced the outcome of the rights issue subscription period, raising approximately NOK 18.1m in gross proceeds, including NOK 1.75m from Board and management.
- In August, announced that NOK 1.5m had been requested from Atlas under the NOK 10m rights issue commitment, thus completing the rights issue transaction structure and bringing the total gross proceeds raised to aprox. NOK 19.6m.
- In July, decided jointly with collaboration partners to close any further enrollment in the Kansas University TG01 clinical trial due to slow recruitment of patients.

Financial review

Financial results

(Figures in brackets = same period 2023 unless stated otherwise)

The Group's products are in the research phase, and it has no revenue from sales of products yet. Other revenue for the first half 2024 was NOK 0 million (NOK 0.1 million).

Total operating expenses for the first half of 2024 were NOK 22.9 million (NOK 72.5 million) and NOK 100.6 million for the full year 2023. The operating expenses are reported net of governmental grants which amounted to NOK 2.6 million in the first half 2024 (NOK 0.3 million) and NOK 1.8 for the full year 2023.

Research and development expenses were NOK 7.5 million (NOK 42.4 million) for the first half 2024 and NOK 49.9 million for the full year 2023. Research and development expenses were driven primarily by CircRNA related research activities.

Payroll and other employee related costs were NOK 10.1 million in the first half 2024 (NOK 22.4 million) vs. NOK 34.4 million for the full year 2023. The decrease in personnel expenses is due to the lower number of employees in 1H 2024.

Other operating expenses amounted to NOK 5.4 million (NOK 6.8 million) for the first half 2024 vs. NOK 14.5 million for the full year 2023.

The operating loss for the first half, was NOK 22.9 million (loss of NOK 72.5 million) vs. operating loss of NOK 100.5 million for the full year 2023.

Net financial items amounted to an income of NOK 67.2 million (cost of NOK 3.4 million) for the first half 2024 and a cost of NOK 10.7 million for the full year 2023. The income in the first half 2024 is mainly related to the waiver in full of three R&D loans from Business Finland totaling EUR 6.2m or 71.3m NOK which were granted to Oncos Therapeutics OY more than 10 years ago towards the development of ONCOS-102, which was discontinued in 2023.

The profit after tax for the first half 2024 was NOK 44.3 million (loss of NOK 76.0 million) vs. loss of NOK 110.7 million for the full year 2023.

Financial position

As of June 30, 2024, total assets decreased to NOK 7.5 million from NOK 28.1 million on 31 December 2023 mainly due to losses from operational activities.

As of 30 June 2024, total liabilities were NOK 50.7 million vs. NOK 124,5 million as of 31 December 2023.

As of 30 June 2024, total equity was negative NOK 43.2 million vs. negative NOK 96.3 million as of 31 December 2023, corresponding to an equity ratio of -576.5% (-342,4% as of 31 December 2023). Circio is exploring various options and is in active discussion to address and address the current situation.

Cash Flow

Net cash flow from operating activities was negative NOK 19.1 million in the first half of 2024 (negative 59.1 million) vs. negative NOK 89.2 million for the full year 2023, reflecting the shift in research and development activities.

Net cash flow from investing activities was zero in the first half 2024 (negative NOK 0.2 million) and negative NOK 3.0 million for the full year 2023, mainly due to the purchase of equipment.

Net cash flow from financing activities was negative NOK 0.4 million in first half 2024 (positive NOK 24.7 million) and positive NOK 43.0 million for the full year 2023. The positive cash flow in 2023 was mainly due to the convertible bond and offset by interest paid to Business Finland. Business Finland waived the loan in full in first half 2024, hence as of 30 June the Group has no outstanding debt to Business Finland.

Cash and cash equivalents were NOK 2.8 million on 30 June 2024 vs. NOK 31.4 million on 30 June 2023 and NOK 22.3 million on 31 December 2023.

Share information

During the first half of 2024, Circio shares traded in the NOK 1.98 – 10.16 range using VWAP. During the first half of 2024, approx. 21.3 million shares were traded, with an aggregate trading value of NOK 113.8 million.

30 June 2024 there were 10 654 822 shares outstanding. The closing price on 30 June 2024 was NOK 2.45 per share, corresponding to a market value of NOK 26 million.

By 26 August 2024 there were 24 519 674 shares outstanding, distributed between 5 537 shareholders. The 20 largest shareholders controlled 51.2% of the shares.

The estimated share ownership on 26 August 2024:

Shareholder	Estimated	
	Shares million	Ownership
Citibank, N.A (Atlas Special Opportunities nom.)	4.3	17.7 %
Høse AS	1.8	7.5 %
Bækkelaget Holding	1.1	4.5 %
Nordnet Bank AB (nom.)	0.6	2.6 %
Egil Pettersen	0.6	2.5 %
NCS Energy Consultants AS	0.5	2.2 %
Tor Arne Storkås	0.5	2.1 %
Vaktmestergruppen AS	0.4	1.6 %
Ole Andre Skotheim	0.3	1.3 %
Kjell Olav Lunde	0.3	1.3 %
10 largest shareholders	10.6	43.3 %
Other shareholders (5 527)	13.9	56.7 %
Total shareholders	24.5	100.0 %

Risks and uncertainties

The Company's business is exposed to several general operational and financial risks which have been outlined in Circio's annual report 2023 as well as in the last prospectus, both available at www.Circio.com.

As earlier reported, Circio has no activities affected by the ongoing conflict in Ukraine.

Outlook

Following the restructuring of the company and recently completed financing, Circio is now fully focused on the circVec circRNA platform and conducts pre-clinical testing of its novel gene therapy candidates. The cost-base has been substantially reduced and the lean organization has the capabilities and expertise to advance the circVec platform towards in vivo proof-of-concept and entering its first strategic partnership during 2025.

The main R&D priorities for the next twelve months are to strengthen the circVec in vivo gene therapy data package and to continue to enhance the circVec platform towards generation 3.0. The Circio Board and management are confident that this strategy maximizes the opportunities to attract specialist investors and one or more business development partners that will bring revenue into the company. In parallel, the TG01 program is advancing in the clinic with limited financial resources provided by Circio.

Oslo, 28 August 2024

The Board of Directors of Circio Holding ASA

Damian Marron
Chairperson of the Board

Thomas Falck
Board member

Diane Mellett
Board member

Erik Digman Wiklund
Chief Executive Officer

Responsibility Statement from the Board of Directors and the Managing Director

We confirm, to the best of our knowledge that the financial statements for the period 1 January to 30 June 2024 have been prepared in accordance with current applicable accounting standards and give a true and fair view of the assets, liabilities, financial position, and profit or loss of the entity and the group taken as a whole. We also confirm that the Report includes a true and fair view of the development and performance of the business and the position of the entity and the group, together with a description of the principal risks and uncertainties facing the entity and the group.

Oslo, 28 August 2024

The Board of Directors of Circio Holding ASA

Damian Marron
Chairperson of the Board

Thomas Falck
Board member

Diane Mellett
Board member

Erik Digman Wiklund
Chief Executive Officer

First half 2024 results

Condensed consolidated statement of profit or loss

<i>Amounts in NOK thousands except per share data</i>	<i>Note</i>	Unaudited 1H 2024	Unaudited 1H 2023	FY 2023
Other revenues		-	-	123
Total revenue		-	-	123
Research and development expenses	<i>3,4</i>	-7 463	-42 429	-49 890
Payroll and related expenses	<i>5,11</i>	-10 053	-22 351	-34 442
Other operating expenses	<i>3,4</i>	-5 371	-6 753	-14 522
Depreciation, amortizations and write downs		-4	-986	-1 773
Total operating expenses		-22 891	-72 519	-100 626
Operating profit/ loss (-)		-22 891	-72 519	-100 503
Finance income		71 139	2 089	1 541
Finance expense		-3 965	-5 531	-11 774
Net finance income/ expense (-)		67 173	-3 443	-10 233
Profit/ Loss before income tax		44 282	-75 962	-110 736
Income tax income/ expense (-)			-	-
Profit/ Loss for the period		44 282	-75 962	-110 736
Earnings/ loss (-) per share				
Basic and dilutive earnings/loss (-) per share	<i>10</i>	5.33	-0.40	-16.33

Consolidated statement of other comprehensive income/ loss (-), net of income tax

<i>Amounts in NOK thousands</i>	Unaudited 1H 2024	Unaudited 1H 2023	FY 2023
Income/ loss (-) for the period	44 282	-75 962	-110 736
Items that may be reclassified to profit or loss:			
Exchange differences arising from the translation of foreign operations	-1 245	-6 681	-4 183
<u>Total comprehensive income/ loss (-) for the period</u>	<u>43 038</u>	<u>-82 643</u>	<u>-114 919</u>

Condensed consolidated statement of financial position

<i>Amounts in NOK thousands</i>	Unaudited 30.06.2024	Unaudited 30.06.2023	31.12.2023	<i>Amounts in NOK thousands</i>	Note	Unaudited 30.06.2024	Unaudited 30.06.2023	31.12.2023
ASSETS				EQUITY AND LIABILITIES				
Intangible assets	9	17	13	Shareholders' equity				
Property, plant, and equipment	185	5 494	-	Share capital	9	6 393	20 209	4 484
Right-of-use asset	-	592	-	Share premium reserve		7 228	6 149	-
Total non-current assets	194	6 104	13	Other reserves		997	64 652	-
Receivables	4 454	12 471	5 872	Retained earnings		-95 965	-199 633	-140 248
Cash and cash equivalents	2 839	31 363	22 250	Translation differences		38 183	36 929	39 427
Total current assets	7 293	43 834	28 122	Total equity		-43 164	-71 695	-96 336
TOTAL ASSETS	7 487	49 938	28 135	Non-current liabilities				
				Interest-bearing liabilities	7	-	62 371	-
				Deferred tax		-	-	-
				Lease liabilities		-	-	-
				Total non-current liabilities		-	62 371	-
				Current liabilities				
				Convertible bond		35 000	30 000	44 500
				Interest-bearing liabilities	7	-	5 044	66 153
				Short-term lease liabilities		-	705	-
				Trade payables		5 522	6 303	3 450
				Accrued public charges		1 199	3 356	1 673
				Other current liabilities		8 931	13 854	8 696
				Total current liabilities		50 651	59 262	124 471
				TOTAL EQUITY AND LIABILITY		7 487	49 938	28 135

Condensed consolidated statement of changes in equity

<i>Amounts in NOK thousands</i>	<i>Note</i>	Share capital	Share premium	Other reserves	Translation differences	Retained earnings	Total equity
Balance at 31 December 2022		18 847	-	63 780	43 611	-123 672	2 566
Loss for the period		-	-	-	-	-110 736	-110 736
Exchange differences arising from the translation of foreign operations		-	-	-	-4 183	-	-4 183
Other comprehensive income/loss, net of tax		-	-	-	-	-	-
Total comprehensive income for the period		-	-	-	-4 183	-110 736	-114 919
Share issuance, employee share options & RSU's		10	-	-	-	-	10
Transaction costs – Share based payments		-	-	-	-	-	-
Recognition of share-based payments & RSU's		-	-	1 523	-	-	1 523
Share issuance - Convertible bonds		2 820	11 680	-	-	-	14 500
Transaction cost - Convertible bonds		-	-17	-	-	-	-17
Capital decrease - Reverse split		-17 193	-	-7 810	-	25 003	-
Reclassification of Other reserves		-	-	-57 493	-	57 493	-
Reclassification of Share premium		-	-11 664	-	-	11 664	-
Balance at 31 December 2023		4 484	-	-	39 427	-140 248	-96 336
Loss for the period		-	-	-	-	44 282	44 282
Exchange differences arising from the translation of foreign		-	-	-	-1 245	-	-1 245
Other comprehensive income/loss, net of tax		-	-	-	-	-	-
Total comprehensive income for the period		-	-	-	-1 245	-	43 038
Share issuance, employee share options & RSU's	9	-	-	-	-	-	-
Transaction costs – share issuance employee share options &		-	-	-	-	-	-
Share issuance – Convertible bonds		1 909	7 228	-	-	-	9 137
Recognition of share-based payments & RSU's	11	-	-	997	-	-	997
Balance at 30 June 2024		6 393	7 228	997	38 183	-95 965	-43 164

Condensed consolidated statement of cash flow *Unaudited* *Unaudited*

<i>Amounts in NOK thousands</i>	<i>Note</i>	<i>1H 2024</i>	<i>1H 2023</i>	<i>FY 2023</i>
Cash flow from operating activities				
Loss before income tax		44 282	-75 962	-110 736
<i>Adjustments for:</i>				
Finance income		-71 139	-2 089	-1 541
Finance expense		3 965	5 531	11 774
Interest received		38	435	658
Other finance income/expense		-335	497	-427
Share option & RSU expense	11	997	872	1 523
Depreciation, amortizations and write downs		4	986	1 773
Change in receivables		1 418	21 090	28 225
Change in other current liabilities		1 635	-10 462	-20 446
Net cash flow from/(used in) operating activities		-19 134	-59 102	-89 196
Cash flow from investing activities				
Purchases of property, plant, and equipment (PPE)		-	-193	-193
Sale of assets		-	-	3 140
Net cash received from/(paid in) investing activities		-	-193	2 947
Cash flow from financing activities				
Repayment of borrowings		-	-2 712	-2 712
Repayment of lease liabilities		-	-825	-1 496
Interest paid	7	-	-244	-244
Payment for share issue cost -Rights issue, Private Placement and repair offering		-	-	-
Proceeds from convertible bond		-	37 500	59 000
Payment for convertible bond fees		-363	-9 000	-12 630
Proceeds from exercise of share options & RSUs		-	10	10
Payment for share issue cost – share options & RSUs		-	-	-
Net cash generated from/(paid in) financing activities		-363	24 730	41 929
Net increase/(decrease) in cash and cash equivalents		-19 497	-34 565	-44 321
Net exchange gain/loss on cash and cash equivalents		86	-87	555
Cash and cash equivalents at beginning of period		22 250	66 015	66 015
Cash and cash equivalents at end of period		2 839	31 363	22 250

Notes

1. General information

Circio Holding ASA ("the Company") and its subsidiaries (together the Group) is a biotechnology company developing novel circular RNA and immunotherapy medicines.

The Group has established a unique circular RNA (circRNA) platform to develop novel circRNA gene therapies. The proprietary circVec technology is based on a modular genetic cassette design for efficient biogenesis of multifunctional circRNA from DNA and viral vectors, which can be deployed for many purposes. The circVec platform has demonstrated enhanced and more durable protein expression than classic mRNA vector systems. The circRNA R&D activities are being conducted by the wholly owned subsidiary Circio AB based on the campus of the Karolinska Institute in Stockholm, Sweden.

In addition, the Group is continuing to support its legacy program, TG01, targeting KRAS driver mutations. TG01 is currently being tested in three clinical trials which are led and managed by academic collaborative networks and supported by prestigious research grants from Innovation Norway and the Norwegian Research Council.

The Company is a limited public liability company incorporated and domiciled in Norway and listed on the Oslo Stock Exchange in Norway. The address of the registered office is St. Olavs Plass 5, 0165 Oslo, Norway.

The condensed interim financial information is unaudited. These financial statements were approved for issue by the Board of Directors on 28 August 2024.

2. Accounting principles

The interim condensed consolidated financial statements for the Group are prepared using the same accounting principles and calculation methods as used for the statutory, annual financial statements 2023 for Circio Holding ASA.

The accounting principles used have been consistently applied in all periods presented, unless otherwise stated.

Amounts are in thousand Norwegian kroner unless stated otherwise. The Groups presentation currency is NOK (Norwegian kroner). This is also the parent company's functional currency.

2.1 Basis of preparation

The half yearly financial statements of the Group have been prepared in accordance with IAS 34 Interim Financial Reporting, as adopted by the EU.

2.2 Standards and interpretations in issue but not yet adopted

Certain new accounting standards and interpretations have been published that are not mandatory for 30 June 2024 reporting period and have not been early adopted by the Group. These new standards and interpretations are assessed to be of no material impact for the Group in 2024.

2.3 Basis of consolidation

The consolidated financial statements comprise the financial statements of the Company and its subsidiaries. As at 30 June 2024, Targovax Solutions AS located in Oslo, Norway, Targovax OY, located in Espoo, Finland, and Circio AB located in Stockholm, Sweden is 100% owned and controlled subsidiaries by Circio Holding ASA.

3. Research and development expenses

The Group is developing new products. Uncertainties related to the regulatory approval process and results from ongoing clinical trials generally indicate that the criteria for asset recognition is not met until the time when marketing authorization is obtained from relevant regulatory authorities.

The following research and development expenditures have been expensed:

<i>Amounts in NOK thousands</i>	1H 2024		1H 2023		FY 2023	
	Total	of which R&D	Total	of which R&D	Total	of which
R&D expenses	7 463	7 463	42 429	42 429	49 890	49 890
Payroll and related expenses	10 053	5 243	22 351	12 921	34 442	18 215
Other operating expenses	5 371	93	6 753	142	14 522	201
Depreciation, amortizations and write downs	4	-	986	-	1 773	-
Total operating expenses	22 891	12 799	72 519	55 492	100 626	68 305

4. Government grants

Government grants have been recognized in profit or loss as a reduction of the related expense with the following amounts:

The Group is awarded research grants of NOK 9.8 million from the Research Council of Norway and NOK 8.2 million from Innovation Norway, towards product and clinical development for the TG mutant KRAS cancer vaccine program. These grants are for the period 2021-2025.

For the first half 2024, the Group has recognized costs reductions of NOK 0.9 million related to the grant from the Research Council of Norway and NOK 1.7 million from Innovation Norway. The recognized costs reduction for the Innovation Norway grant relates to costs up until first half 2024, which were deferred awaiting the fulfillment of all grant criteria.

See note 8 Government grants in the Annual Report 2023 for more information about grants.

<i>Amounts in NOK thousands</i>	1H 2024	1H 2023	FY 2023
R&D expenses	1 846	286	1 722
Payroll and related expenses	798	56	108
Other operating expenses	-	-	-
Total grants	2 644	342	1 830

5. Payroll and related expenses

Total payroll and related expenses for the Group are:

<i>Amounts in NOK thousands</i>	1H 2024	1H 2023	FY 2023
Salaries and bonus	7 819	17 157	25 977
Employer's national insurance contributions	1 217	2 246	3 567
Share-based compensation ¹⁾	997	872	1 523
Pension expenses – defined contribution plan	631	1 860	2 843
Other	104	273	640
Governmental grants	-798	-56	-108
Total payroll and related expenses	9 970	22 351	34 442

1) Share-based compensation has no cash effect.

	30.06.2024	30.06.2023	31.12.2023
Number of employees calculated on a full-time basis as at end of period	8.2	17.0	9,0
Number of employees as at end of period	9	17	11

6. Convertible bond

In February 2023, Circio announced that it has agreed the terms and conditions for an investment and subscription agreement for a convertible bond facility with Atlas Special Opportunities (the "Investment Agreement"), which will provide financing of up to gross NOK 300 million over three years. The Investment agreement was approved by the extraordinary general meeting (EGM) of Circio held in March 2023, and an amendment agreement was later approved at an EGM in September.

The financing is made available to Circio through tranches of convertible bonds at Circio's discretion. For access to the capital over 3 years, Circio has paid Atlas a 2% fee (6m NOK) which was deducted from the first tranche in 2023. In addition, Atlas holds a one-time option to request convertible bonds in an amount of up to NOK 30 million, valid for a period of 24 months from September 2023. Circio's right to request a tranche is dependent on the fulfillment of condition precedents which are a combination of legal, regulatory and financial conditions. Any outstanding bonds will mature in full on the maturity date, 24 March 2026, and shall be converted to shares by Atlas, at the Conversion Price defined by the agreement. See note 23 Convertible Bond in the Annual Report 2023 for more information about the convertible bond facility.

As of 30 June 2024, three tranches with an aggregate nominal value of NOK 59 million have been exercised.

The use of the convertible bond facility and the subsequent conversion of bonds will lead to dilution of the Group's shareholders. Atlas is a provider of debt instruments and does not have a mandate to hold shares over longer periods. While Atlas does hold the convertible bonds issued by Circio, Atlas is expected to sell their shares following each bond conversion according to the trading limitation of 35% of total volume stipulated in the Investment Agreement. As of 30 June, Atlas has converted 48 of the total 118 issued bonds. Circio plans to use the convertible bond facility only when needed while management is continuing the efforts to secure new capital from specialists or long investors.

In accordance with the authorization granted by the extraordinary general meeting in March 2023, in 1H 2024, the Company's Board of Directors resolved to increase the share capital with NOK 1 908 607,60 by the issuance of 3 181 011 new shares, each with a par value of NOK 0.60 to facilitate the conversion of convertible bonds.

In May 2024, Circio announced a financing structure combining a rights issue with a financing commitment from Atlas, securing the required capital to fund the company's operations until 30 June 2025. The proposed transaction structure was approved by the company's Annual General Meeting held on 19 June 2024.

As part of financing structure and as support for the rights issue, Atlas has made several financing commitments to Circio:

- o The Company has issued new convertible bonds with a nominal value of NOK 4 million to Atlas to ensure that the Company has sufficient funds for the completion of the Rights Issue.
- o Atlas has, as part of the announced completion of the rights issue in the third quarter 2024, converted outstanding bonds in the total amount of NOK 15 million at the subscription price of the rights issue, NOK 2.5.
- o Atlas has given a financing commitment: If the Company is not successful in gaining sufficient financing for the period until end June 2025 through the Rights Issue, including the exercise of the Warrants in December 2024, Atlas will cover the Company's estimated financing needs until the end June 2025, limited to a monthly cash requirement of NOK 4 million and to a total amount of NOK 48 million.

These financing commitments shall be provided in the form of additional convertible bonds issued by the Company under the terms of the Investment Agreement. As part of this commitment to fund the Company until the end of June 2025, should Circio be in breach with any of the conditions precedent defined the Investment Agreement, then Atlas shall waive these for an additional fee equal to either 8% paid in cash, or 12% paid in shares, at the discretion of Circio.

The convertible loan is classified as a financial liability and measured at amortized cost. According to IFRS 9 the convertible loan contains a conversion right which is an

embedded derivative. The embedded derivative is accounted for separately from the host instrument and measured at fair value with changes recognized in profit or loss.

The conversion right of convertible bonds has been measured to have zero value at initial recognition and will be reevaluated annually under subsequent measurement according to IFRS 9 as long as the conversion right exists.

The 8% fee, related to the subscription of bonds at 92 percent of its nominal value, is recognized as finance expense in the statement of profit and loss at the issue date of the convertible bond. For the first half 2024 no new tranches were exercised, hence no fees were expensed.

NOK 6 million, the 2% fee of the loan facility of NOK 300 million, is recognized as a prepaid expense, classified as receivable in the statement of financial position. The fee is amortized over the three-year loan period and recognized as finance expense in the statement of profit and loss. For the first half 2024 NOK 1 million, for the full year 2023 NOK 1.5 million, of the 6 million was expensed.

7. Interest bearing debt

Business Finland is a publicly financed funding agency that finances research and development activities for young innovative companies in Finland.

The Group has received three R&D loans, for the development of ONCOS-102 from Business Finland under loan agreements dated September 2010, February 2012 and December 2013, respectively, for a total outstanding amount of EUR 6,2 million as of 31 December 2023. Due to the decision to halt development of ONCOS-102 and liquidate our subsidiary Targovax Oy, Business Finland waived the loan in full in the first half of 2024. The Group has no outstanding loan to Business Finland as of 30.06.2024.

Hence, for the first half 2024 the loan amount of EUR 6.2 million was recognized as other finance income and the outstanding amortized interests amount of EUR 0.3 million was recognized as finance cost in the statement of profit or loss.

The table below shows a reconciliation of the opening balances for the liabilities arising from financing activities:

Changes in liabilities arising from financing activities (Amounts in NOK thousands)	Interest-bearing liabilities Business Finland loans
Interest-bearing liabilities 31 December 2022	61 964
Cash flow from financing activities	-2 712
Exchange differences	4 100
Additions to existing loans	-
Change to loan repayment schedules	-
Other transactions without cash settlement	2 800
Interest-bearing liabilities 31 December 2023	66 153
Cash flow from financing activities	-
Exchange differences	-
Additions to existing loans	-
Change to loan repayment schedules	-
Other transactions without cash settlement	-66 153
Interest-bearing liabilities 30 June 2024	0

See note 21 Interest-bearing debt in the Annual Report 2023 for more information about the Business Finland loans.

8. Fair value of financial instruments

The carrying value of receivables, cash and cash equivalents, borrowings and other short-term payables are assessed to approximate fair value.

<i>Amounts in NOK thousands</i>	1H 2024		1H 2023		FY 2023	
	Carrying amounts	Fair value	Carrying amounts	Fair value	Carrying amounts	Fair value
Receivables	4 454	4 454	7 007	7 007	5 872	5 872
Cash and cash equivalents	2 839	2 839	31 363	31 363	22 250	22 250
Total financial assets	7 293	7 293	38 370	38 370	28 122	28 122
Convertible bond	35 000	35 000	30 000	30 000	44 500	44 500
Interest-bearing borrowings	-	-	67 415	67 415	66 153	66 153
Lease liabilities	-	-	705	705	-	-
Trade payables	5 522	5 522	6 303	6 303	3 450	3 450
Total financial liabilities	40 522	40 522	104 423	104 423	114 102	114 102

The tables below analyze financial instruments carried at fair value, by valuation method. The different levels have been defined as follows:

- o Level 1: Quoted prices (unadjusted) in active markets for identical assets or liabilities
- o Level 2: Inputs other than quoted prices including Level 1 that are observable for the asset or liability, either directly (that is, as prices) or indirectly (that is, derived from prices)
- o Level 3: Inputs in asset or liability that are not based on observable market data (that is, unobservable inputs)

As at 30 June 2024:

<i>Amounts in NOK thousands</i>	Level 1	Level 2	Level 3	Total
Convertible bond	-	-	35 000	35 000
Interest-bearing borrowings	-	-	-	-
Total financial instruments at fair value	-	-	35 000	35 000

As at 31 December 2023:

<i>Amounts in NOK thousands</i>	Level 1	Level 2	Level 3	Total
Convertible bond	-	-	44 500	44 500
Interest-bearing borrowings	-	-	66 153	66 153
Total financial instruments at fair value	-	-	110 653	110 653

As at 30 June 2023:

<i>Amounts in NOK thousands</i>	Level 1	Level 2	Level 3	Total
Convertible bond	-	-	30 000	30 000
Interest-bearing borrowings	-	-	67 415	67 415
Total financial instruments at fair value	-	-	97 415	97 415

9. Share capital and number of shares

At the extraordinary general meeting (EGM) in March 2023, the EGM approved the convertible bond facility with Atlas Special Opportunities, LLC ("Atlas"). In 1H 2024, the Company's Board of Directors, in accordance with the authorization granted by the extraordinary general meeting in March 2023, resolved to increase the share capital with NOK 1 908 606.6 by the issuance of 3 181 011 new shares, each with a par value of NOK 0.60 in order to facilitate the conversion of convertible bonds.

To comply with minimum share price obligations for companies listed on the Oslo Stock Exchange, pursuant to which the market value for listed shares shall not be lower than NOK 1 for a period of longer than six months, the EGM 27 September 2023 resolved that the Circio Holding ASA shares would be consolidated in the ratio of 30:1 (reverse split), whereby 30 existing shares, each with a nominal value of NOK 0.1, would be consolidated to one share with nominal value NOK 3. Following the share consolidation, the Company's share capital was reduced by NOK 2.4 to NOK 0.6 per share, and the reduction amount was used to cover a portion of the Company's accumulated losses, as reflected in the balance sheet per 31 December 2022.

The share capital as of 30 June 2024 is 6 392 893,2 (31 December 2023: 4 484 286.60) comprising 10 654 822 ordinary shares at nominal value NOK 0.60 (31 December 2023: 7 473 811 at NOK 0.60). All shares carry equal voting rights.

The movement in the number of shares during the period was as follows:

	1H 2024	1H 2023	FY 2023
Ordinary shares at beginning of period	7 473 811	188 473 783	188 473 783
Modifications due to reverse share split Oct 2023 1)	-	-	-182 191 324
Share issuance – bond agreement	3 181 011	13 514 199	1 187 892
Share issuance, employee share options and RSUs	-	103 789	3 460
Ordinary shares at end of period	10 654 822	202 091 771	7 473 811

The 20 largest shareholders are as follows at 30 June 2024:

Shareholder	# shares	%
Citibank, N.A (Atlas Special Opportunities nom.)	709 449	7 %
Høse AS	462 189	4 %
Nordnet Bank AB (nom.)	300 328	3 %
Tor Arne Storkås	220 000	2 %
Sverre Gunnar Thalberg	217 697	2 %
Nordnet Livsforsikring	196 284	2 %
Bækkelaget Holding	150 018	1 %
NCS Energy Consultants AS	150 000	1 %
SJ Byggservice A/S	133 532	1 %
Trond Are Selsbak	116 900	1 %
Kai Fredrik Johansen	110 000	1 %
Kjell Olav Lunde	94 338	1 %
Danske Bank (nom.)	87 982	1 %
Arne Hellestø AS	78 734	1 %
Svein Martin Johansen	74 000	1 %
Goldman Sachs Bank Europe SE	73 781	1 %
Rune Ramsvik	70 000	1 %
Ragnvald Gabrielsen AS	65 197	1 %
Danske Bank A/S	62 797	1 %
Granum & Co AS	62 560	1 %
20 largest shareholders	3 435 786	32 %
Other shareholders (5 610)	7 219 036	68 %
Total shareholders	10 654 822	100 %

Shareholdings Key Management

The following table provides the total number of shares owned by the Key Management of the Group and member of the Board of Directors, including close associates, as of 30 June 2024 and as of 28 August which includes the shares acquired through the right issue:

Name	Position	No. of shares outstanding	No. of shares outstanding
		at 30 June 2024	at 28 August 2024
Key Management:			
Erik Digman Wiklund ¹⁾	Chief Executive Officer	3 333	143 733
Ola Melin	VP and Head of CMC	1 667	48 466
Lubor Gaal ²⁾	Chief Financial Officer	-	93 600
Thomas Birkballe Hansen	Chief Technology Officer	-	46 800
Victor Levitsky	Chief Scientific Officer	333	47 133
Total no. of shares owned by Key Management of the Group ²⁾		5 333	379 732
Board of Directors:			
Damian Marron	Board member	1 852	169 256
Diane Mellett	Board member	4 098	130 458
Thomas Falck ³⁾	Board member	-	93 600
Robert Burns	Deputy board member	9 958	68 458
Total no. of shares owned by the Board of Directors of the Group ²⁾		15 908	461 772

1) Part of the shares are held through Digman AS

2) The shares are held through Biopharma Drug Licensing Group SL

3) The share are held through Sølén AS

10. Earnings per share

<i>Amounts in NOK thousand</i>	1H 2024	1H 2023	FY 2023
Loss for the period	44 291	-75 962	-110 736
Average number of outstanding shares during the period	8 311	191 289	6 783
Earnings/ loss (-) per share - basic and diluted	5.33	-0.40	-16.33

11. Share-based compensation

Share options

The Group operates an equity-settled, share-based compensation plan, under which the entity receives services from employees as consideration for equity instruments (options) in Circio Holding ASA. At the Annual General Meeting (AGM) in June 2024 the Board of Directors was authorized to increase the Group's share capital in connection with share incentive arrangements by up to NOK 2,428,639.50.

Each option, when exercised, will give the right to acquire one share in the Company. The options are granted without consideration Pursuant to the general vesting schedule, 25% of the options will vest 12 months after the day of grant (as long as the option holder is still employed). Thereafter, 1/36 of the remaining options will vest each month (as long as the option holder is still employed), with the first 1/36 vesting 13 months after the day of grant. The exercise price is equal to the volume weighted average trading price of the shares of the Company on Oslo Stock Exchange on the date of the grant. Options that have not been exercised will lapse 7 years after the date of grant.

In the first half of 2024 no options for shares in the Company have been distributed amongst the current members of the Key Management or other employees. The amount of expensed share options in the first half 2024 was NOK 0.2. For the same period in 2023 it was NOK 0.5, and NOK 0.5 million for the full year 2023.

Fair value of the options has been calculated at the grant date. The fair value of the options was calculated using the Black-Scholes model. No options have been granted for 2024, the expected volatility for options issued in 2023 is estimated at average of 75.17% based on the volatility of comparable listed companies and the volume weighted average interest rate applied to the share options grants in 2023 is 3.52%.

The following table shows the changes in outstanding share options in 2024 and 2023:

	6M 2024		FY 2023	
	No. of options	Weighted avg. exercise price	No. of options	Weighted avg. exercise price (NOK)
Outstanding at 1 January	267 230	214.83	10 781 275	10.13
Granted during the period	-	-	30 000	0.83
Exercised during the period	-	-	-	-
Forfeited during the period	-	-	-2 537 409	2.57
Expired during the period	-25 836	528.15	-245 125	7.79
Modifications due to share split Oct 2023	-	-	-7 761 511	214.85
Outstanding no. of share options at end of period	241 394	181.29	267 230	214.83

The following table shows the exercised, expired, granted and outstanding options for shares to Key Management of the Group at 30 June 2024:

Name	Position	Outstanding 31.12.2023	Granted 1H 2024	Exercised 1H 2024	Expired 1H 2024	Outstanding 30.06.2024
Key Management						
Erik Digman Wiklund	Chief Executive Officer	59 999	-	-	-	59 999
Lubor Gaal	Chief Financial Officer	23 329	-	-	-	23 329
Thomas Birkballe Hansen	VP and Head of Research	16 658	-	-	-	16 658
Victor Levitsky	Chief Scientific Officer	21 502	-	-	-	21 502
Ola Melin	VP and Head of CMC	24 185	-	-	-	24 185
Total option for shares to Key Management of the Group		145 673	-	-	-	145 673

From 1 July 2024 to 28 August 2024, no new options for shares have been granted Key Management of the Group.

Restricted Stock Units

The Board of Directors may choose to receive their remuneration, or parts thereof, in the form of restricted stock units (RSUs). If the Board members choose to receive the Board remuneration in RSUs they must choose to either (i) receive 100% of the compensation in RSUs, (ii) receive 1/3 of the compensation in cash and 2/3 in RSUs, or (iii) receive 2/3 of the compensation in cash and 1/3 in RSUs.

The number of RSUs to be granted to the members of the Board of Directors is calculated as the NOK amount of the RSU opted portion of total compensation to the Board member, divided by the market price of the Circio Holding ASA share. The market price is calculated as the volume weighted average share price the 10 trading days prior to the grant date. The RSUs will be non-transferrable and each RSU will give the right and obligation to acquire shares in Circio Holding ASA (at nominal value) subject to satisfaction of the applicable vesting conditions. When the RSUs have vested, the participant must during the following three-year period select when to take delivery of the shares.

The AGM 22 May 2023 resolved to remunerate the Board of Directors for the period between the AGM 2023 to the AGM 2024 with a combination of cash and Restricted Stock Units (RSUs), and an additional 1 931 997 RSU's were granted to the Board of Directors in the year 2023. No RSUs were granted in the first half of 2024.

The expensed RSUs in the first half 2024 were NOK 0.4 million. For the same periods in 2023 expensed RSUs were NOK 0.4 million, and NOK 1,0 million for the full year. A total of 87 707 RSUs were outstanding on 30 June 2024.

The following table shows the changes in outstanding RSUs in 2024 and 2023:

	6M 2024		FY 2023	
	No. of RSUs	Weighted avg. exercise price (NOK)	No. of RSUs	Weighted avg. exercise price (NOK)
Outstanding at 1 January	87 707	0.60	802 921	0.10
Granted during the period	-	-	1 931 997	0.10
Exercised during the period	-	-	-103 789	0.10
Modifications	-	-	-2 543 422	0.60
Forfeited during the period	-	-	-	-
Expired during the period	-	-	-	-
Outstanding no. of RSUs at end of period	87 707	0.60	87 707	0.60

The following table shows the exercised, granted and outstanding RSUs to Board of Directors of the Group at 30 June 2023:

Board of Directors:		Outstanding			
		31.12.23	Granted 1H 2024	Exercised 1H 2024	Outstanding 30.06.24
Damian Marron	Chair of the Board	13 348			13 348
Robert Burns	Board member	1 436			1 436
Diane Mellett	Board member	15 548			15 548
Thomas Falck	Board member	9 884			9 884
Total Restricted Stock Units to Board of Directors of the Group		40 216	-	-	40 216

From 1 July 2024 to 28 August 2024, no new RSUs have been granted to the Board of Directors.
Former board members hold 47 491 RSUs.

12. Subsequent events

- In July, announced the outcome of the rights issue subscription period, raising approximately NOK 18.1m in gross proceeds.
- In August, announced that NOK 1.5m had been requested from Atlas under the NOK 10m rights issue commitment, thus completing the rights issue transaction structure and bringing the total gross proceeds raised to apx. NOK 19.6m.
- In July, decided jointly with collaboration partners to close any further enrollment in the Kansas University TG01 clinical trial due to slow recruitment of patients.

