

Interim report July-September 2022

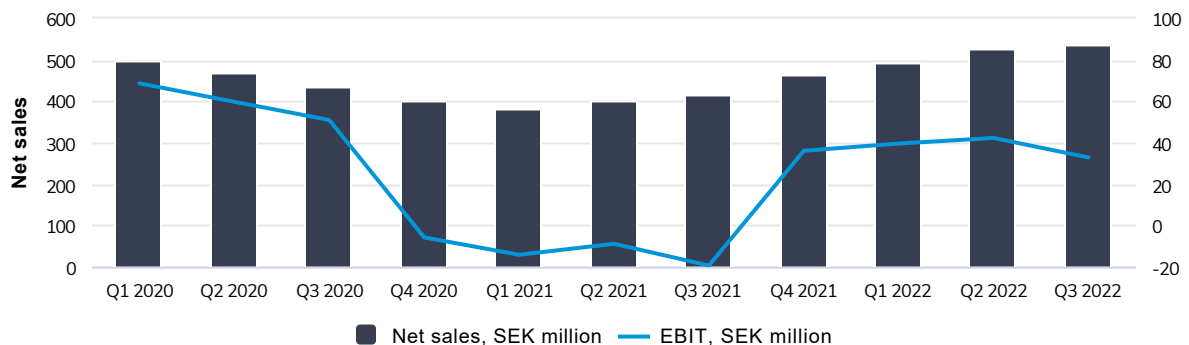
A challenging third quarter

Quarter July-September 2022

- ▶ Net sales amounted to SEK 125.6 (111.8) million, an increase of 12.4 percent. Adjusted for currency effects, a decrease of -8.1 percent.
- ▶ The number of instruments sold amounted to 803 (996), a decrease by 19.4 percent.
- ▶ Operating profit was SEK 3.6 (13.0) million, corresponding to an operating margin of 2.9 (11.7) percent.
- ▶ Profit for the period amounted to SEK 2.4 (7.1) million.
- ▶ Basic earnings per share amounted to SEK 0.12 (0.37) and diluted earnings per share amounted to SEK 0.12 (0.36).
- ▶ Cash flow from operating activities amounted to SEK -15.8 (10.6) million.
- ▶ Net debt on September 30 amounted to SEK 73.7 million compared to last year when it was SEK 6.5 million.
- ▶ August 4th it was announced that Annette Colin leaves the Boule Diagnostics CFO position due to family reasons.
- ▶ September 6th it was announced that Clinical Diagnostic Solutions, Inc. (CDS), a subsidiary to Boule Diagnostics AB, has been issued a Notice of Inspectional Observations (FDA Form 483) by the US Food and Drug Administration (the FDA).

Key figures	Jul-Sep 2022	Jul-Sep 2021	Jan-Sep 2022	Jan-Sep 2021	Oct 21-Sep 22 (R12)	Oct 20-Sep 21 (R12)
Sales growth, %	12.4	13.2	23.5	5.0	-4.9	-4.9
Net sales, SEK million	125.6	111.8	398.9	323.1	539.2	415.7
Gross margin, %	40.7	44.7	40.4	43.6	40.6	43.3
Operating profit (EBIT), SEK million	3.6	13.0	18.9	22.2	32.7	-19.5
Operating margin (EBIT), %	2.9	11.7	4.7	6.9	6.1	-4.7
Profit after tax, SEK million	2.4	7.1	9.8	6.0	27.1	-26.6
Net debt, SEK million	73.7	6.5	73.7	6.5	73.7	6.5
Return on equity, %	0.7	2.7	3.1	2.2	8.7	-9.8
Net debt/EBIT (R12), times	2.2	-0.3	2.2	-0.3	2.2	-0.3
Diluted earnings per share, SEK	0.12	0.36	0.49	0.30	1.40	-0.33

Net sales and EBIT, rolling 12 months



Q4 2020 incl. a write-down of intangible assets of SEK 40 million.

A challenging third quarter

Sales increased by 12 percent to SEK 126 million. Adjusted for exchange rates, organic growth decreased by 8.1 percent. This decrease is due to the challenging market conditions and shortage of electronic components for production of instrument during July and August that we were unable to recover during September.

Our sales are largely denominated in dollars, which means that they were positively affected by the dollar's appreciation. Sales growth was negatively affected, however, as the strong dollar drove up the prices of our products in local currencies. The price increases could not offset the lower volume and the gross margin of 41 percent was squeezed by production disruptions, high component costs for purchases at spot prices and retroactive customs duties. More costly component purchases and retroactive customs duties account for 4.4 percentage points. Operating profit amounted to SEK 3.6 million and the operating margin to just under 3 percent.

Cash flow from operating activities came to SEK -16 million, due to a fall in earnings and a decrease in operating liabilities. To counteract the weak operating cash flow, we have temporarily reduced the level of investment in the new product platform's development. We invested SEK 15 million during the quarter.

In response to the current tough market situation, we are bringing forward certain material purchases, building buffer stocks of critical components and ensuring that we specify electronic components that are more readily available. These measures reduce the risk of production stoppages, but supply chain challenges remain.

Licensing agreement for reagent production in India

During the quarter, we signed a strategic licensing agreement with Q-Line Biotech for the local production of hematology reagents in India. India is a large and important market for us, where more than 30 million tests are performed each year using our automated hematology systems. We have been analyzing the possibility of setting up a local reagent production facility for some time as it would be an advantage for us when it comes to public procurement contracts, and would reduce delivery times, transportation expenses and the environmental impact. Following our analysis, we entered into a licensing agreement that will contribute positively to gross margin growth. Local reagent production is scheduled to start in the third quarter of 2023.



A continued focus on quality management

The FDA conducted a new routine inspection of our US subsidiary's operations and issued a Form 483 with observations regarding the documenting of certain key processes. I take a very serious view of this, and we have wasted no time in bringing in the expertise necessary to identify and assist with the implementation of measures to improve our quality management. These measures include the digitalization of our quality system and the introduction of modern IT support to give us a good overview of all the processes. This new system is first being introduced in the US and we intend to eventually implement it globally. There are no restrictions on sales as a result of the observations.

The ongoing improvement actions and the implementation of the new IVD Regulation in Europe earlier this year will better equip us to meet future increased regulatory requirements for in vitro diagnostics products. The quality improvements increase costs, however, and resources is necessary for their implementation.

Rights issue to ensure the development of a modern technology platform

On 3 October, the Board of Directors decided on a SEK 150 million rights issue, which was approved by an Extraordinary General Meeting on 1 November. The capital injection will be used to complete the development of our new product platform and prepare for the launching of the first instrument - an advanced 5-part instrument, and a future 3-part instrument and cloud connectivity. We are continuing to make progress with the new 5-part instrument and are now finalizing the prototypes and planning for the upcoming verification and validation studies.

A focus on organization and culture in challenging times

The last 12 months have been challenging to say the least. Constantly changing conditions require commitment, creativity and a high degree of flexibility. These are qualities that both our employees and distributors have

demonstrated in getting products to our end customers.

The group management team has been enhanced by the arrival of Aishat Bislieva as the new “People and Culture” manager. Aishat has a solid, international background in HR. She will focus on Boule’s continuing work on values, culture and employee and leadership development.

I would like to take this opportunity to thank CTO Helena Börjesson and SVP instrument production Mikael Ekholm in the group management team for their efforts in Boule. Helena has decided to move on to another international position in mid-January and Mikael will move on outside of Boule. Helena has created a strong R&D organization that is fully dedicated to bringing our new platform to market. Jörgen Jehander, who has been with us for six months now, will become interim Head of Development until a permanent manager is in place. We will merge instrument and consumables production into one organization in order to create synergies and improve efficiency. The organization will be led by Eduardo Pagani, who is currently responsible for consumables production, Eduardo has worked for Boule since 2015, and has been a member of Boule’s group management team since 2020.

In conclusion, although the market situation will be tough in the near future, I would like to stress my optimism about our plan to build Boule’s long-term strength. Many thanks for the trust from our shareholders who have granted the new share issue. We are in an exciting development phase, whose goal is to completely renew our product portfolio and thereby strengthen our position in the decentralized hematology market.



Jesper Söderqvist
CEO and Group President

Group performance July-September 2022

Net sales

Net sales for the quarter amounted to SEK 125.6 (111.8) million, an increase of 12.4 percent. After adjustment for currency effects, net sales decreased by 8.1 percent. Instrument sales increased by 3,9 percent, sales of consumables increased by 18,1 percent and OEM and CDS brand sales decreased by 9.6 percent compared with the same period the previous year.

The lower net sales adjusted for currency effects is mainly related to fewer instruments sold during the first two months of the period caused by shortage of electric components that could not be recovered during the month of September and lower sales of OEM. Furthermore, the market experiences a greater degree of volatility than previously during the year which partly can be explained by the macroeconomic situation.

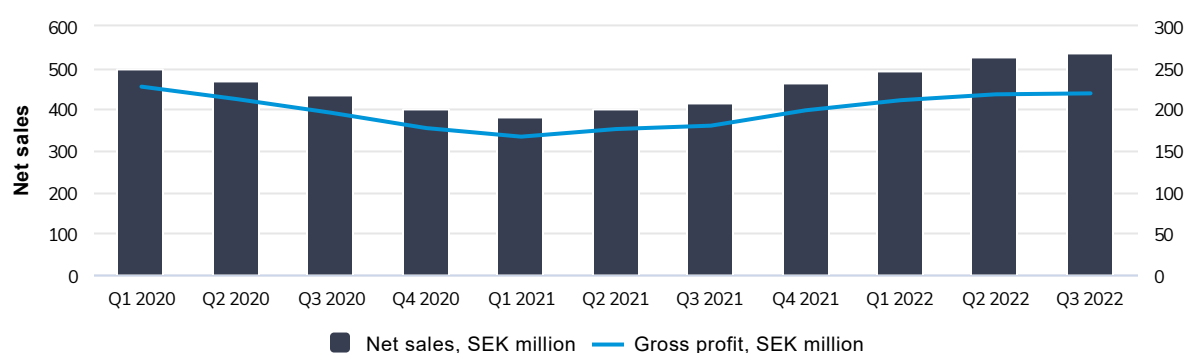
Net sales by region, SEK million	Jul-Sep 2022	Jul-Sep 2021	change	Jan-Sep 2022	Jan-Sep 2021	change	Oct 21-Sep 22 (R12)	Oct 20-Sep 21 (R12)	change (R12)
USA	39.3	37.9	4%	129.6	108.9	19%	173.3	137.9	26%
Asia	38.0	30.2	26%	113.0	81.8	38%	152.5	110.2	38%
Eastern Europe	16.2	14.4	13%	46.6	42.2	10%	65.5	52.9	24%
Latin America	9.3	8.4	11%	37.3	29.3	27%	45.4	34.3	32%
Western Europe	9.9	6.5	54%	27.6	21.3	30%	38.5	31.9	21%
Africa/Middle East	12.9	14.4	-11%	44.8	39.5	13%	63.9	48.5	32%
Total	125.6	111.8	12%	398.9	323.1	23%	539.2	415.7	30%

Net sales by product, SEK million	Jul-Sep 2022	Jul-Sep 2021	change	Jan-Sep 2022	Jan-Sep 2021	change	Oct 21-Sep 22 (R12)	Oct 20-Sep 21 (R12)	change (R12)
Instruments	34.9	33.6	4%	122.4	103.9	18%	167.2	134.9	24%
Consumables, own instruments	57.3	48.5	18%	167.5	133.8	25%	227.2	174.3	30%
Consumables, OEM and CDS brand	18.8	20.8	-9%	73.7	58.5	26%	99.8	71.5	40%
Other	14.6	8.9	64%	35.2	26.8	31%	45.0	35.0	28%
Total	125.6	111.8	12%	398.9	323.1	23%	539.2	415.7	30%

Gross profit

Gross profit for the period was SEK 53.3 (46.1) million, with a gross margin of 37.8 (41.7) percent. The gross margin was negatively impacted by difficulties in the supply-chain with continued expensive purchase of components. It is mainly the supply of electric components in relation to the production of instruments that has been problematic. This has then led to disturbance in production and as a consequence a lower utilization level in the production. During the period the purchase variances amounted to SEK 4.4 million. The period was also impacted by retroactive custom duties of SEK 1.1 million. In combination this corresponds to a decrease in gross margin of 4.4 percentage points.

Net sales and EBIT, rolling 12 months



Expenses

Operating expenses for the period amounted to SEK 46.4 (37.1) million.

Selling expenses amounted to SEK 27.4 (19.8) million. The increase is mainly due to recruitment expenses, cost for trade fairs and a stronger USD.

Administrative expenses amounted to SEK 7.6 (8.1) million.

Research and development expenses, including costs related to the quality assurance organization, amounted to SEK 11.4 (9.3) million, corresponding to 9.1 (8.3) percent of net sales. Expenses includes redesign of components due to shortages and increased cost for the new European IVDR. Development expenses of SEK 14.9 (11.1) million were capitalized. Total research and development expenses correspond to 21.0 (18.3) percent of net sales.

The net of other operating income and other operating expenses for the period amounted to SEK -1.2 (0.2) million and consists of positive and negative exchange differences.

Operating profit

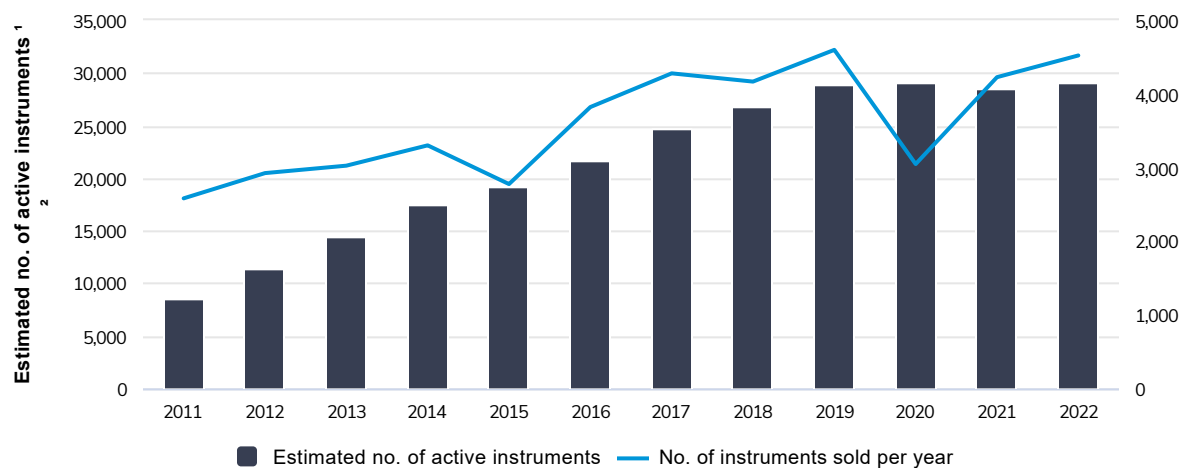
Operating profit amounted to SEK 3.6 (13.0) million, corresponding to an operating margin of 2.9 (11.7) percent.

Inventory of installed base

Following an inventory count of instrument installed base in collaboration with our distributors during 2021, our previous assumptions about longevity and use of the instruments have been confirmed. This resulted in an estimated life of instruments of 7.5 years from 2021.

At the end of the quarter, active installed base is estimated at 29,000 instruments.

Estimated number of active instruments



¹ Estimated number of active instruments is based on an expected lifespan of 8 years, changes to 7.5 years from 2021.

² Accumulated number of instruments sold since 2006 was 47,833 on September 30, 2022.

³ Number of instruments sold in 2022 refers to sales on a rolling 12-month basis.

Net financial items

Net financial items amounted to SEK -1.8 (-1.7) million, mainly interest expenses SEK 3.4 million (1.4) whereof SEK 0.3 (0.3) million is related to financial leasing. The currency effects amounted to SEK 1.1 (-0.5) million.

Earnings

Profit before tax was SEK 1.8 (11.3) million. Profit for the period was SEK 2.4 (7.1) million.

Financing and cash flow

Cash flow from operating activities for the quarter was SEK -15.8 (10.6) million. The change is mainly due to a lower operating profit as well as operating liabilities decreasing by SEK 11.6 million. Inventory increased by SEK 2.2 million.

The Swedish Export Credit Agency (EKN) guarantees some of Boules trade receivables at up to 75-95 percent of the receivables' total amount. Receivables may be pledged, in which case the liabilities are reported as interest-bearing liabilities. The change in trade receivables guaranteed by EKN is included in cash flow from operating activities, while the change in other interest-bearing liabilities is reported under cash flow from financing activities.

Cash flow for the period was SEK -7.8 (7.1) million and cash and cash equivalents on September 30 amounted to SEK 39.4 (35.7) million.

The Group's available cash and cash equivalents, including unutilized credit facilities, was SEK 68.0 (82.2) million on September 30. The main difference is related to investments in development expenses in the new product-platform amounting to SEK 79.5 million during the last twelve months.

Investments

Total investments amounted to SEK 16.6 (12.1) million, with investments in future product platforms accounting for SEK 14.9 (11.1) million of the figure.

Equity and liabilities

The Group's equity on September 30 was SEK 336.4 (273.9) million and the equity/assets ratio was 48.6 (51.0) percent.

Interest-bearing liabilities excluding leases are primarily related to pledged trade receivables guaranteed by EKN and amounted to SEK 225.1 (118.9) million on September 30, of which SEK 47.3 (35.3) million of these liabilities were non-current and SEK 177.8 (83.6) million were current. On September 30, SEK 51.1 (10.3) million of the credit facility had been utilized and other current non-interest-bearing liabilities and trade payables amounted to SEK 99.4 (96.4) million.

Lease liabilities on September 30 amounted to SEK 20.1 (30.5) million, of which SEK 11.9 (17.8) million liabilities were non-current liabilities and SEK 8.2 (12.7) million were current liabilities.

Net debt on September 30 amounted to SEK 73.7 million compared to last year when it was SEK 6.5 million. The main reason for the difference is related to new loans of SEK 35 million in April 2022 and an increased bank overdraft facility of SEK 20 million in July 2022. The rationale for these loans is related to insufficient cash flow for investments in the new product-platform.

Deferred tax liabilities were SEK 7.3 (18.2) million on September 30.

Non-current provisions consist of direct pension provisions of SEK 3.9 (3.3) million.

Significant risks and uncertainties

The Group's operations are subject to risks and uncertainties that may, to a varying extent, affect the Company's ability to achieve defined goals. Boule works continuously on management of existing risks and uncertainties and on the risk inventory that forms the basis for detecting new risks and uncertainties. The systematic and internally coordinated work is aimed at identifying risks, limiting risk exposure and minimizing any impact should a risk materialize. Currently, primary risks and uncertainties have been identified in the following areas: regulatory risks, product portfolio risks, distributor risks, production and quality risks, counterfeit reagents, price pressure, supplier risks, market risks and competition, bribery, and corruption, currency risks, IT security and systems, financing risks and future cash flows, health and safety in the workplace, dependence on key personnel and the effects of Covid-19.

A more detailed description of risks, risk management and related opportunities can be found on page 36 in the 2021 Annual Report.

Uncertainties due to the war in Ukraine

In 2021, Boule's sales in Eastern Europe amounted to 13 percent of net sales, with the majority referring to Russia. During the period January to September, sales amounted to 12 percent (13%) of net sales. The company has employees in Russia and a production facility for consumables that are distributed to the Russian market. The Eastern European market is uncertain due to the war in Ukraine and the current sanctions against Russia. The company monitors the situation on an ongoing basis.

Covid-19

Like other companies, Boule faced new challenges related to the spread of covid-19. Initially healthcare visits decreased affecting the number of blood samples and also new sales of instruments as the care providers prioritized covid-19 patients. Both sales and order intake have recovered during 2022.

Problems with components and raw material shortages, logistics and distribution to customers have arisen and continue to arise due to a lack of transport capacity and obstacles related to border closures. Boule is taking active measures to mitigate the impact by working closely with the Group's subcontractors, redesign of components and planning and booking deliveries well in advance.

Tax audit

On October 6th the Swedish tax authorities have decided to impose increased social security contributions and tax penalties on Boule Diagnostics AB and Boule Medical AB amounting to approximately SEK 1.6 million, in relation to what they see as incorrectly valued warrants issued to senior executives in the group. The three warranty programs, 2017/2020, 2019/2022 and 2020/2023 are impacted. The decision means that the basis for the price of the warrants, determined by a third party engaged by the company, is deemed to be too low and the warrants as a consequence undervalued. The difference between the set price and the estimate now completed by the tax authorities implies that the tax authorities also intend to impose the warranty holders with benefit taxation. No provision has been recorded in the period. The company has appealed the decision to the Swedish administrative court ("Förvaltningsdomstolen").

Related-party transactions

Other than remuneration of the Board and senior executives, no related-party transactions have taken place during the period.

Nomination Committee

At the Annual General meeting 2022, it was resolved that a Nomination Committee based on the ownership as of September 30, 2022, should be elected. The largest shareholders at this time were Svolder AB, AB Grenspecialisten and Thomas Eklund representing approximately 135 percent of shares and votes. The Nomination Committee has thereafter elected Ulf Hedlundh as its chairman and co-opted the chairman of the Board of Directors Yvonne Mårtensson. Shareholders who would like to contact the Nomination Committee are welcome to contact the chairman of the Nomination Committee Ulf Hedlundh via e-mail at ulf.hedlund@svolder.se or via phone at number 08-440 37 70. In order for the proposals to be evaluated in a proper manner these proposals should not be delivered at the latest February 1, 2023.

Significant events during the interim period

August 4th it was announced that Annette Colin leaves the position as CFO due to family reasons. Annette will continue in her role during her six-month notice period in order to ensure an orderly transition period up until a new CFO assumes the position. The company has initiated the recruitment of a successor.

September 6th it was announced that Clinical Diagnostic Solutions, Inc. (CDS), a subsidiary to Boule Diagnostics AB, had been issued a Notice of Inspectional Observations (FDA Form 483) by the US Food and Drug Administration (the FDA). After a routine inspection of CDS' operations, inspectional observations were issued by the FDA regarding documentation relating to change management processes and complaints handling. CDS is engaging a well-reputed consulting firm, who employ former FDA personnel, to provide third-party independent subject matter experts with the required experience and background to support the efforts to address the observations identified by the FDA. CDS has submitted to the FDA a response that includes a corrective action plan that has been implemented. The inspectional observations do not place limitations on production or the sale of products.

The FDA has previously also announced a routine inspection of the Swedish operations during the month of November.

There are no other significant events to report for the period.

Events after the end of the interim period

October 3rd it was announced that the Board of Directors had resolved on a new issue of shares corresponding to approximately SEK 150 million with preferential rights for the Company's existing shareholders. The Rights Issue is subject to approval by an extraordinary general meeting, to be held on November 1, 2022. The nomination committee also proposed that Emil Hjalmarsson, Portfolio Manager at Grenspecialisten, should be elected to the

Company's Board of Directors.

October 3rd a notice of shareholders meeting was distributed in relation to the extraordinary general meeting, to be held on November 1, 2022, at 4 PM at Domnarvsgatan 4, Spånga.

October 20th it was announced that Boule had signed a strategic contract manufacturing agreement with Q-Line Biotech for local hematology reagent manufacturing in India.

November 1st it was announced that the extraordinary general meeting ("EGM") resolved in accordance with the Board of Director's proposal to amend the articles of association. The resolution means that the limits for the share capital and the number of shares are changed so that the share capital shall amount to a minimum of SEK 4,800,000 and a maximum of SEK 19,200,000, and the number of shares shall amount to a minimum of 19,000,000 and a maximum of 76,000,000.

In accordance with the Board of Directors' proposal, the EGM also resolved to approve the Board of Directors' resolution on a new issue of shares with preferential rights for existing shareholders. The resolution means that Boule's share capital will increase by a maximum of SEK 4,854,138 by new issue of a maximum of 19,416,552 shares with preferential rights for existing shareholders. Furthermore, the EGM resolved, in accordance with the Nomination Committee's proposal, to increase the number of board members from five members to six members with election of Emil Hjalmarsson as a new member of the Board of Directors. For further information refer to the bulletin from the EGM available on the company's website.

There are no other significant events to report after the end of the period.

Parent Company

Boule Diagnostics AB (publ), corporate ID 556535-0252, is a Swedish limited liability company with its registered office in Stockholm. The address of the head office is Domnarvsgatan 4, SE-163 53 Spånga, Sweden.

The Parent Company's revenue is derived from Group-wide services.

Risks and uncertainties for the Parent Company indirectly correspond with those for the Group.

Personnel

The average number of employees in the Group during the quarter was 242 (222), including 5 (7) employees at the Parent Company. The average number of employees by country was as follows: Sweden 135 (123), United States 93 (86), Mexico 2 (2) and Russia 12 (11). The average number of women in the Group was 103 (103) and the average number of men was 139 (119). Personnel in countries where Boule does not have a legal entity are not included in the number of employees as they are employed via external companies and therefore included as consultancy costs.

Number of shares

The total number of shares and votes in Boule Diagnostics AB is 19,416,552 and has remained unchanged during the year. After full dilution, the number of shares amounts to 19,949,349.

Shareholders, Sept 30, 2022 (accord. to Euroclear)	Number of shares, Sept 30	Share of capital/votes
AB Grenspecialisten	2,443,634	12.6%
Svolder AB	2,414,194	12.4%
Thomas Eklund inkl bolag	1,956,055	10.1%
Swedbank Robur Fonder AB	1,929,181	9.9%
Nordea Invesment Funds	1,769,281	9.1%
Tredje AP-fonden	1,625,771	8.4%
Andra AP-Fonden	684,974	3.5%
Skandinaviska Enskilda Banken AB	683,169	3.5%
Sijoitusrahasto Aktia Nordic	496,270	2.6%
Société Générale	424,794	2.2%
Fondita Nordic	290,462	1.5%
CBNY-Norges Bank	220,159	1.1%
Other shareholders (2,637)	4,478,608	23.1%
Total number of shares	19,416,552	100.0%

Warrant programs

The Board of Directors believes that it is important and in the interest of all shareholders that the CEO and key employees, who are considered important to the Company's further development, have a long-term interest in good value growth for the Company's shares. A personal, long-term shareholder commitment would be expected to contribute to increased interest in the Company's operations and financial performance, and to increase the CEO's and key employees' motivation and affinity with the Company and its shareholders.

The warrants have been allotted and purchased by employees at market conditions. The market value has been determined using the Black & Scholes option valuation model.

If a warrant holder's employment ceases, Boule has the right of first refusal and may choose to exercise that right. The Board has decided to exercise the right of first refusal regarding former employees who purchased warrants in the 2019 program, and 110,638 warrants have accordingly been repurchased since allotment. There are no restrictions on transferring warrants in the programs.

Outstanding programs	Outstanding warrants			Corresponding shares	Proportion of total no. of shares	Exercise price	Exercise period
	CEO	Key employees	Total				
2019/2022	0	352,797	352,797	352,797	1.8%	67.50	1 Juni 2022-30 Dec 2022
2020/2023	130,000	50,000	180,000	180,000	0.9%	86.70	1 juni 2023-30 dec 2023
	130,000	402,797	532,797				

The Board of Directors and the CEO certify that this interim report provides a true and fair view of the operations, financial position and earnings of the Parent Company and the Group and describes the material risks and uncertainties faced by the Parent Company and the other Group companies.

Stockholm, November 10, 2022

Boule Diagnostics AB

Yvonne Mårtensson
Chairman of the Board

Thomas Eklund
Board member

Karin Dahllöf
Board member

Jon Risfelt
Board member

Torben Jørgensen
Board member

Emil Hjalmarsson
Board member

Jesper Söderqvist
CEO

Auditor's report

Boule Diagnostics AB (publ), org nr 556535-0225

Introduction

We have reviewed the condensed interim financial information (interim report) of Boule Diagnostics AB (publ) as of 30 September 2022 and the nine-month period then ended. The board of directors and the CEO are responsible for the preparation and presentation of the interim financial information in accordance with IAS 34 and the Swedish 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 the International Standard on Review Engagements ISRE 2410, Review of Interim Report Performed by the Independent Auditor of the Entity. A review 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, ISA, and other generally accepted auditing standards in Sweden. The procedures performed in a review do 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, in accordance with IAS 34 and the Swedish Annual Accounts Act, regarding the Group, and with the Swedish Annual Accounts Act, regarding the Parent Company.

Stockholm, 10th of november 2022

Öhrlings PricewaterhouseCoopers AB

Lars Kylberg

Authorized Public Accountant