

# Interim Report 2 (2021-08-01 – 2021-10-31)

Phase Holographic Imaging PHI AB (publ)

Lund, December 29, 2021

Cell therapy manufacturing

## AUGUST 2021 – OCTOBER 2021

Net sales	1 818 (826) KSEK
Operating result before depreciation (EBITDA)	-2 733 (-2 946) KSEK
Net result	-3 901 (-4 777) KSEK
Earnings per share	-0.27 (-0.33) SEK
Gross margin	93 (77) %

## MAY 2021 – OCTOBER 2021

Net sales	4 191 (957) KSEK
Operating result before depreciation (EBITDA)	-6 172 (-7 495) KSEK
Net result	-8 370 (-11 194) KSEK
Earnings per share	-0.58 (-0.78) SEK
Gross margin	75 (64) %

## IN SHORT

- Strong sales growth for the 3<sup>rd</sup> consecutive quarter.
- The HoloMonitor fluorescence unit is planned to be launched in the first half of 2022.
- Recent advancements in regenerative medicine create additional growth potential in clinical applications for the company.

# CEO COMMENTARY

## A window of opportunity created by the advancement of regenerative medicine

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PHI spearheads the next generation of advanced instrumentation for non-invasive imaging and analysis of cell cultures. Today, cells are cultured in well over 100 000 laboratories worldwide, academic and commercial.

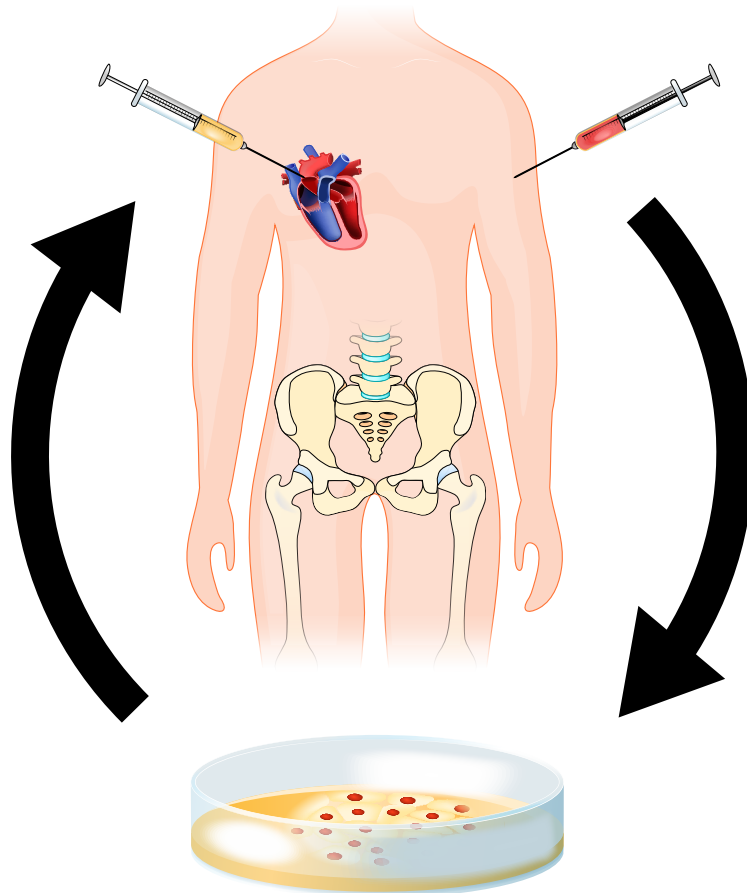
The growth rate and advances in regenerative medicine have motivated Big Pharma to enter the field. **In regenerative medicine, the cells themselves are the treatment.** Therefore, the number of cell culture laboratories and the market for non-invasive cell culture analysis is expected to grow rapidly over the coming years.

The growth is driven by the demand for large-scale cell culturing capacity to treat major diseases like diabetes, Parkinson's, Alzheimer's, heart disease and several cancer forms. As cell culturing transform from a craft to large-scale industry, the future number of **clinical** cell culture laboratories is expected to dwarf the current +100 000 pre-clinical laboratories.

In addition to its pre-clinical business, we see that PHI has a significant competitive advantage within regenerative medicine, given PHI's proven core technology, proprietary software and cost position. Our customers have collectively published over **200 scientific papers** based on results created by PHI's non-invasive cell analysis technology. PHI's more well-known customers include Bayer AG, National Institutes of Health, Harvard and Stanford University, and Novo Nordisk A/S.

### The Future of Medicine

**Regenerative medicine** is the collective term for treatments that regrow, repair or replaces damaged or diseased cells, organs or tissues. The rapidly expanding field includes the generation and use of therapeutic stem cells, tissue engineering and the production of artificial organs.



Gene and cell-therapies involve extracting cells from the patient or a donor, modifying and multiplying the cells in a laboratory before transplanting the treatment cells back to the patient.

## The Future is Here

According to the latest report from **Alliance for Regenerative Medicine**, the number of ongoing regenerative medicine trials worldwide has grown to 2 600. 1 320 trials are industry-sponsored by nearly 1 200 companies. 243 of these trails are in Phase 3. As of October 2021, **FDA has approved** over 20 regenerative medicine treatments.

Also, according to the alliance, nearly **20 billion USD was invested in regenerative medicine** during 2020, widely eclipsing the investments in 2019. With an annual growth rate of 10 – 30 %, market surveys estimate that the global regenerative medicine market has reached a value of up to 150 billion USD by 2028.

*Source: Allied Market Research, MarketsandMarkets, Verified Market Research and GrandviewResearch.*

## Third Pillar of Healthcare

Pharmaceuticals and surgery have been the two pillars of medical treatment for centuries. As now recognized by Big Pharma, **regenerative medicine is set to become the third pillar of healthcare.**



However, to fulfill its promise of curing a range of common diseases and to make treatment safe and accessible to all, regenerative medicine must transition from a craft (left) to a regulated large-scale industry where cells are grown in clean-rooms without manual handling (right).



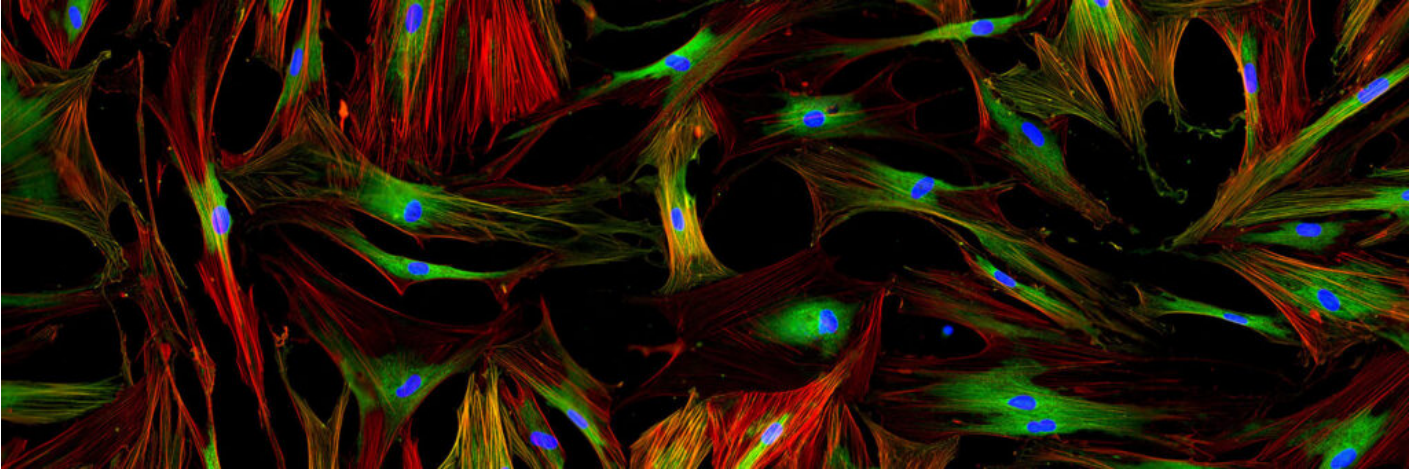
Regenerative medicine will not be the first cell-based process that has made the transition from craft to industry.

## Fluorescence Launch

For decades, medical scientists have used fluorescence microscopy to study the genetic activity of cells. However, the research community has become increasingly aware that the toxic side-effects created by fluorescence microscopy could lead to misleading results and incorrect conclusions. Academic and commercial scientists are therefore looking for non-invasive alternatives.



To date, there are **no good solutions available** to this toxicity problem. However, the integration of holographic and fluorescence microscopy in a single instrument solves this long-standing issue. By combining the two techniques, the number of fluorochromes and their use is minimized, reducing the amount of toxin released by the fluorochromes to a minimum.



Fluorescent cells can be incredibly beautiful. However, brilliant and beautiful cells often mean dead cells due to the released toxins. Fluorescence images of living healthy cells are mundane and far less cinematic, for a layman.

Presently HoloMonitor addresses a market of well over 100 000 medical research laboratories. The vast majority of these laboratories use fluorescence today. HoloMonitor's coming fluorescence capability will significantly strengthen the HoloMonitor product range. The add-on fluorescence unit will allow commercial and academic researchers to use fluorescence more efficiently while reducing the undesired toxic effects of fluorescence imaging.

The yet-to-be-named HoloMonitor fluorescence unit is planned to be launched in the first half of 2022, expanding PHI's current product line.

## **HoloMonitor in Regenerative Medicine**

The **non-invasive qualities** of HoloMonitor make it especially well-suited for regenerative medicine applications. As a result, the number of HoloMonitor units that have been purchased for use within regenerative medicine has increased notably over the past year. The most notable customers within the field are both Bayer AG and its subsidiary BlueRock Therapeutics. In July this year, BlueRock was granted an **FDA Fast Track designation** for their cell therapy for advanced Parkinson's disease.

## AI, Fluorescence and Holography

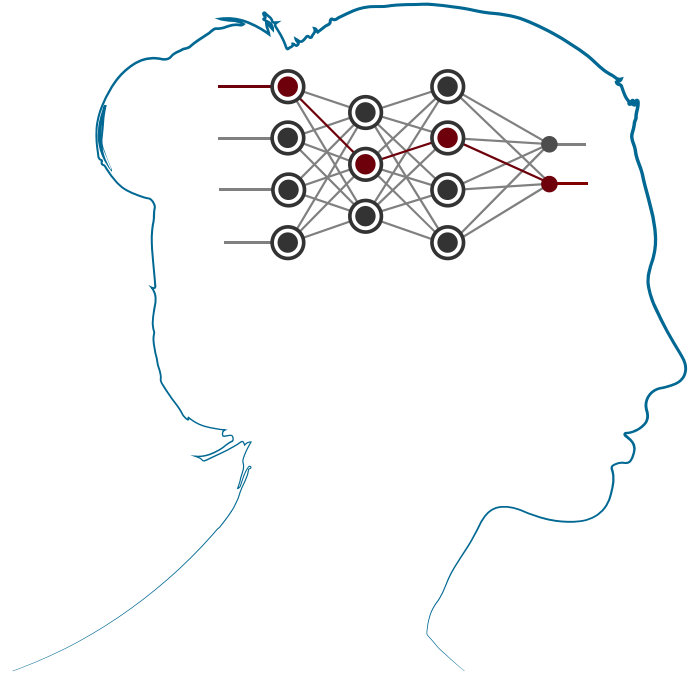
Modern AI software learns by example. Before training begins, a large training dataset is collected where each example is paired with the correct answer. For instance, a training dataset could be images of individual cells paired with the cell type.

The dataset is then presented to a network of digital “brain cells”. Each time the network gives the wrong answer, the network connections are adjusted to provide a more correct answer next time the example is shown to the network. Eventually, the network will learn to give the right answer for all the examples in the dataset.

Minimally invasive fluorescence is essential not only in pre-clinical research but also for identifying cellular transformations when developing biomanufacturing quality and process control standards.

During therapy production, the patient cells transform from the extracted to the desired cell type in several stages. As the cells will be transplanted back to the patient, it is by no means acceptable to stain or biochemically label the cells to assess the transformation progress.

By combining fluorescence imaging with holographic imaging, an **AI-based system may be taught to recognize the intermediate cell types** without fluorescence imaging. Each example in the training dataset is created by determining the cell type using fluorescence, while holographic imaging provides the example cell image. Provided there is sufficient discriminating information in the example images, the AI software will learn to recognize cell types without fluorescent labeling **to remove the need for fluorescence imaging completely**, as desired.



## Biomanufacturing Consortium

As previously communicated, we entered a partnership with the [Wake Forest Institute for Regenerative Medicine](#) (WFIRM) and its biomanufacturing scale-up initiative RegenMed Development Organization (ReMDO) in August 2021. At both the federal and state levels in the United States, WFIRM is considered to be the leader of regenerative medicine.

To achieve the goal of industrializing regenerative medicine, WFIRM has identified several technologies that need to be developed, outlined in [An Industry-Driven Roadmap for Manufacturing in Regenerative Medicine](#). WFIRM has further recognized that it cannot develop and promote these technologies on its own. WFIRM has therefore initiated the creation of a stakeholder consortium that brings industry, academia and government agencies together to facilitate regenerative medicine's transition from craft to industry. **PHI's natural role in the established consortium would be to provide the critical non-invasive cell imaging and analysis technology** outlined above.



Peter Egelberg, CEO

## Sales

As of last spring, sales have steadily increased. We anticipate that this positive sales trend will continue. However, we expect sales to be temporarily slower when international restrictions are imposed during pandemic surges. But, as we have seen, sales quickly rebound as soon as restrictions once again are lifted.

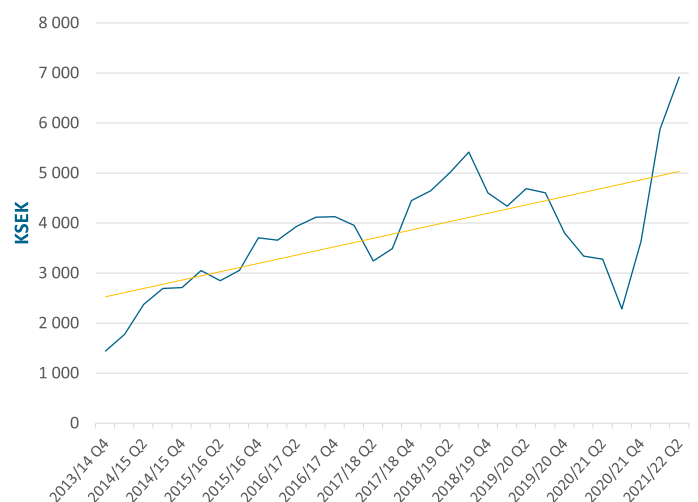
## NET SALES AND RESULT

Net sales for the second quarter amounted to 1 818 (826) KSEK and operating results before depreciation (EBITDA) to -2 733 (-2 946) KSEK. The net result amounted to -3 901 (-4 777) KSEK.

## INVESTMENTS

With an emphasis on application development and the development of fluorescence capability, the company invested 1 246 (1 048) KSEK in the product, patent, and application development during the period.

## Rolling 12-month sales with trendline



## FINANCING

Cash, cash equivalents, and unutilized granted credits amounted to 21 261 (21 595) KSEK by the end of the period. The equity ratio was -13 (62) %.

PHI has secured working capital until 2023. One of the loans from Formue Nord A/S of 20 000 KSEK, of the total approved loan amount of 35 000 KSEK, can be repaid in cash or by debt/equity swap, under certain specific conditions.

Based on that working capital is secured, calculation of the net sales value of inventories and valuation of intellectual property rights, the Board makes the assessment that the share capital is intact and that the company has sufficient working capital.

## RISKS

The company may be affected by various factors, described in the 2020/21 Annual Report. These factors may individually or jointly increase risks for the operation and result of the company.

## ACCOUNTING PRINCIPLES

The accounts are prepared in accordance with the Annual Accounts Act and general advice from the Swedish Accounting Standards Board BFNAR 2012:1 Annual accounts and consolidated accounts (K3).

## REVIEW

This interim report has not been subject to review by the company's auditor.

## STATEMENTS ABOUT THE FUTURE

Statements concerning the company's business environment and the future in this report reflect the board of director's current view of future events and financial developments. Forward-looking statements only express the judgments and assumptions made by the board of directors on the day of the report. These statements have been carefully assessed. However, it is brought to the reader's attention that these statements are associated with uncertainty, like all statements about the future.

## CALENDAR

- 23 of March 2022, Interim Report 3



## ABOUT PHI

Phase Holographic Imaging (PHI) develops instrumentation and software for time-lapse cytometry. The products are used for long-term quantitative analysis of the dynamics of live cells, particularly significant in the research of cancer, as well as in the treatment of inflammatory and autoimmune diseases. The products are sold globally through the company's distributors. The company is based in Lund, Sweden, and in Boston, Massachusetts.

On behalf of the Board of Directors

Peter Egelberg, CEO

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## CONSOLIDATED – PHI GROUP

### Income statement (KSEK)

	Q2 2021/22	Q2 2020/21	YTD 2021/22	YTD 2020/21	FY 2020/21
Net sales	1 818	826	4 191	957	3 637
Cost of products sold	-124	-190	-1 067	-347	-1 346
Gross profit	1 694	636	3 124	610	2 291
<i>Gross margin</i>	<i>93%</i>	<i>77%</i>	<i>75%</i>	<i>64%</i>	<i>63%</i>
Selling expenses	-1 891	-1 874	-3 961	-3 482	-8 773
Administrative expenses	-1 658	-1 025	-3 715	-3 859	-7 084
R&D expenses	-1 947	-3 041	-3 617	-6 161	-11 720
Operating income	0	523	0	1 723	1 972
Operating result (EBIT)	-3 802	-4 781	-8 169	-11 169	-23 314
Financial net	-99	4	-201	-25	-195
Result before tax (EBT)	-3 901	-4 777	-8 370	-11 194	-23 509
Net Result (EAT)	-3 901	-4 777	-8 370	-11 194	-23 509

## Balance sheet (KSEK)

	Q2 2021/22	Q2 2020/21	FY 2020/21
<b>ASSETS</b>			
<b>Non-current assets</b>			
Intangible assets	15 674	14 954	14 823
Tangible assets	235	518	337
Total non-current assets	15 909	15 472	15 160
<b>Current Assets</b>			
Inventory	2 499	1 604	1 334
Short-term receivables	3 211	2 981	2 938
Cash and equivalents	1 261	8 345	2 256
Total current assets	6 971	12 930	6 528
Total assets	22 880	28 402	21 688
<b>EQUITY AND LIABILITIES</b>			
Equity	-3 004	17 675	5 384
Financial liabilities	18 650	4 625	7 400
Operating liabilities	7 234	6 102	8 904
Total equity and liabilities	22 880	28 402	21 688

## Changes in equity (KSEK)

	Q2 2021/22	Q2 2020/21	FY 2020/21
Opening Balance	893	22 476	28 896
Equity issues, net			
Net profit	-3 901	-4 777	-23 509
Translation difference	4	-24	-3
Closing balance	-3 004	17 675	5 384
Equity ratio	-13%	62%	25%

## Cash flow analysis (KSEK)

	Q2 2021/22	Q2 2020/21	YTD 2021/22	YTD 2020/21	FY 2020/21
<b>Operating activities</b>					
Net result	-3 901	-4 777	-8 370	-11 194	-23 509
Depreciation	996	1 835	1 997	3 674	6 541
Translation difference	4	-24		-27	-4
Operating cash flow	-2 901	-2 966	-6 373	-7 547	-16 972
Increase (-)/decrease (+) in inventories	-890	-211	-1 165	-74	196
Increase (-)/decrease (+) in operating receivables	347	-824	-273	-470	-348
Increase (+)/decrease (-) in operating liabilities	-209	-244	-1 670	159	2 882
Change in working capital	-752	-1 279	-3 108	-385	2 730
Cash flow from operating activities	-3 653	-4 245	-9 481	-7 932	-14 242
<b>Investing activities</b>					
Development expenses	-1 246	-1 048	-2 747	-1 707	-4 091
Patents	1	0	1	0	-170
Tangible assets	0	0	0	0	0
Cash flow after investments	-4 898	-5 293	-2 746	-9 639	-18 503
<b>Financing activities</b>					
Net proceeds from equity issues	0	0	-18	0	0
Increase (+)/decrease (-) in borrowings	-8	-250	11 250	3 500	-6 275
Cash flow from financing activities	-8	-250	11 232	3 500	6 275
Cash flow for the period	-4 906	-5 543	-995	-6 139	-12 228
Cash and cash equivalents at the beginning of the period	6 167	13 888	2 256	14 484	14 484
Cash and cash equivalents at	1 261	8 345	1 261	8 345	2 256

the end of the period

*Incl. unutilized credits*                      21 261    21 595    21 261    21 565    35 506

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## Data per share

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	Q2 2021/22	Q2 2020/21	YTD 2021/22	YTD 2020/21	FY 2020/21
Earnings per Share, SEK	-0,27	-0,33	-0.58	-0,78	-1,63
Equity per share, SEK	-0,21	1,23	-0.21	1,23	0,37
Number of Shares, end of period	14 394 971	14 394 971	14 394 971	14 394 971	14 394 971
Average number of shares	14 394 971	14 394 971	14 394 971	14 394 971	14 394 971
Share price end of period, SEK	23.75	27.60	23.75	27.60	25.00

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## PARENT COMPANY

### Income statement (KSEK)

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	Q2	Q2	YTD	YTD	FY
	2021/22	2020/21	2021/22	2020/21	2020/21
Net sales	656	1 015	2 478	1 137	2 991
Cost of products sold	-142	-424	-1 067	-581	-1 358
Gross profit	514	591	1 411	556	1 633
<i>Gross margin</i>	<i>78%</i>	<i>58%</i>	<i>57%</i>	<i>49%</i>	<i>55%</i>
Selling expenses	-1 103	-1 495	-2 522	-2 403	-6 617
Administrative expenses	-1 658	-1 025	-3 715	-3 859	-7 084
R&D expenses	-1 947	-3 041	-3 617	-6 161	-11 720
Other Income	0	523	0	1 723	1 972
Operating result (EBIT)	-4 194	-4 447	-8 443	-10 144	-21 816
Financial net	-99	4	-201	-25	-1 137
Result before tax (EBT)	-4 293	-4 443	-8 644	-10 169	-22 953
Net Result (EAT)	-4 293	-4 443	-8 644	-10 169	-22 953

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## Balance sheet (KSEK)

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	Q2 2021/22	Q2 2020/21	FY 2020/21
<b>ASSETS</b>			
<b>Non-current assets</b>			
Intangible assets	15 674	14 954	14 823
Tangible assets	235	518	337
Financial assets	0	942	0
Total non-current assets	15 909	16 414	15 160
<b>Current Assets</b>			
Inventory	2 499	1 337	1 334
Short-term receivables	5 230	4 067	4 578
Cash and equivalents	0	7 998	1 711
Total current assets	7 729	13 402	7 623
Total assets	23 638	29 816	22 783
<b>EQUITY AND LIABILITIES</b>			
Equity	-2 246	19 183	6 399
Financial liabilities	18 650	4 625	7 400
Operating liabilities	7 234	6 008	8 984
Total equity and liabilities	23 638	29 816	22 783

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