Devyser

Earnings call Q1 2024

May 8, 2024

Dvysr

Today’s presenters

Fredrik Alpsten
CEO

Sabina Berlin
CFO

Theis Kipling
CCO

Dvysr®

The value of correct and fast diagnosis

Waiting for test results is a stressful experience for patients and their families

The outcome can be life-changing

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Our mission

Be the pioneering leader of diagnostic solutions and provide fast, accurate, and easy-to-use solutions to labs worldwide.

Our vision

A world where personalized medicine is universally available thanks to simplified and reliable genetic tests.

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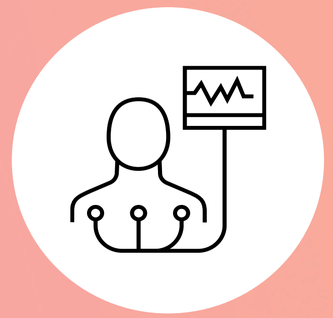
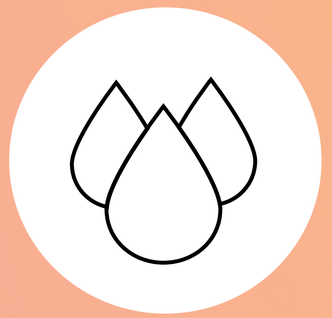
Our diagnostic areas



Post-transplantation

Oncology

HEREDITARY DISEASES



Hematology

Reproductive Health

Cystic Fibrosis

Cardiovascular Diseases

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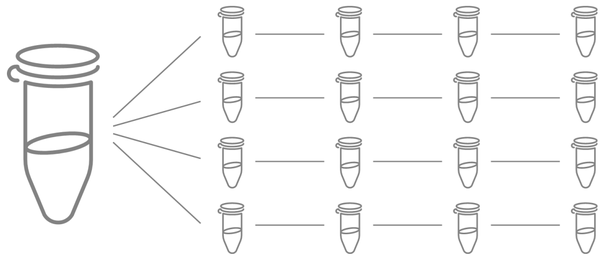
Simplified workflow – faster, better and safer

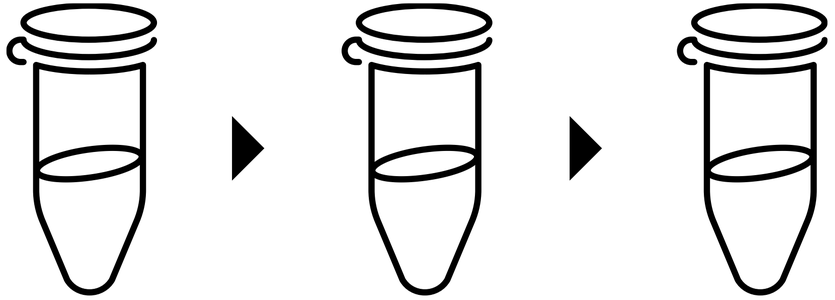
Traditional solutions

Multi-step and multi-tube process



Devyser solution

Single-tube process



- **Faster** <45 minutes hands-on time
- **Better** Achieve turnaround time of 2-3 days
- **Safer** Easy to use, minimize risk of sample mix up

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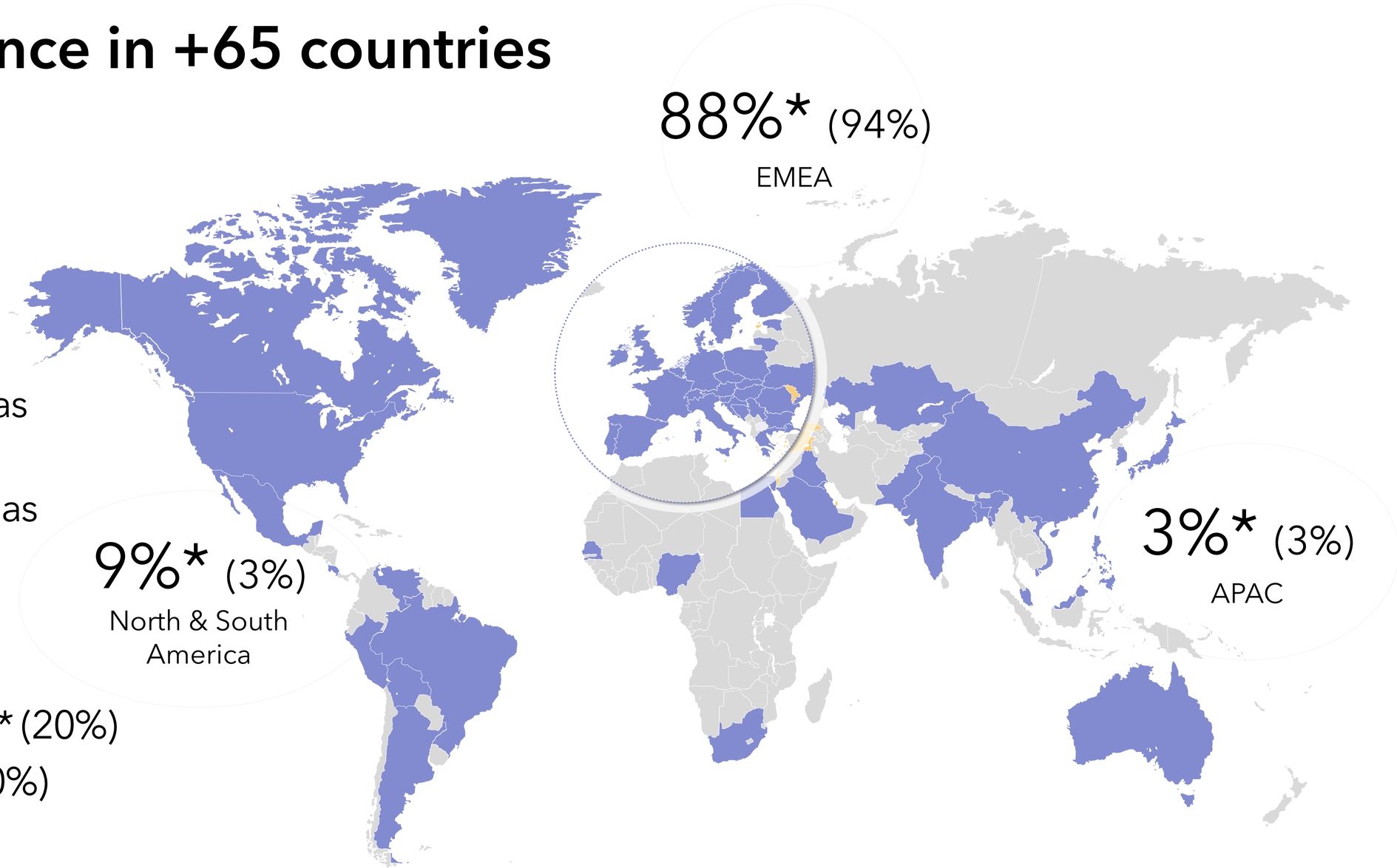
Market presence in +65 countries

Four sales channels
- Direct sales
- Partners (reported as distributor sales)
- CLIA-lab (reported as direct sales)
- Distributor sales

Distributor sales 25%* (20%)

Direct sales 75%* (80%)

*) LTM (Last twelve months)



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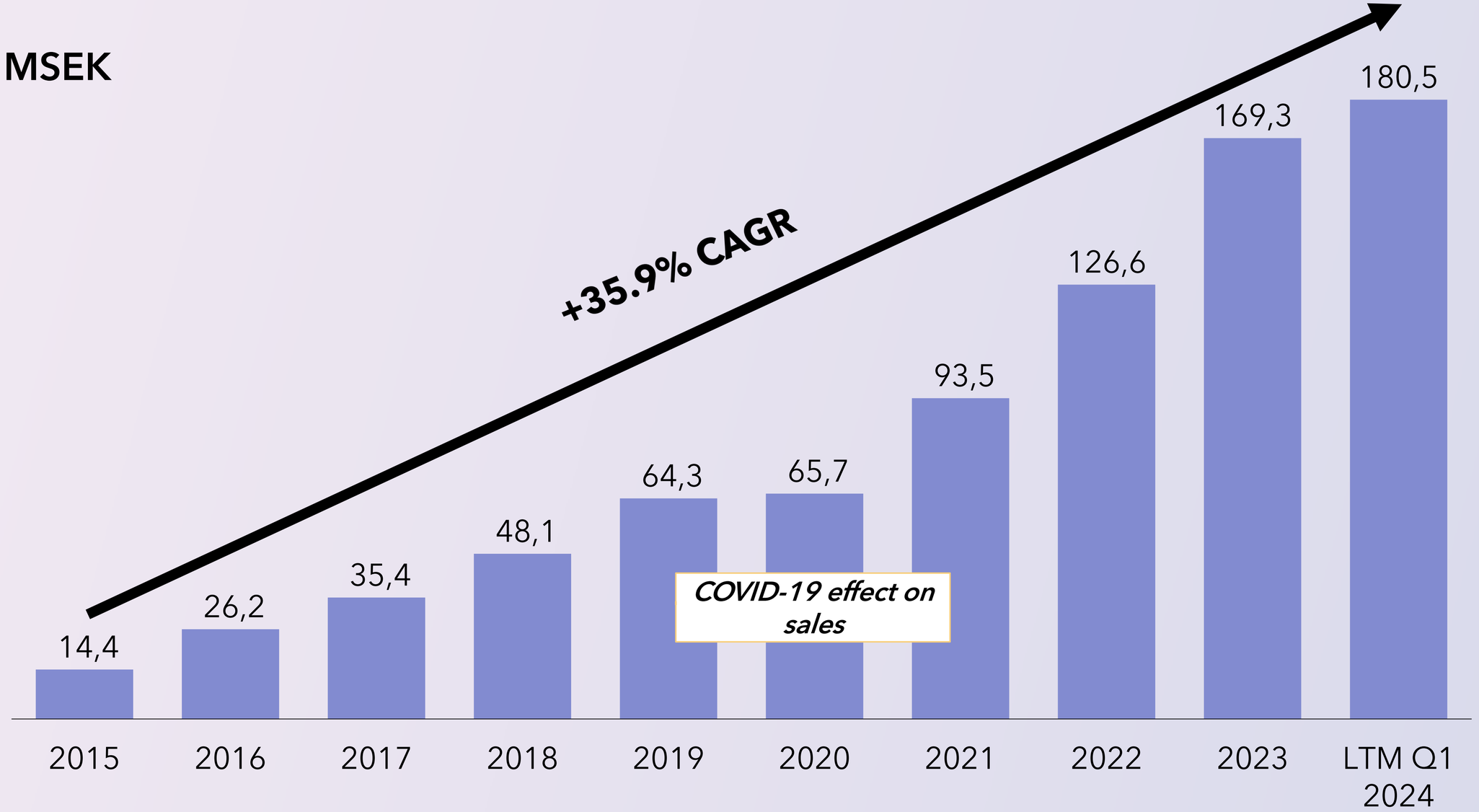
High sales growth



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First quarter 2024

First quarter

- Continued strong sales growth
  - Sales 50.7 MSEK (39.5 MSEK)
  - Growth + 28.5% (all organic)
  - Growth local currency +27.7%

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  - -12.2 MSEK (-19.1)

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- Strong financial position
  - 215 MSEK in liquidity
  - No debts

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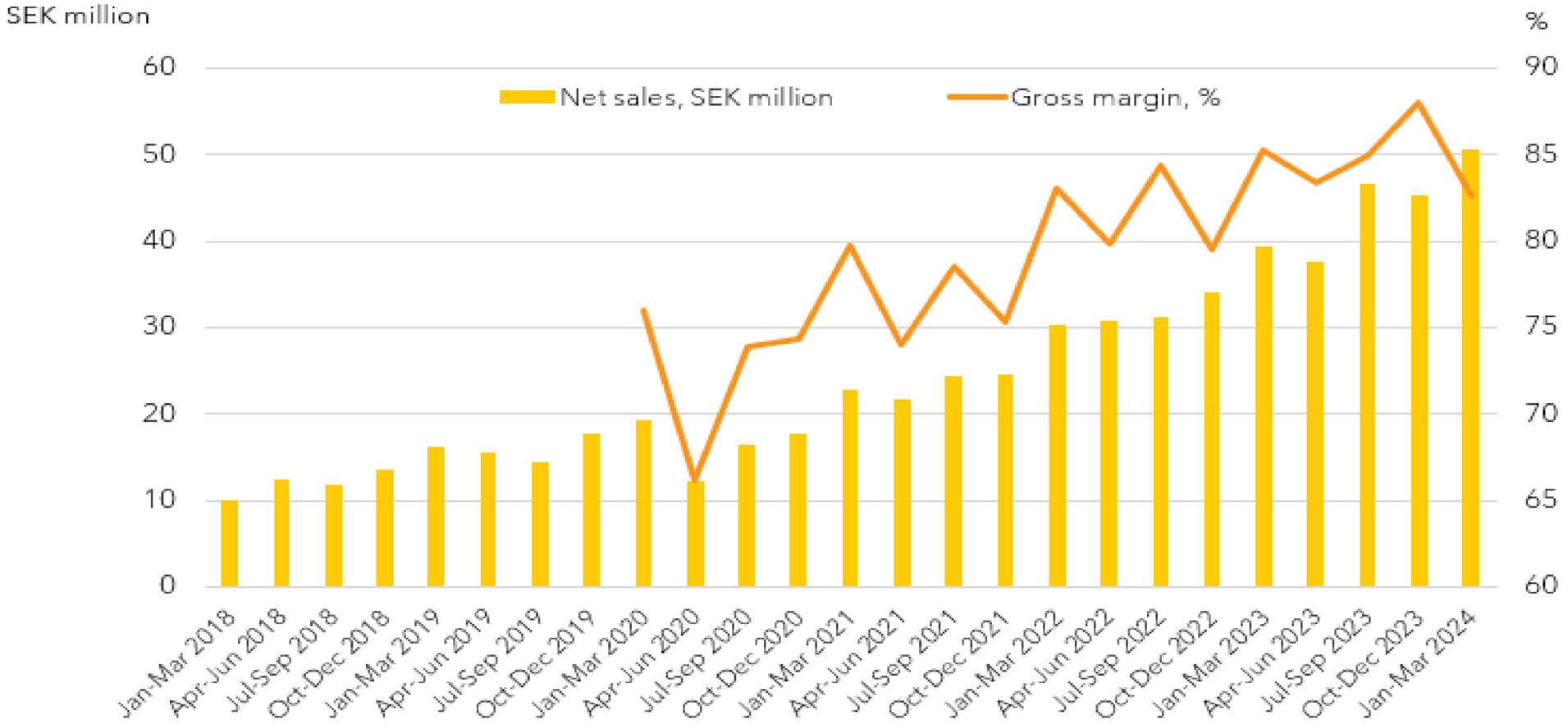
Quarterly sales and gross margins



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Commercial outlook

We have four main channels, and we use the channel that best serves our objective

Direct sales

- We use Direct sales for established countries, i.e. we convert from Distributor
- Direct sales is our preferred channel
- Revenues will continue to go up, but our total share of Direct Sales is estimate to go down due to our partnership with Thermo Fisher and potential new partnerships

Partners

- Partners take a larger responsibility for regulatory issues, customer support, contacts with key opinion leaders, clinical studies etc. Contracts are normally exclusive
- Revenues from partners and total share will grow more than our other channels
- We have one partner today (Thermo Fisher) for transplantation but expect more to come across the portfolio

Lab services

- Laboratory services utilizing our US based CLIA laboratory is a strong platform for continued growth
- Pharmaceutical companies and other Laboratories are the main target customers
- We validate new product services when enough customer requests these services
- We expect revenues to increase rapidly as we get our tests reimbursed

Distributors

- We have approx. 50 distributors today
- We assume that we will only add a smaller number of Distributors going forward
- Contracts are both exclusive and non-exclusive
- We use Distributors make market entry into new countries
- If we see a large market demand, we will convert this market to Direct Sales




Agreement with Thermo Fisher Scientific

- The collaboration continues well and we remain being very optimistic for 2024 and beyond
- We are gearing up for the launch of additional 3 indications (Liver, Lung, Heart) for solid organs (Accept cfDNA)
- We are in dialogue with One Lambda around two additional new products for transplantation to be launched during 2025

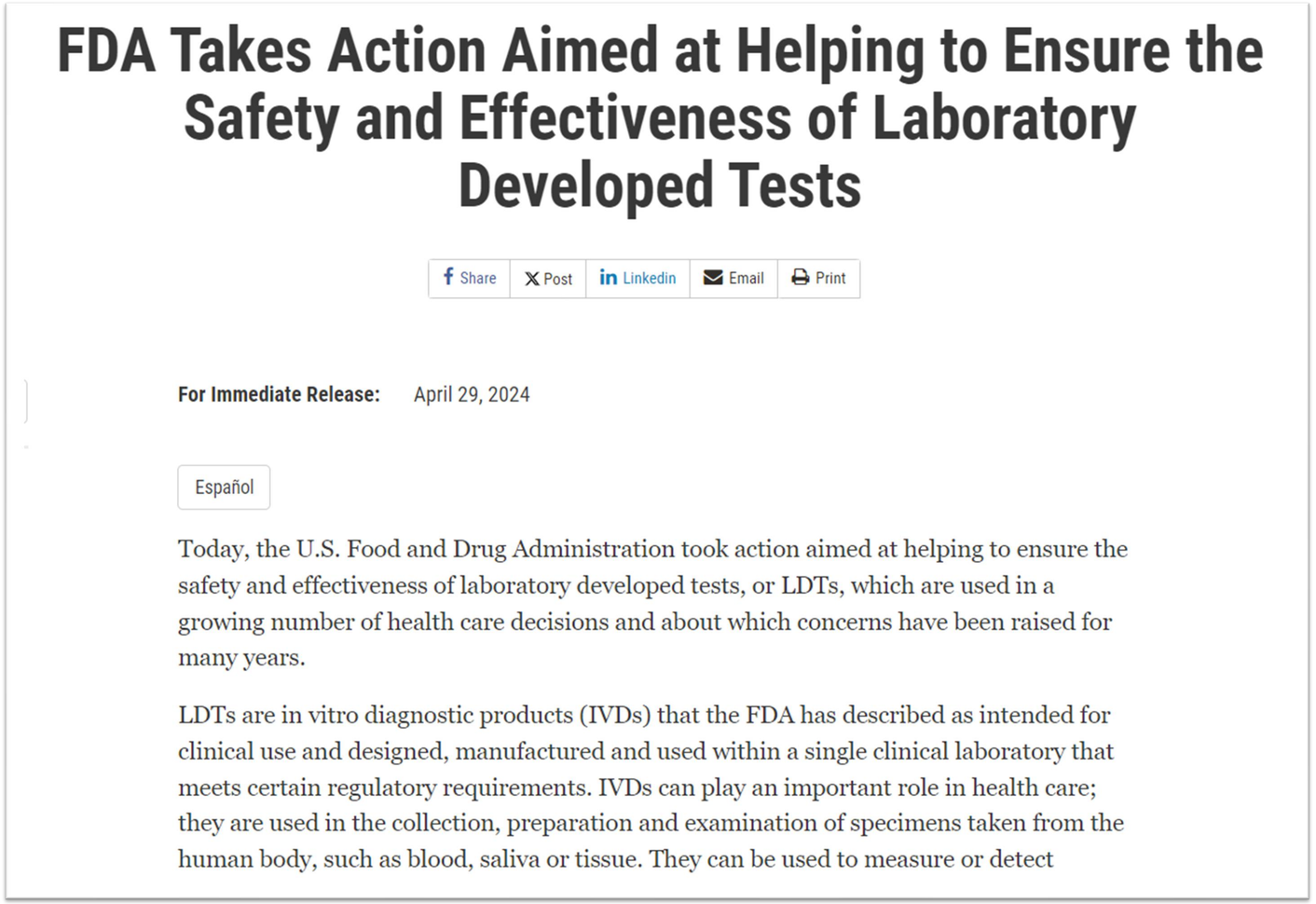
Devyser Genomic Laboratories

- We signed our first agreement with the UK based oncology company, Cyted incl. estimated revenues of 25 MSEK over 2 years
- This collaboration came nicely off the ground during Q1 and is off to a promising start
- Currently, RHD and Chimerism has been validated with Accept cfDNA and Cystic Fibrosis as immediate next products for validation
- Reimbursement process initiated led by new VP, Global market access & public affairs who joined Devyser on April 29th

Devyser CFTR NGS

- In 2023, The American College of Medical Genetics and Genomics updated its recommendations regarding the number of screening variants, from 23 to 100
- Devyser CFTR NGS one of few products that meet the new recommendations
- Breakthrough in the US announced on March 11
- First won deal with UNC Hospitals (University of North Carolina). Estimated order value 10M SEK
- 1.4 million tests performed yearly in the US

New FDA rule to regulate laboratory developed tests in the US



FDA Takes Action Aimed at Helping to Ensure the Safety and Effectiveness of Laboratory Developed Tests

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For Immediate Release: April 29, 2024

Español

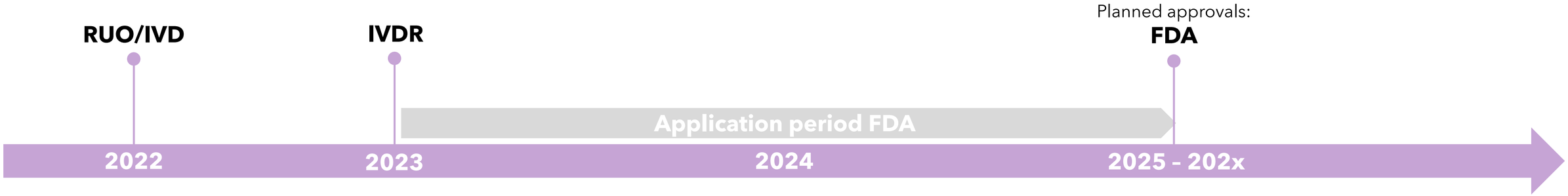
Today, the U.S. Food and Drug Administration took action aimed at helping to ensure the safety and effectiveness of laboratory developed tests, or LDTs, which are used in a growing number of health care decisions and about which concerns have been raised for many years.

LDTs are in vitro diagnostic products (IVDs) that the FDA has described as intended for clinical use and designed, manufactured and used within a single clinical laboratory that meets certain regulatory requirements. IVDs can play an important role in health care; they are used in the collection, preparation and examination of specimens taken from the human body, such as blood, saliva or tissue. They can be used to measure or detect

Devyser will pursue a clinical claim-based strategy in both Europe & US and actively working towards regulatory approvals

Securing regulatory approval(s) based on solid clinical data will establish Devyser's clinical claims and reimbursement levels as a clear competitive advantage and company edge. This will enable higher prices and stronger differentiation of our products.

- Historically, Devyser focused on RUO and IVD however, have today established a strong position as a leading IVD-R company which is recognized by the market (both customers, competitors and partners)
- Bringing this to FDA clearance further strengthens the position in the large US market and is also timely considering the expected increased oversight and regulation by the FDA over LDT's
- Several of our products are well positioned for FDA approval considering that there is already a predicate device on the market
- Our agreement and collaboration with Illumina was a strategic decision to move towards FDA approvals



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Developing FDA & IVDR approved tests in collaboration with Illumina

- The agreement enables Devyser to develop and commercialize IVD end-to-end solutions on the Illumina MiSeqDx NGS instrument across United States and Europe
- We expect both our transplantation products as well as our product targeting Cystic Fibrosis will be some of the first ones to become FDA approved
- Until FDA approval is achieved these products are sold as Research Use Only (Laboratory developed test)

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Strong development

- Really strong (and fast) development
- +30 employees within R&D (assay, software, innovation, clinical affairs)
- 7-8 new products launched in the last 12 months
- Continued work to upgrade products from IVD to IVDR
- Launching 5-10 new products within the next 6-18 months
- Invested in our clinical affairs group and running plenty of studies

Going forward

- Focus on North America and Europe
- Increased US presence with the CLIA lab and our US commercial partner
- Optimistic about sales development
- New products in the pipeline
- Continue our way to profitability

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Q&A

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