



Q1 Presentation 2019

Oslo, 9th May 2019

Hilja Ibert, CEO
Njaal Kind, CFO

Important notice

This presentation has been prepared by and is the sole responsibility of Gentian Diagnostics AS (the “Company” or “Gentian”). The presentation is furnished to you solely for your information and may not be reproduced or redistributed, in whole or in part, to any other person. The information herein and any other material discussed is subject to change

The presentation contains certain forward-looking statements relating to the business, future financial performance and results of the Company and/or the industry in which it operates. Forward-looking statements concern future circumstances and results and other statements that are not historical facts, sometimes identified by the words “believes”, “expects”, “predicts”, “intends”, “projects”, “plans”, “estimates”, “aims”, “foresees”, “anticipates”, “targets”, and similar expressions. Any forward-looking statements contained herein, including assumptions, opinions and views of the Company or cited from third party sources are solely opinions and forecasts which are subject to risks, uncertainties and other factors that may cause actual events to differ materially from any anticipated development. Potential investors are expressly advised that financial projections, such as the revenue and cash flow projections contained herein, cannot be used as reliable indicators of future revenues or cash flows. Neither the Company (nor any of its parent or subsidiary undertakings) or the Managers (or any such person’s representatives, officers, employees or advisors) provide any assurance that the assumptions underlying such forward-looking statements are free from errors nor does any of them accept any responsibility for the future accuracy of the opinions expressed in this presentation or the actual occurrence of the forecasted developments. No obligation is assumed to update any forward-looking statements or to conform these forward-looking statements to our actual results.

The distribution of this presentation may also in other jurisdictions be restricted by law. Accordingly, this presentation may not be distributed in any jurisdiction except under circumstances that will result in compliance with applicable laws and regulations. The Company require persons in possession of this presentation to inform themselves about, and to observe, any such restrictions.

Nothing in this presentation shall constitute an offer to sell or a solicitation of an offer to buy any shares in the Company in any jurisdiction in which such offer or solicitation is unlawful.

Nothing contained in this presentation is or should be relied upon as a promise or representation as to the future. Except where otherwise expressly indicated, this presentation speaks as of the date set out on its cover. In addition, no responsibility or liability or duty of care is or will be accepted by the Company for updating this presentation (or any additional information), correcting any inaccuracies in it which may become apparent or providing any additional information.

Agenda



1

Introduction and Highlights

2

Q1 Financials

3

Sales, Operations, R&D

4

Outlook



In vitro diagnostics market

- Detection and prevention of disease
- Estimated market value of 80B\$

Immunochemistry is our core segment

- The immunochemistry market segment is estimated to represent about 30B\$ of the total IVD market
- Detection and quantification of biomarkers in patient samples (e.g. plasma)
- Our NanoSense technology enables the transfer of assays from low- to high-throughput clinical chemistry instruments and with this providing significant efficiency benefits to healthcare providers:
 - capacity increase
 - faster time-to-result
- Our focus disease categories are:
 - Inflammation
 - Renal
 - Cardiac
- The estimated market value of these disease categories represent a value of 7B\$

Highlights for Q1 2019

- 10 % growth in sales revenue in 1Q19 compared to 1Q18
- Total sales revenues of MNOK 10.6 in 1Q19, up from MNOK 9.6 in 1Q18
- Record sales of fCAL®turbo with 90% growth from 1Q18.
- Cystatin C sales of MNOK 4.7 negatively affected by supply chain planning of our partners, especially in China
- New scientific study results confirm GCAL as a promising biomarker for the diagnosis of bacterial infections.



Agenda



1

Introduction and Highlights

2

Q1 Financials

3

Sales, Operations, R&D

4

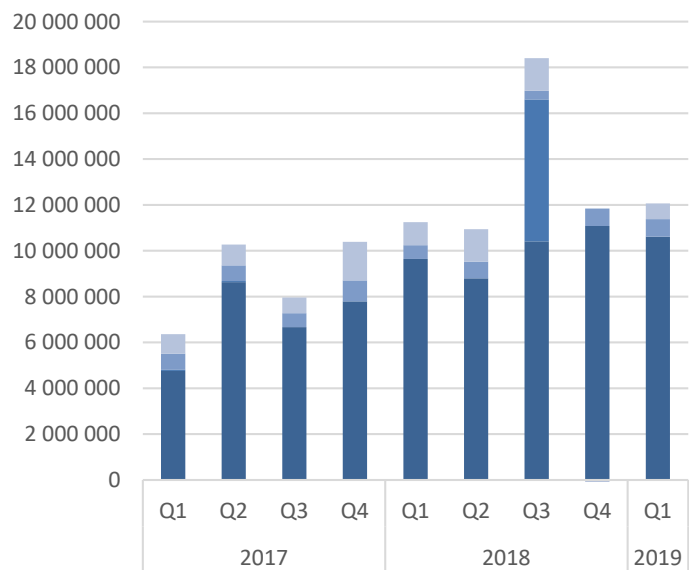
Outlook

Financial highlights 1Q 2019

MNOK	1Q 2019	1Q 2018
Sales	10.6	9.6
Other Revenues	1.5	1.6
Total Revenues	12.1	11.2
COGS	2.6	2.3
Production Costs	4.0	4.3
R&D Costs	4.1	3.2
SG&A	7.9	5.1
Capitalization	-0.9	-0.6
OPEX	17.7	14.3
EBITDA	-5.6	-3.0
EBIT	-7.3	-4.0

Sales and revenues

Revenues and Grants Consolidated (NOK)



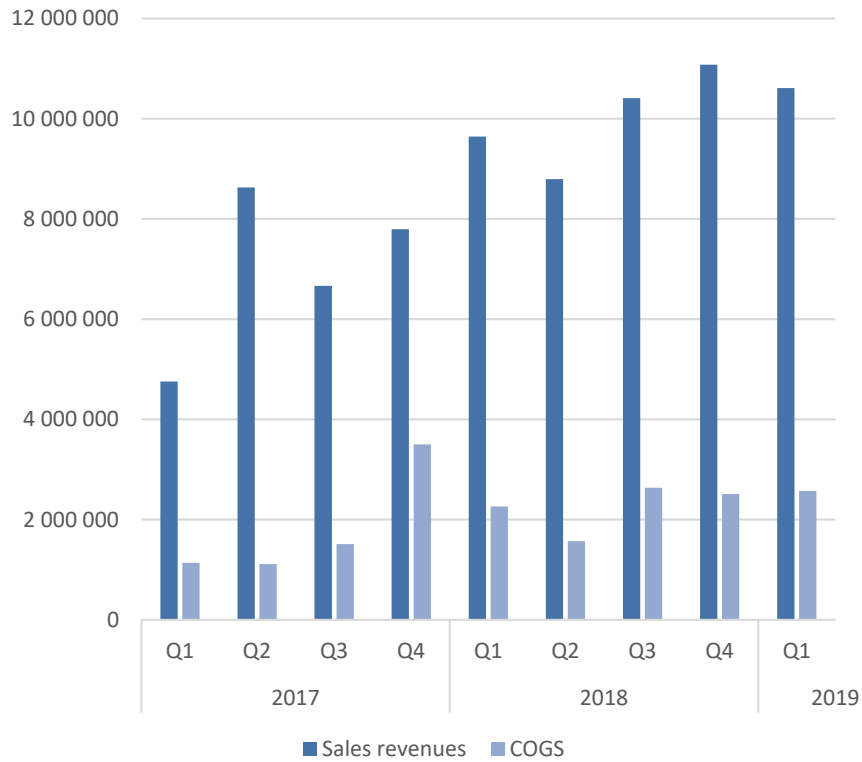
■ Sales revenues ■ Royalties ■ Governmental grants ■ SkatteFUNN

Sales revenues - geographic split

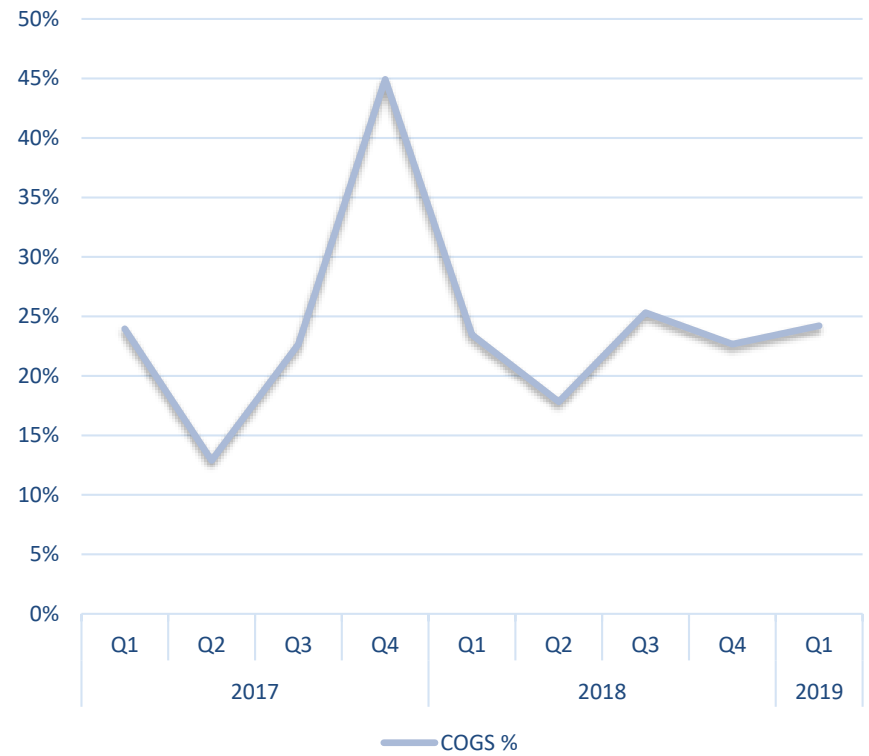
MNOK	1Q19	1Q18
US	0.5	0.4
Europe	7.4	6.1
Asia	2.7	3.1
Total	10.6	9.6

Cost of Goods Sold

Sales vs. COGS

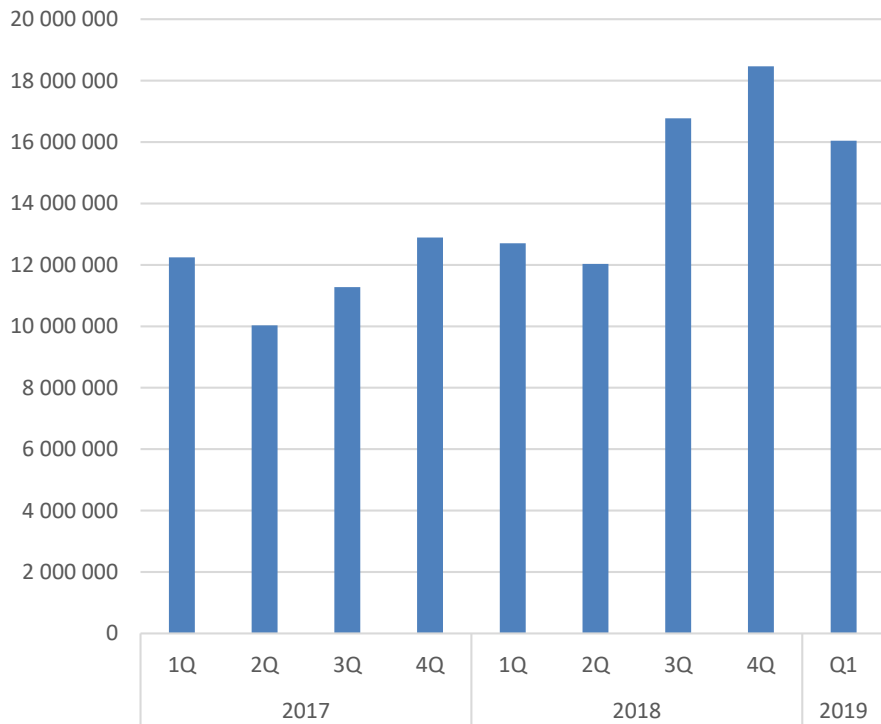


COGS %

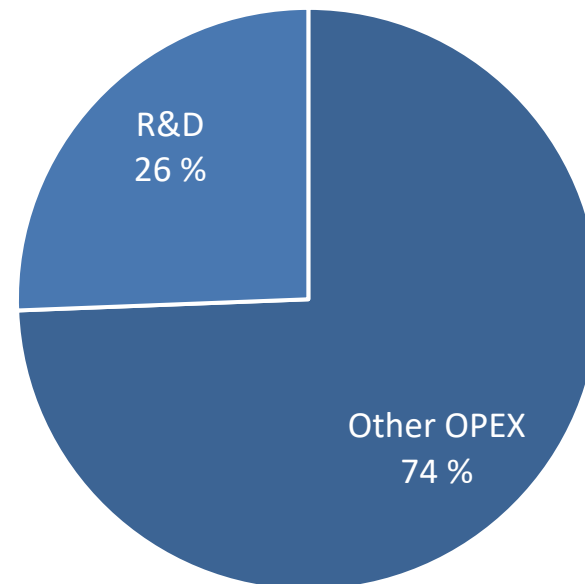


OPEX

OPEX



OPEX Q1 2019



Total OPEX before capitalization: 16.0MNOK

Cash flow and cash position

MNOK	1Q19	1Q18	2018
Operating activities	-6.2	- 5.5	- 16.0
Investing activities	- 1.2	- 0.8	- 6.1
Other changes in financial items	0.0	0.0	5.0
Financing activities	0.0	0.0	68.8
Changes in cash and cash equivalent	-7.4	-6.3	51.7
Cash and cash equivalent at the beginning of period	198.6	146.9	146.9
Cash and cash equivalent at the end of period	191.3	140.6	198.6

Agenda



1

Introduction and Highlights

2

Q1 Financials

3

Sales, Operations, R&D

4

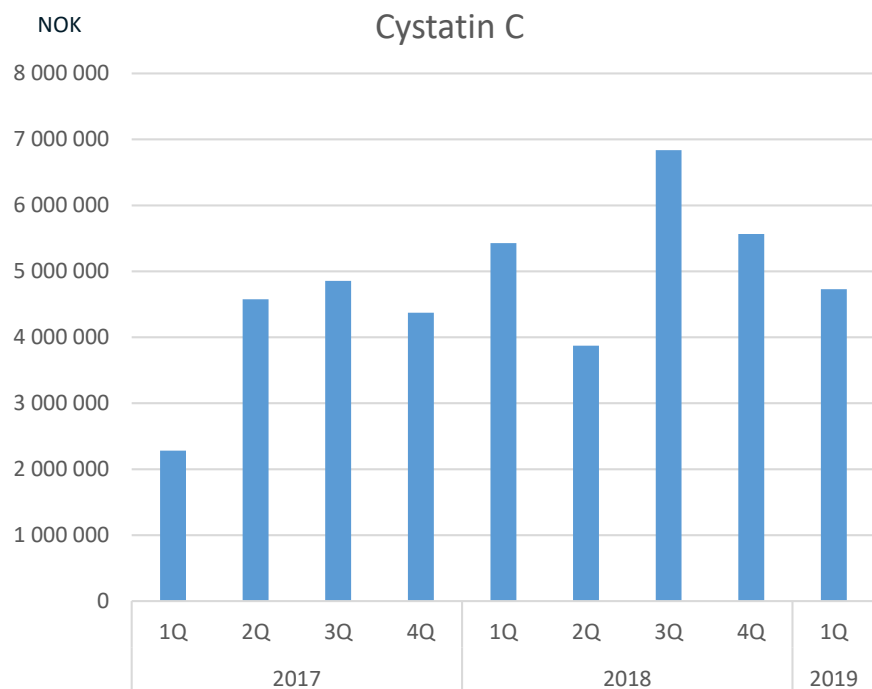
Outlook

Cystatin C

- Early detection of reduced kidney function
- Estimated market value of 0.5B\$
- Continued growth for the company mainly coming from China and US

Sales Cystatin C

Kidney function test, diagnosis and monitoring



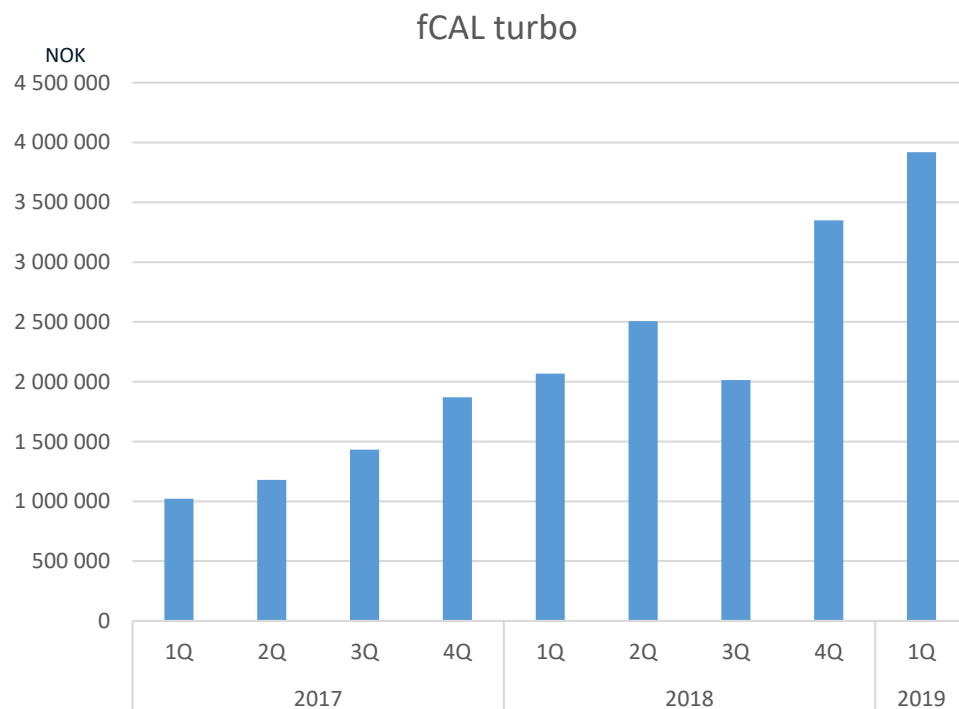
- Sales decline of Cystatin C vs 1Q18, mainly coming from stock adjustments in Asia
- 2Q19 expected to grow significantly over 2Q18
- Business in China expected to drive accelerated growth as of Q3/Q4 2019
- Focus on the US market will contribute to expected growth in Q3/Q4

fCAL® turbo

- Testing of faecal samples on clinical chemistry analysers provide significantly faster results to clinicians
- fCAL turbo support diagnosis of inflammatory bowel disease (IBD)
- Reduces the need for endoscopic examinations of the colon
- Estimated market value of >10M\$
- Continued growth due to increasing demand and competitive conversions by our trusted partner Buehlmann Laboratories AG

Sales fCAL® turbo

Test for inflammatory bowel disease (IBD), diagnosis and monitoring



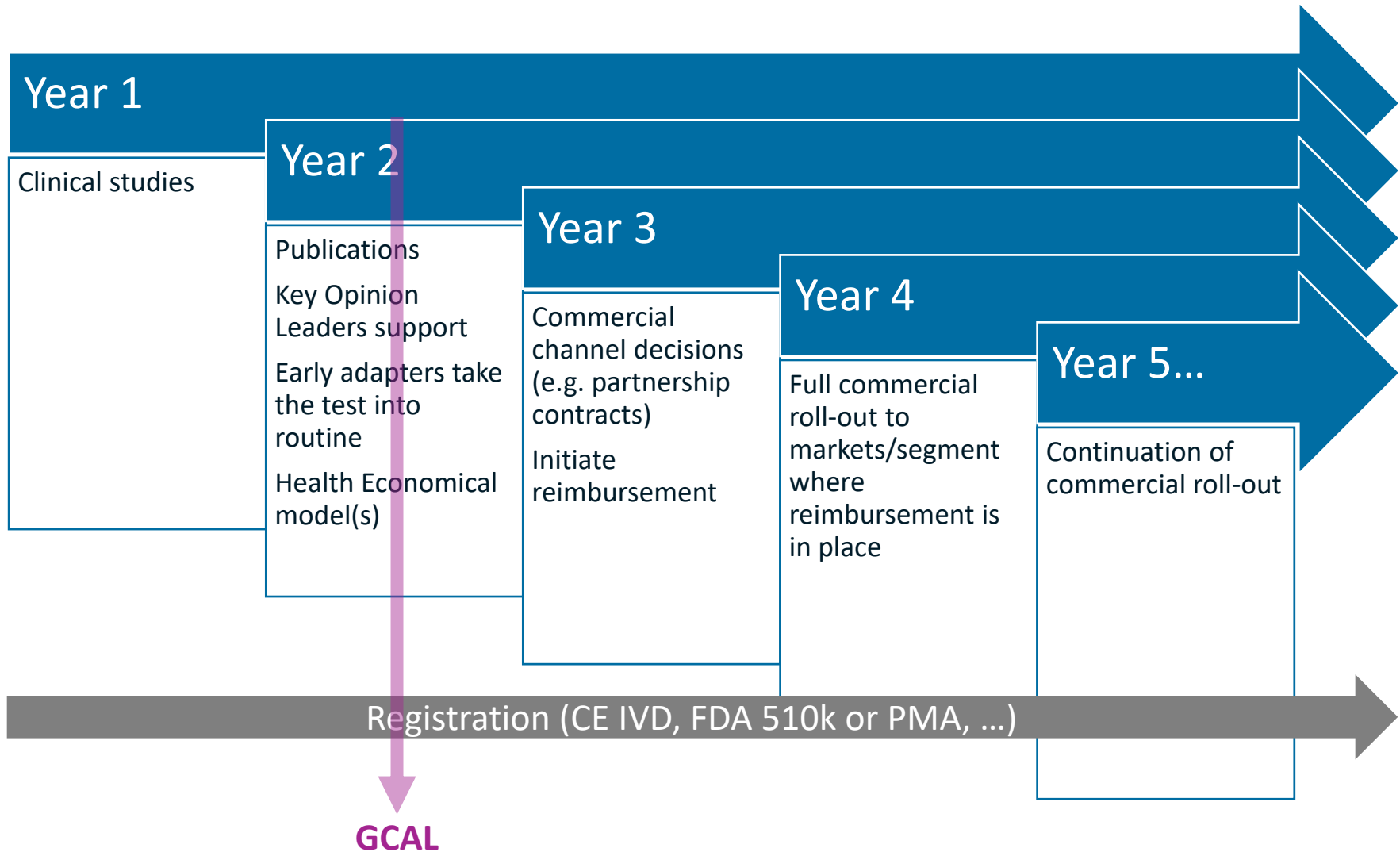
- Strong quarter for fCAL turbo
- 90% revenue growth from 1Q18 comes from both existing and new customers
- Very high sales in UK due to Brexit preparations
- Growth will continue, but variations from quarter to quarter should be expected
- FDA 510k clearance process on plan

GCAL[®] (continue market development)

- Early detection and monitoring of sepsis, other severe infections and rheumatoid arthritis
- Informed treatment decisions and laboratory efficiency
- Reported infectious diseases market value is 4.0B\$ (BCC, 2018)
- Estimated inflammation biomarkers market is 0.5B\$

Market development timeline – example

Process has to be country specific



Clinical study results on the GCAL performance

Jonsson et al., Critical Care and Resuscitation, 2017

Plasma calprotectin appears to be a useful early marker of bacterial infections in critically ill patients, with better predictive characteristics than WBC (white blood cell count) and PCT.

Lipcsey et al., ISF 2018

Calprotectin may be superior to Procalcitonin and Heparin Binding Protein in indicating patients with sepsis.

Calprotectin performed better than Procalcitonin and Heparin Binding Protein in diagnosis of sepsis and distinguishing between patients with sepsis and trauma patients.

Calprotectin had also higher predictive ability regarding 30-day mortality than Procalcitonin.

Clinical study results on the GCAL performance

Larsson et al., ISICEM 2019

Calprotectin is a promising biomarker for diagnosis of bacterial infections. Calprotectin is superior to Procalcitonin in differentiation between viral infections, Streptococcal tonsillitis or Mycoplasma infections.

Rapid determination of calprotectin should be an improvement in the management of infections and allow more selective use of antibiotics.

In product development

fPELA (Pancreatic Elastase)

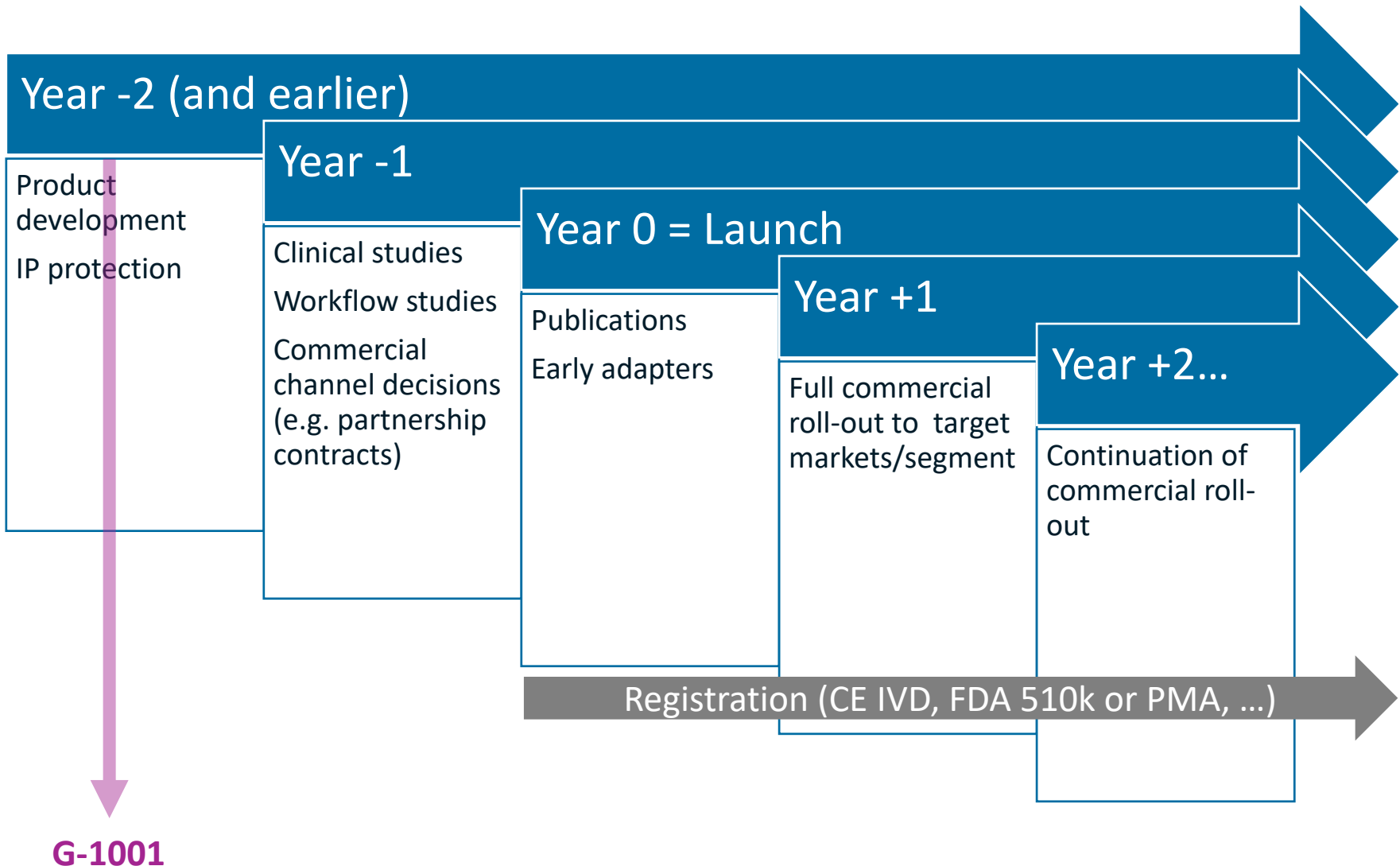
- Marker for pancreatic exocrine insufficiency (PEI)
- Same sample as fCAL® turbo
- Same market as fCAL® turbo
- Launch of fPELA is planned for 2020 by our fCAL® turbo OEM partner (Buehlmann)

In product development

G-1001

- Cardiac disease marker
- Total cardiac disease marker market value is reported as >2B\$ (BCC, 2018)
- Launch of G-1001 is planned for 2021
- Go-To-Market via OEM partner(s)
- Short ramp-up time, as it is established in the medical routine

Launch plan G-1001



Agenda



1

Introduction and Highlights

2

Q1 Financials

3

Sales, Operations, R&D

4

Outlook

Outlook 2019

- The Company expects continued sales growth in 2019 with normal quarterly variations
- Cystatin C sales growth expected to be driven by increased demand in China and increased focus on the US market
- Continued sales growth for fCAL turbo in Europe and a decision regarding our partner's FDA clearance application expected by the end of 1H19
- For GCAL, preparing new publications with anticipated release in 2019 and intensifying work with Key Opinion Leaders will be key focus areas
- As part of the GCAL market development program, the company organizes an educational workshop at the Euromedlab (European Congress of Clinical Chemistry and Laboratory Medicine) in Barcelona on 21st May 2019
- G-1001 development on track with expected launch in 2021
- Elastase development on plan with aim to launch in 2020