



Lundbeck teleconference

H1 2020

COPENHAGEN, 13 AUGUST 2020

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H1 2020: Executing through the COVID-19 pandemic while investing for long-term growth

Revenue

DKK 8,934 million
+5%

Strategic brands

DKK 5,360 million
+25%

Core EBIT

DKK 2,483 million
-9%

Core EBIT margin

27.8%
-4.4pp

- The COVID-19 pandemic has reduced Lundbeck's activity level and therefore the cost spend. As a consequence the earnings guidance for 2020 has been increased
- Q2 showed destocking and somewhat reduced demand due to the COVID-19 pandemic
- Solid momentum for strategic brands was maintained, including an encouraging Vyepti start considering the COVID-19 impact
- Solid cash-flow generation and balance sheet

Update on COVID-19

Lundbeck's priorities are the health and safety of our employees, safeguarding product supply to ensure patients' access to medicine and business continuity

Q1 2020

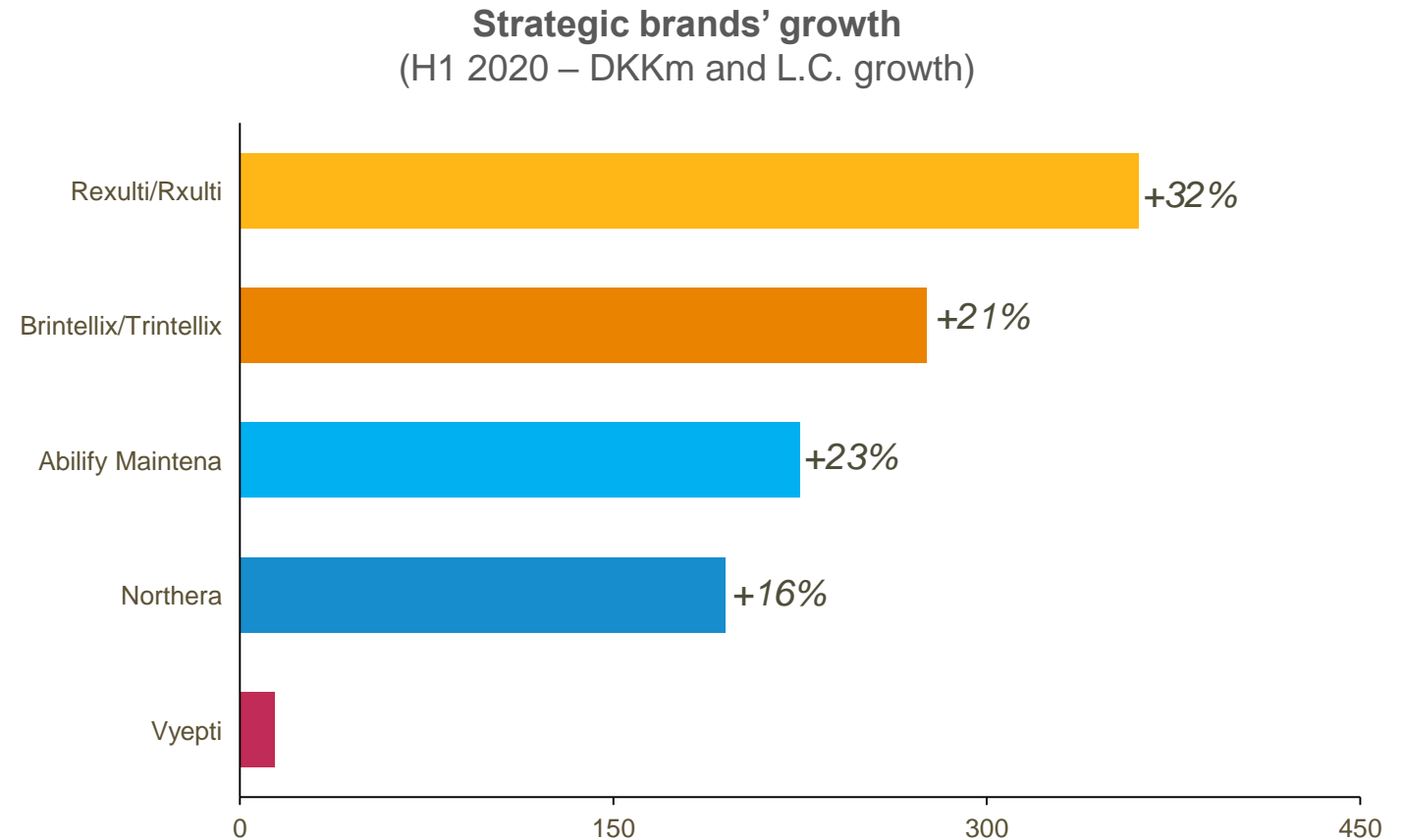
- Safeguarding product supply, production, logistics and operations
- Positive impact from stocking especially in Europe and the U.S. Some weakness in China
- Several clinical programmes delayed
- Extensive use of technology to support work from home and increased digitalization

Q2 2020

- Many countries returning to office
- Q1 inventory increase reversed in Q2
- Fewer new patient starts, reduced pharmacy traffic and deferral of elective procedures
- Lower than anticipated SG&A cost spend due to COVID-19
- Clinical activity slowly picking-up: Indication and site dependent

Lundbeck's five strategic brands added DKK 1,071 million in additional revenue in H1 2020

- **Strategic brands***: Up 25% in H1 2020 (23% in L.C.) to DKK 5,360 million representing 60% of total revenue
- **Rexulti/Rxulti**: Up 35% to DKK 1,393 million
- **Brintellix/Trintellix**: Up 21% to DKK 1,575 million
- **Abilify Maintena**: Up 24% to DKK 1,176 million
- **Northera**: Up 19% to DKK 1,202 million
- **Vyepti**: Sales reached DKK 14 million following launch in April

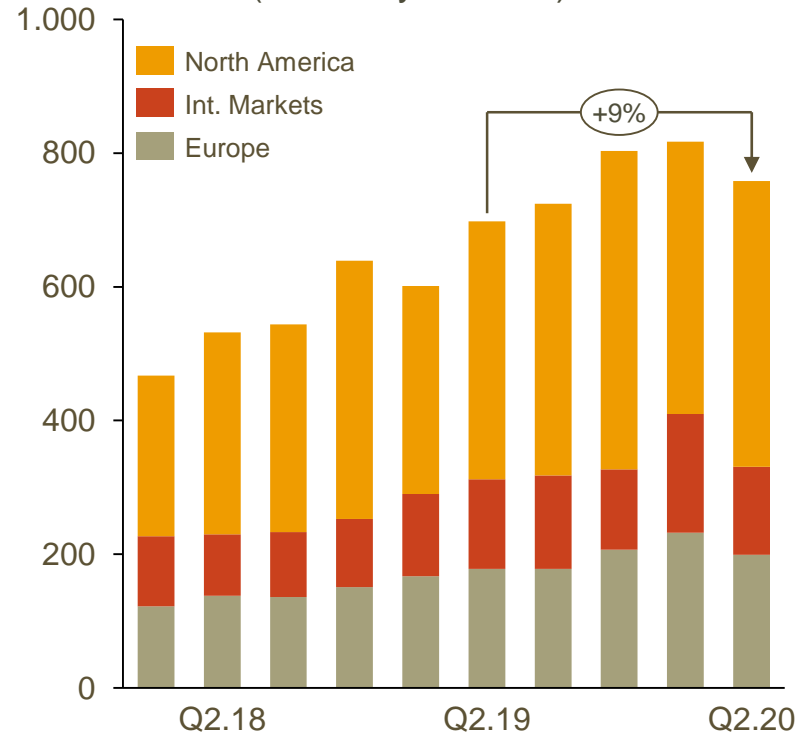


*) Abilify Maintena, Brintellix/Trintellix, Northera, Rexulti/Rxulti and Vyepti

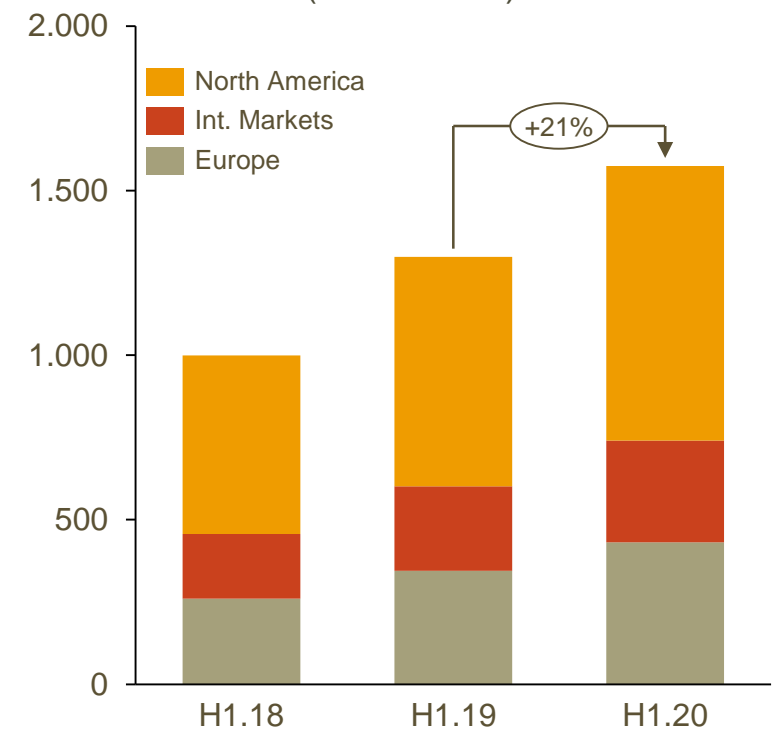
Brintellix/Trintellix: Solid growth momentum despite COVID-19

- Grew 21% (21% in L.C.) to DKK 1,575 million in H1 2020
- Continued solid traction in volume share*)
 - >5%: Finland
 - >3%: France, Italy, Spain, South Korea, Switzerland
 - >1%: Canada, Denmark, Japan (Feb.), Mexico, Norway, Sweden
 - >0.5%: Brazil and the U.S.
- In the U.S.:
 - Volume is up 11% y/y in H1 2020**)
 - Value share of 23.9%**)
 - Reduced PCP sales and promotional activity

Brintellix/Trintellix sales per region
(Quarterly - DKKm)



Brintellix/Trintellix sales
(H1 - DKKm)

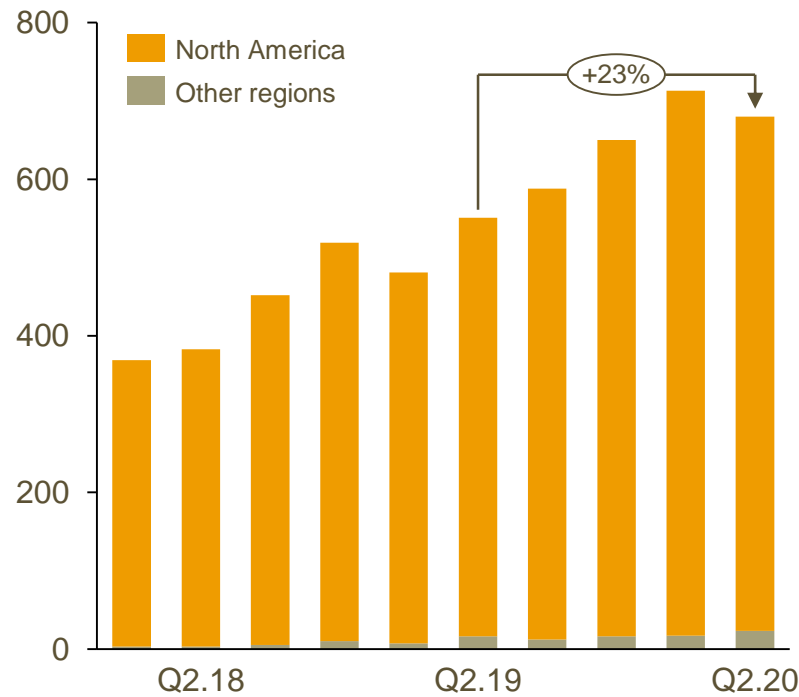


*) IQVIA, June 2020 (April data). **) Symphony Health (c.f. Bloomberg)

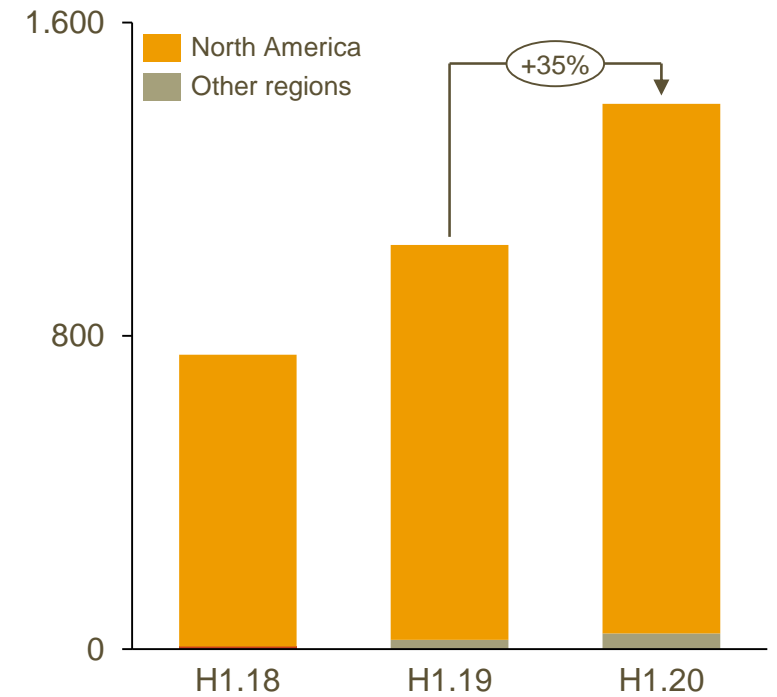
Rexulti: Significant growth momentum despite COVID-19 impact

- Grew 35% (32% in L.C.) to DKK 1,393 million in H1 2020
- Continued solid traction in volume share*)
 - >2%: Canada and the U.S.
 - >1.5%: Australia, Mexico, Saudi Arabia, Switzerland
- In the U.S., volume is up 20% y/y in H1 2020**)
- Launch planned for Brazil, Czech Republic, Italy and Spain later in 2020

Rexulti sales per region***
(Quarterly - DKKm)



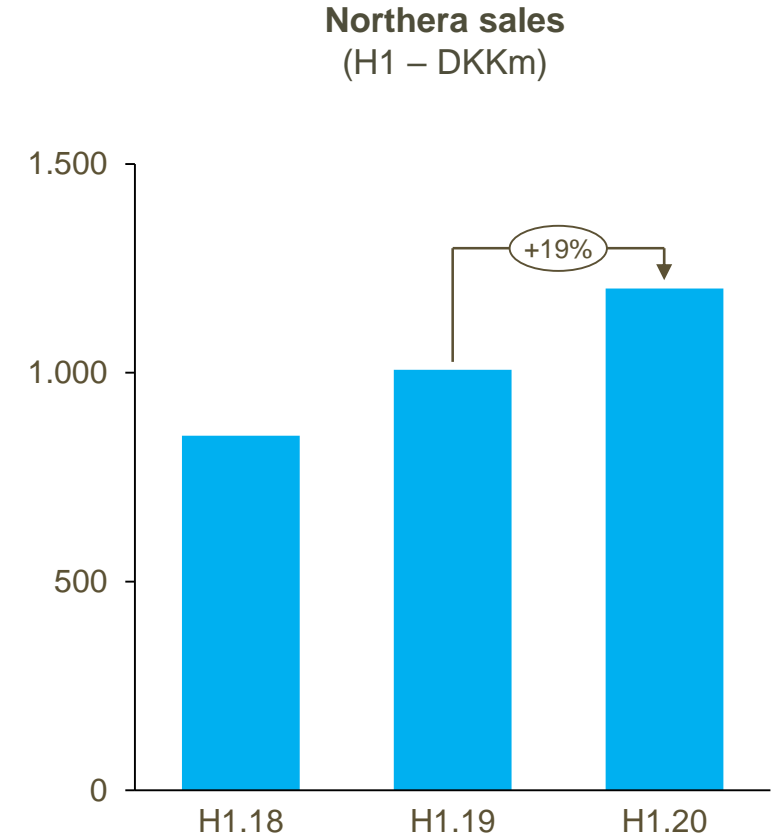
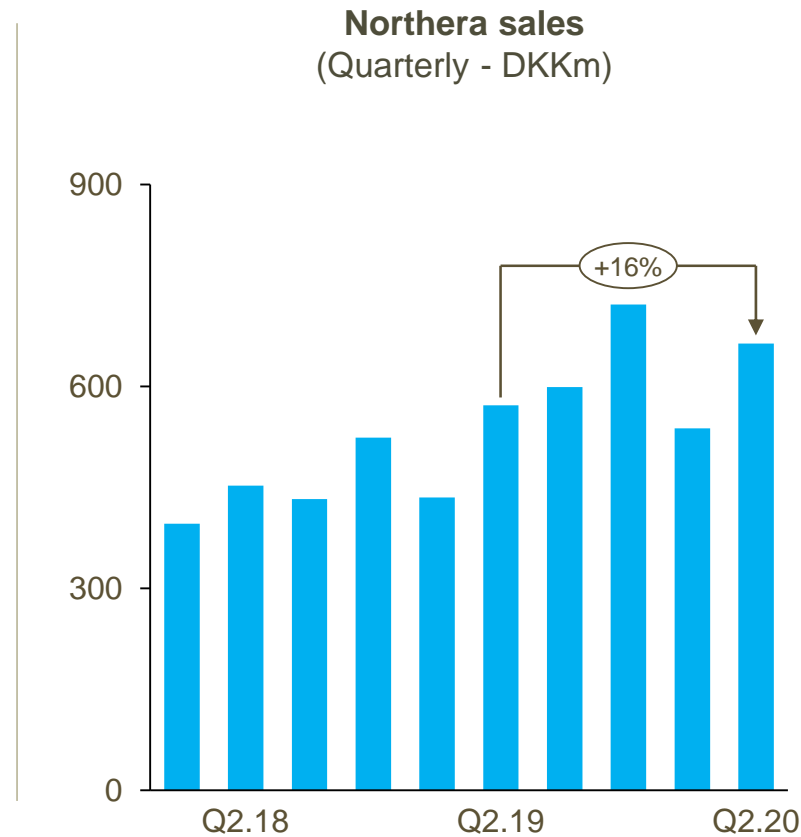
Rexulti sales*
(H1 - DKKm)



*) IQVIA, June 2020 (April data). **) Symphony Health (c.f. Bloomberg). ***) Lundbeck's share of revenue

Northera: Solid growth in sales and demand

- Grew 19% (16% in L.C.) to DKK 1,202 million in H1 2020
- Volume is up 11%*) compared to H1 2019
- Northera impacted by normal quarterly fluctuations driven by e.g. seasonality and pharmacies' buying pattern
- Lundbeck only promotes Northera in the U.S.

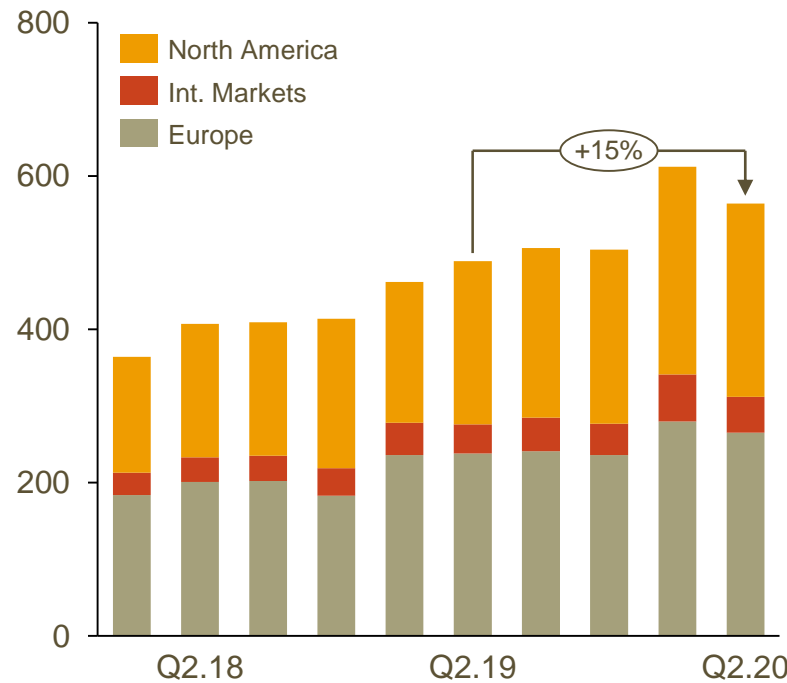


*) *Symphony Health* (c.f. *Bloomberg*)

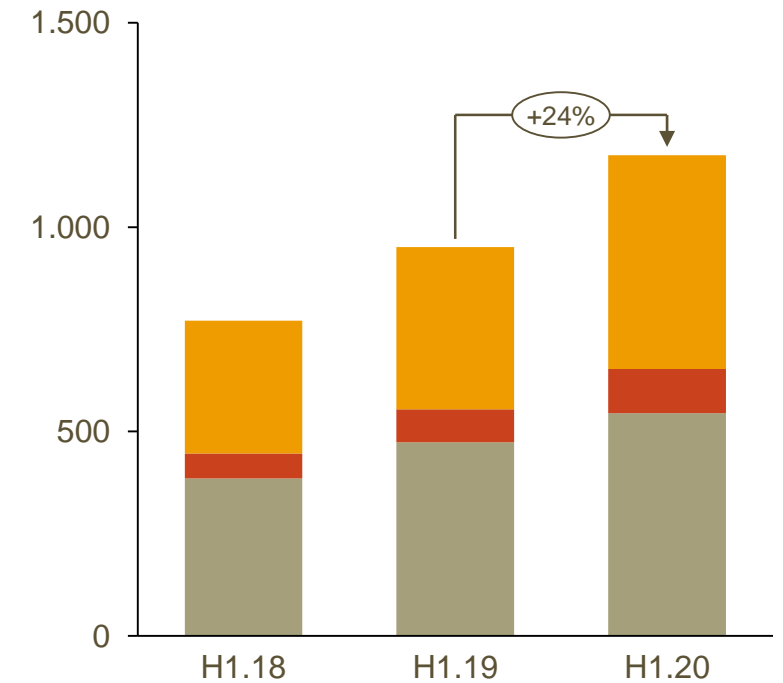
Abilify Maintena: Robust growth across all regions

- Grew 24% (23% in L.C.) to DKK 1,176 million in H1 2020
- Continued solid traction in volume share*)
 - >40%: United Kingdom
 - >30%: Canada, Italy, Switzerland
 - >20%: Australia, Denmark, Finland, France, Germany, Spain, Sweden
 - >15%: The U.S.
- LAI market continues double-digit growth to USD 2.7bn (H1 2020)**)
- Abilify Maintena’s share of the LAI market was 19% in H1 2020**)

Abilify Maintena sales per region***
(Quarterly - DKKm)



Abilify Maintena sales*
(H1 - DKKm)



*) IQVIA, June 2020 (April data). **) Reported net sales of atypical LAIs. ***) Lundbeck’s share of revenue

Vyepti: Encouraging interest from launch despite significant COVID-19 impact

Anecdotally, the early clinical experiences suggest Vyepti is delivering on it's fast, powerful, and sustained promise

- In the quarter, we observed ~10% penetration of our segment 1A accounts* and ~30% penetration of the top 20 targeted accounts
- ~80% of the total accounts are buying and billing Vyepti, consistent with our initial expectations
- >100m patient lives have access to Vyepti without being required to step through any branded treatments
- J-code approved by CMS (Center for Medicare & Medicaid Services) and active from 1 October

Recent publications

- *PROMISE-2* published in Neurology in May
- *PROMISE-1* published in Cephalalgia in February

*) Those that have high volume of aCGRP use and are able to infuse



ARTICLE OPEN ACCESS CLASS OF EVIDENCE

Efficacy and safety of eptinezumab in patients with chronic migraine

PROMISE-2

Richard B. Lipton, MD, Peter J. Goadsby, MD, PhD, Jeff Smith, MD, FRCP, Barbara A. Schaeffler, MBA, David M. Biondi, DO, Joe Hirman, PhD, Susan Pederson, BS, Brent Allan, DO, MPH, and Roger Cady, MD
Neurology 2020;94:e1365-e1377. doi:10.1212/WNL.000000000000169

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Abstract

Objective

To evaluate the efficacy and safety of eptinezumab, a humanized anti-calcitonin gene-related peptide monoclonal antibody, in the preventive treatment of chronic migraine (CM).

Methods

The Prevention of Migraine via Intravenous ALD403 Safety and Efficacy-2 (PROMISE-2) study was a phase 3, multicenter, randomized, double-blind, placebo-controlled study. Adults with CM were randomly assigned to receive IV eptinezumab 100 mg or 300 mg or placebo for up to four intravenous (IV) doses administered every 12 weeks. The primary endpoint was change from baseline in monthly migraine days (MMDs) over weeks 1–12.

MORE ONLINE
→ Class of Evidence
Criteria for rating
therapeutic and diagnostic
...1...

Cephalalgia
International
Headache Society

Eptinezumab in episodic migraine: A randomized, double-blind, placebo-controlled study (PROMISE-1)

Messoud Ashina¹, Joel Saper², Roger Cady³, Barbara A Schaeffler⁴, David M Biondi^{4*}, Joe Hirman⁵, Susan Pederson², Brent Allan^{4,6} and Jeff Smith⁷

Abstract

Objective: To evaluate the efficacy and safety of eptinezumab, a humanized anti-calcitonin gene-related peptide monoclonal antibody, in the preventive treatment of episodic migraine.
Methods: The Prevention of Migraine via Intravenous ALD403 Safety and Efficacy-1 (PROMISE-1) study was a phase 3, multicenter, randomized, double-blind, placebo-controlled, parallel-group study. Adults with episodic migraine were randomized to eptinezumab 30 mg, 100 mg, 300 mg, or placebo for up to four intravenous (IV) doses administered every 12 weeks. The primary endpoint was change from baseline in monthly migraine days (MMDs) over weeks 1–12. Results: A total of 888 patients received treatment across 84 study sites. Mean MMDs at baseline were ~8.6 across treatment groups. Eptinezumab 100 mg and 300 mg met the primary endpoint, significantly reducing MMDs across weeks 1–12 compared with placebo (30 mg, -4.0; 100 mg, -3.9, p=0.0182; 300 mg, -4.3; placebo, -3.2, p=0.0001). Treatment-emergent adverse events were reported by 58.4% (30 mg), 63.2% (100 mg), 57.6% (300 mg), and 59.5% (placebo) of patients. Treatment-emergent adverse events reported by ≥2% of eptinezumab-treated patients at an incidence greater than placebo included: upper respiratory tract infection (30 mg, 11.4%; 100 mg, 9.9%; 300 mg, 10.3%; placebo, 7.2%), and fatigue (30 mg, 2.3%; 100 mg, 3.6%; 300 mg, 3.6%; placebo, <1%).
Conclusion: Eptinezumab (100 mg or 300 mg) significantly reduced migraine frequency, was well tolerated, and had an acceptable safety profile when used for the preventive treatment of migraine in adults with episodic migraine.
ClinicalTrials.gov identifier: NCT02559895

Cephalalgia
July 1–4
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DOI: 10.1177/0333102420961112
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Project status

COVID-19 impact on clinical trials

- Continued yet varied impact on recruitment pace and operations e.g. brexpiprazole LCM

Vyepti (eptinezumab)

- DELIVER-study: The phase IIIb study initiated
- RELIEF-study: Headline results due in Q3
- Cluster headache: Phase III study planned to be initiated in Q4
- Regulatory submissions: Australia, Canada, Kuwait, Indonesia, Singapore, Switzerland and UAE

Brintellix (vortioxetine)

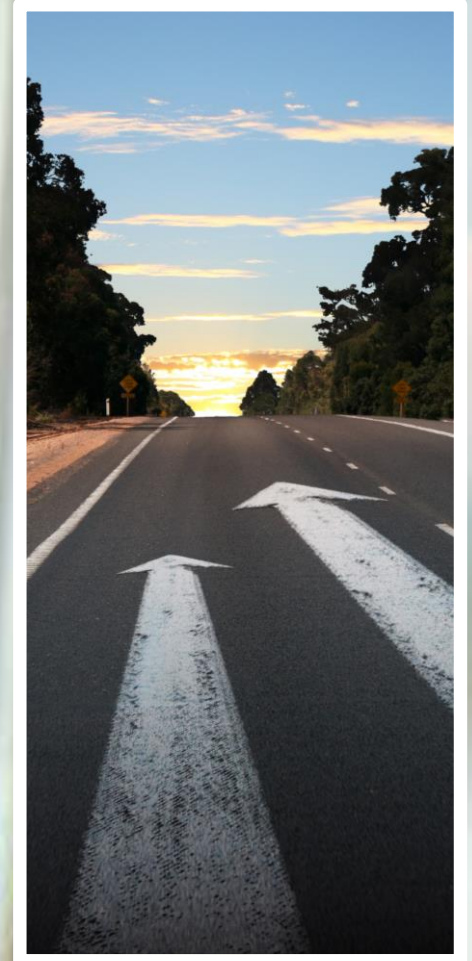
- VIVRE study initiated (vs. desvenlafaxine)

MAGL inhibitor platform

- Lu AG06466 planned to enter the first (PTSD) out of four new exploratory clinical studies in late 2020
- Additional molecule (Lu AG06479) started phase I

Lu AF11167 (PDE10 inhibitor)

- Phase II PoC study discontinued based on futility interim analysis



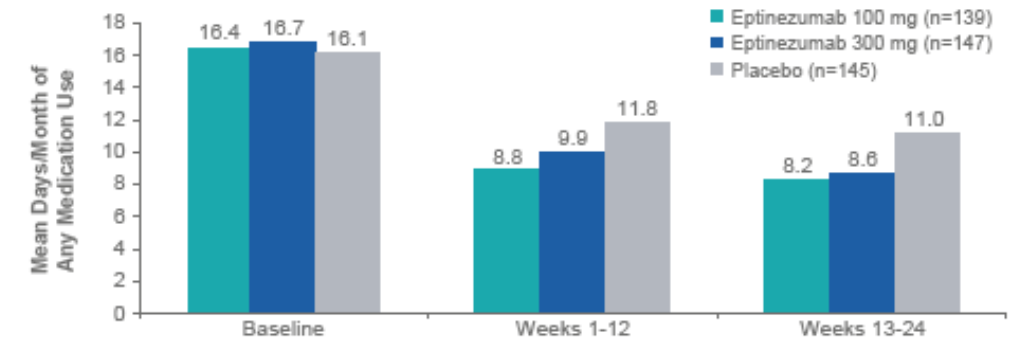
Vyepti: Data from subgroup analysis of *PROMISE-2* in patients with medication-overuse headache presented at AHS 2020

Eptinezumab reduced mean days of acute headache medication use - including triptans specifically - by ~50% over Weeks 1–12 in patients with chronic migraine and medication-overuse headache (compared with ~25% with placebo), with results sustained or further decreased over Weeks 13–24

Reductions in acute headache medication use were greater with eptinezumab than placebo across 24 weeks of treatment

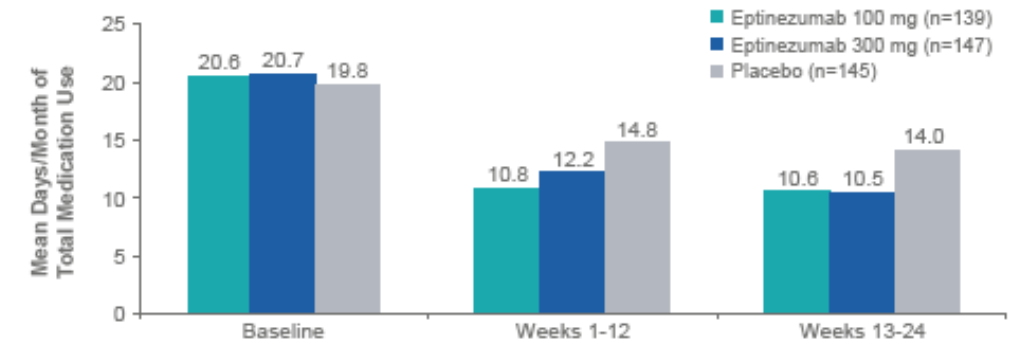
In patients diagnosed with both chronic migraine and medication-overuse headache, eptinezumab treatment reduced acute headache medication use, including triptans, more than placebo

Figure 2. Mean Days/Month of Any* Acute Headache Medication Use in Patients With MOH



*Days of "any acute headache medication use" is the sum of all days of acute headache medication use, regardless of class. If a patient uses 2+ classes of medication on the same day, they are counted once.

Figure 3. Mean Days/Month of Total* Acute Headache Medication Use in Patients With MOH



Michael J. Marmura, Hans-Christoph Diener, Joe Hirman, Roger Cady, Thomas Brevig, Elizabeth Brunner, Lahar Mehta. Poster presented at the 62nd Annual Scientific Meeting of the American Headache Society June 4–7, 2020 San Diego, CA

RELIEF-study*: Recruitment finalized, headline results due in Q3 2020

Vyepti has...

- ...previously demonstrated Day 1 efficacy in trials on migraine prevention
- ...the potential to impact ongoing migraine attacks while providing a sustained preventive benefit

The RELIEF study

- Assesses the efficacy and safety of Vyepti administered during a migraine attack
- Has patients randomized to 100 mg Vyepti or placebo
- Completed recruitment of 485 subjects who are candidates for preventive therapy

Co-primary endpoints

- Time to headache pain freedom
- Time to absence of most bothersome symptom

Key secondary endpoints

Measured 2 hours after start of treatment

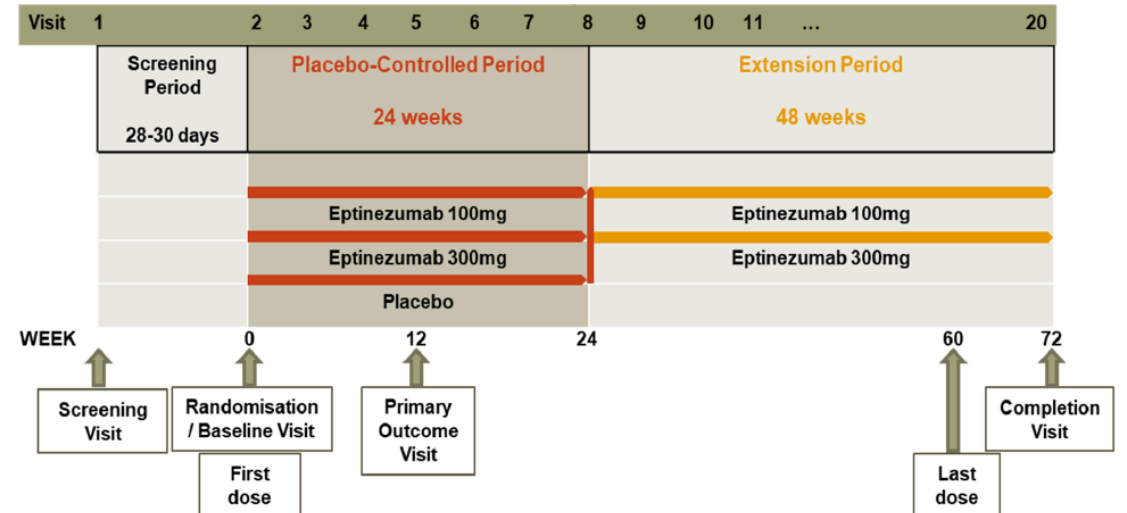
- Patients achieving freedom from pain
- Absence of most bothersome symptom

*) *Clinicaltrials.gov ID: NCT04152083*

Vyepti: Phase IIIb study, *DELIVER*, commenced in June

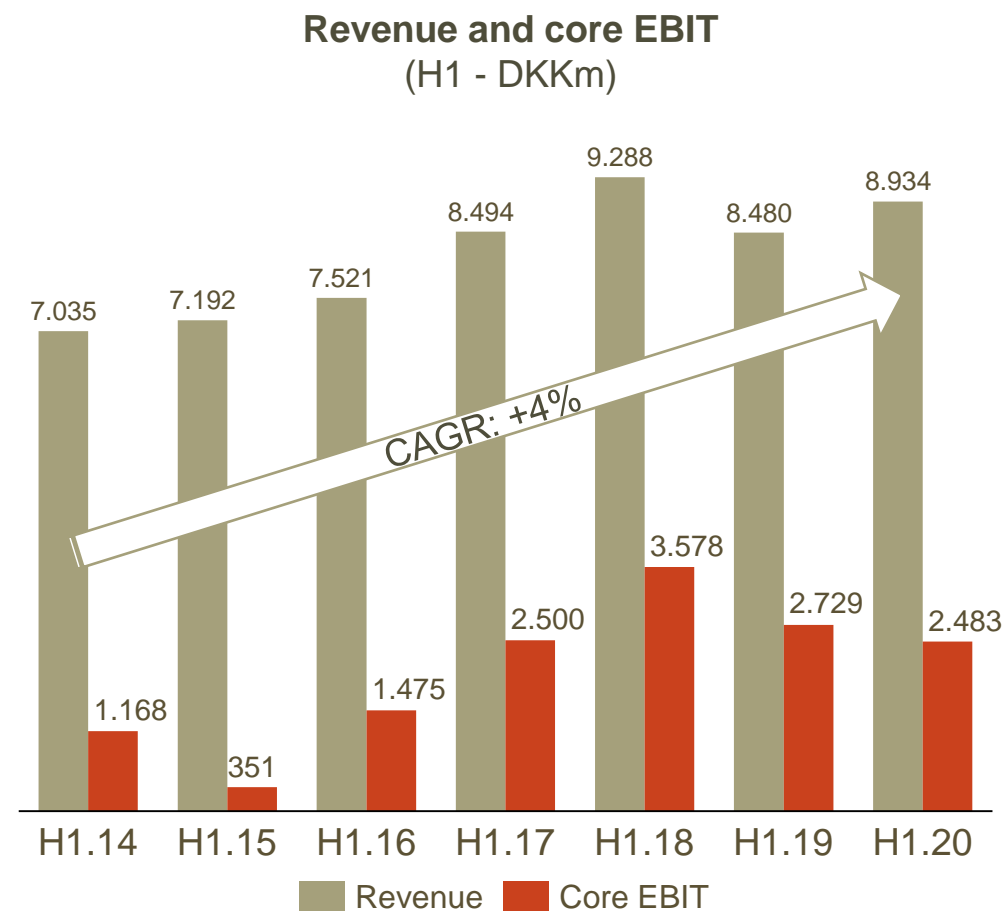
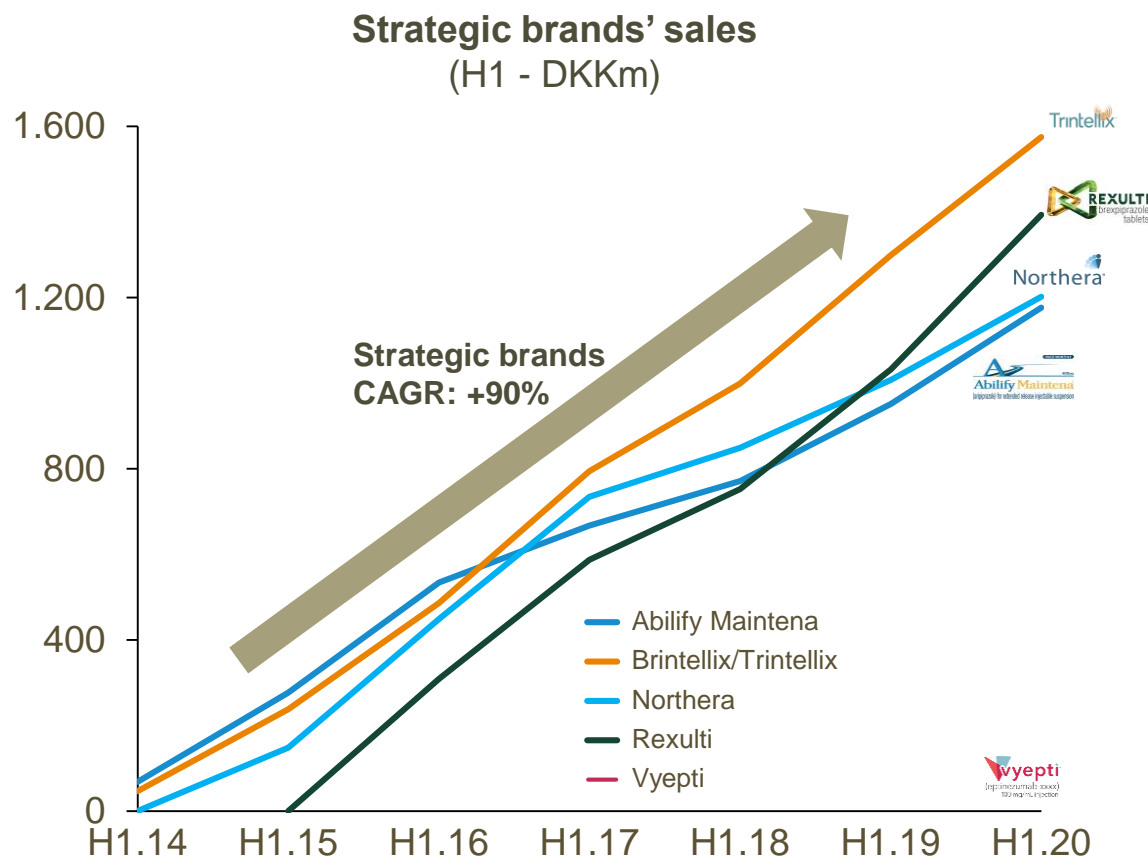
Study objective:

- Evaluate eptinezumab in the prevention of migraine in patients with unsuccessful prior preventive treatments
- Documented evidence of treatment failure in the past 10 years of 2-4 different migraine preventive medications
- History of either previous or active use of triptans for migraine
- Two active arms (100 and 300mg) or placebo
- Number of patients: 840



*) *Clinicaltrials.gov* ID: NCT04152083

Solid financial performance driven by strategic brand portfolio



Solid financial performance in H1 2020 – COVID-19 has resulted in lower than expected operational expenses of 6-7%

Revenue

- Continued strong momentum for strategic brands
- Q2 negatively impacted by reduced demand following the COVID-19 pandemic
- Continued erosion of mature U.S. neurology franchise

Margins

- Gross margin in line with expectations
- Operational expenses increased due to foliglurax impairment, R&D restructuring costs and costs related to Vyepti
- Core tax rate 17.5% vs. 24.3% in H1 2019

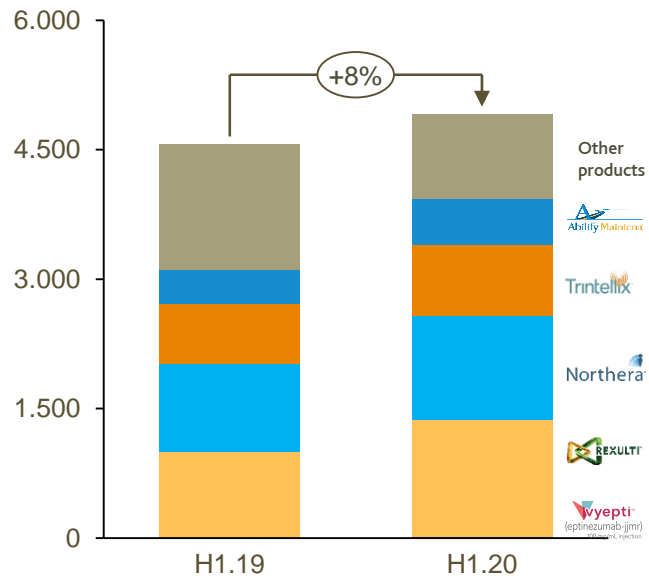
Net financials

- Positive impact from IPO on Imara, Inc.

DKKm	H1 2020	Δ% y/y	Q2 2020	Δ% y/y
Revenue	8,934	+5%	4,370	+3%
<i>Gross margin</i>	80.7%	0pp	79.0%	-1.8pp
Operational expenses	6,080	+34%	2,689	+16%
- SG&A	3,369	+11%	1,649	+5%
- R&D	2,711	+81%	1,040	+39%
Other operating items, net	(46)	-	(16)	-
EBIT	1,085	-53%	747	-32%
<i>EBIT margin</i>	12.1%	-15.1pp	17.1%	-8.9pp
Core EBIT	2,483	-9%	1,126	-15%
<i>Core EBIT margin</i>	27.8%	-4.4pp	25.8%	-5.3pp
Net financials	-	-	97	-
<i>Effective tax rate</i>	32.5%	+5.5pp	31.0%	
EPS	3.69	-56%	2.93	-26%
Core EPS	10.30	-1%	5.41	+10%

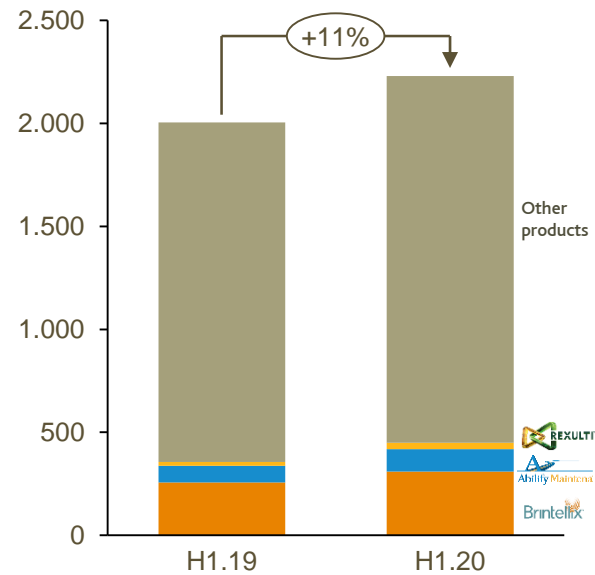
Robust growth in all three regions

North America revenue
(H1 - DKKm)



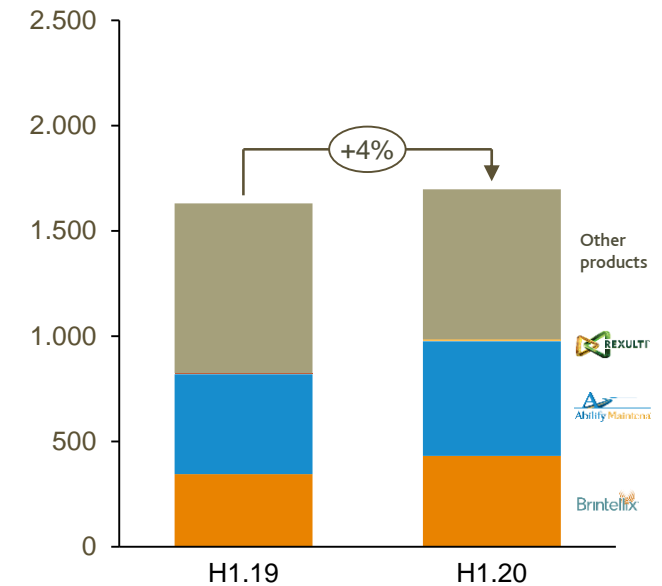
- Strategic brands up 26% to DKK 3,926m
- 24% growth ex. Onfi, Sabril and Xenazine
- Vyepti will add modestly to growth in 2020

International Markets revenue
(H1 - DKKm)



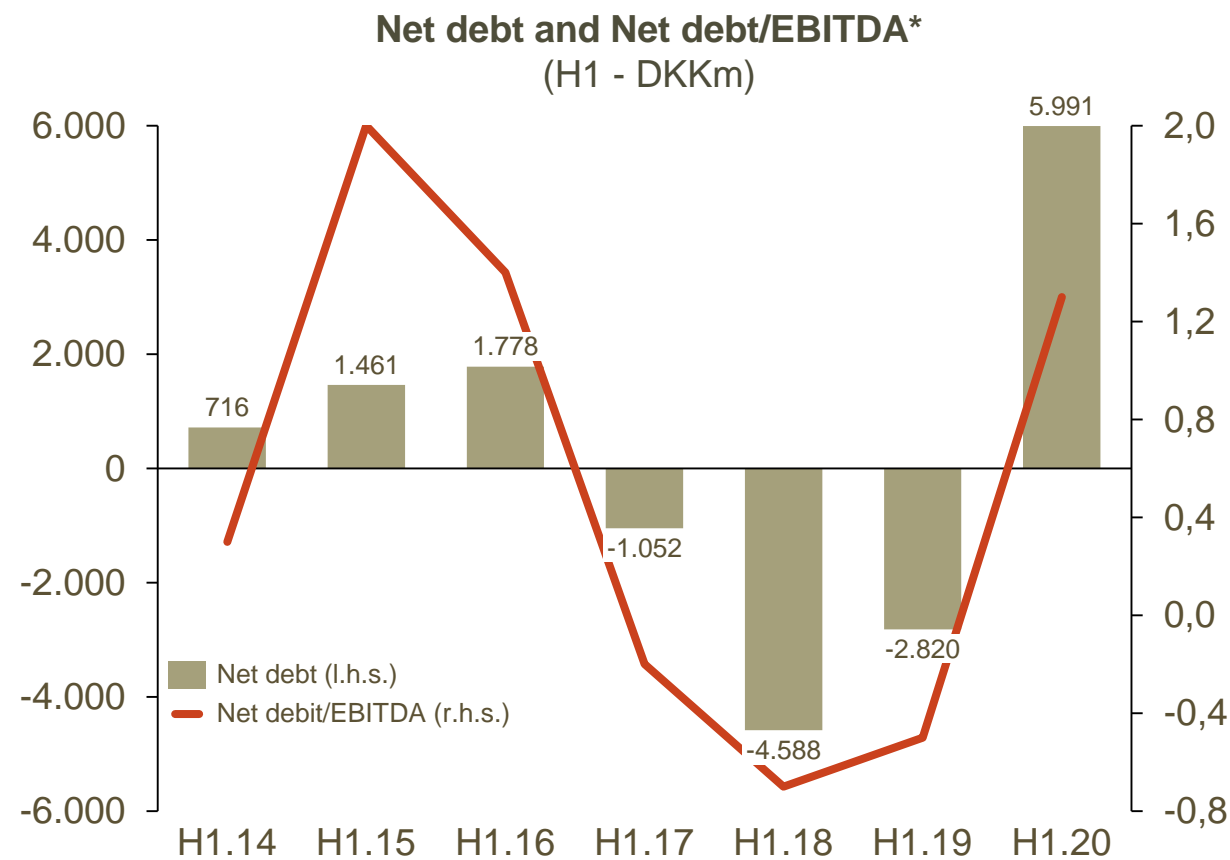
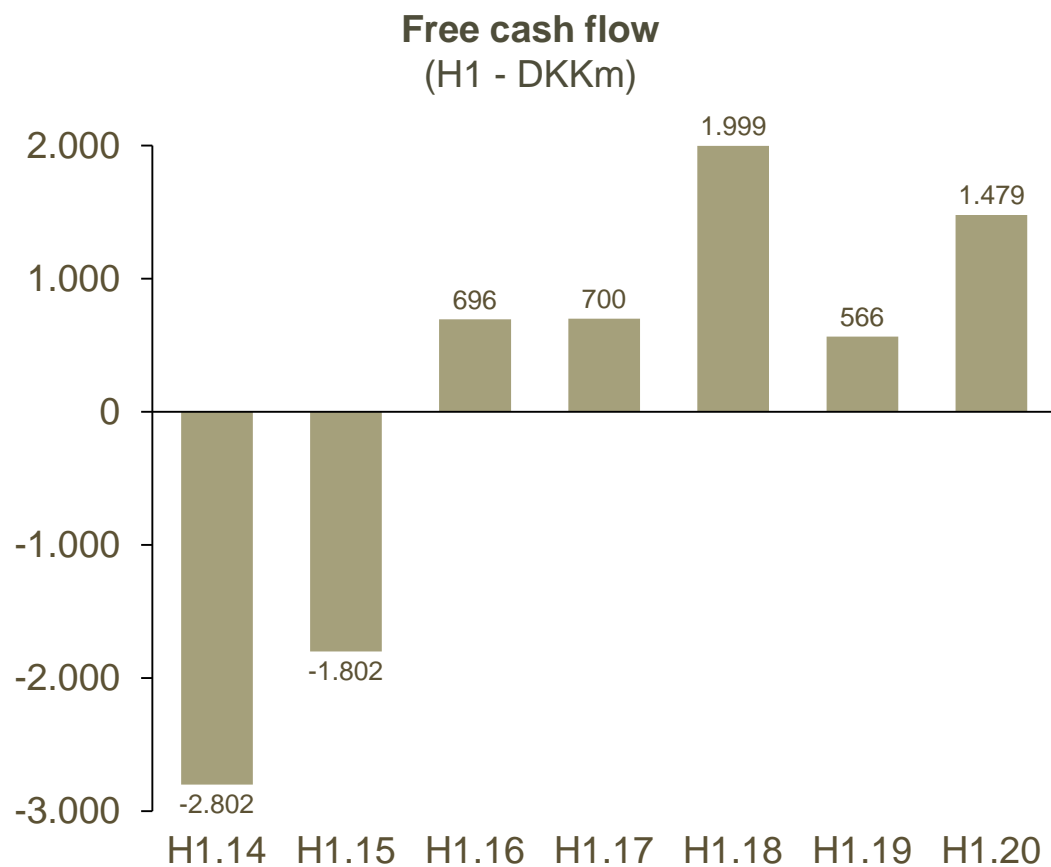
- Strategic brands up 26% to DKK 450m
- Cipralelex/Lexapro continues to perform well
- China up 14%

Europe revenue
(H1 - DKKm)



- Strategic brands up 20% to DKK 984m
- Ability Maintena and Brintellix show strong growth across most markets

Strong cash flow; net debt rise driven by acquisitions in 2019



*) Rolling four quarters

2020 profit guidance increased following reduced cost-spend

- Continued strong growth for strategic brands
- Elevated uncertainty following the COVID-19 pandemic
- Substantial investments in launch and R&D activities for Vyepti
- Expected effects from hedging is a loss of around DKK 100 - 150 million
- Expected net financial expenses of DKK 100 - 200 million
- Financial guidance based on currency levels end-July 2020*

2020 financial guidance

DKK	FY 2019 actual	Previous FY 2020 guidance	Revised FY 2020 guidance
Revenue	17,036m	17.4 – 18.0bn	17.4 – 18.0bn
EBITDA	4,823m	3.9 – 4.4bn	4.3 – 4.7bn
Core EBIT	4,976m	3.5 – 4.0bn	3.9 – 4.3bn
EBIT	3,608m	1.4 – 1.9bn	1.8 – 2.2bn

**) Lundbeck's main trading currencies are the USD, CNY, CAD and JPY. The financial guidance is based on the current hedging rates for our main currencies; i.e. USD/DKK (6.63), CNY/DKK (0.95), CAD/DKK (5.01) and JPY/DKK (0.0633)*

Maintaining focus on our role and responsibility in society

Lundbeck is part of the largest ever UN-backed CEO-led climate advocacy effort, the *We Mean Business Coalition* led by the CEOs of 155 global corporations and backed by the UN Global Compact and the Science Based Targets initiative

Lundbeck’s focuses on reducing energy consumption and CO₂ emission by optimizing our facilities and replacing conventional energy sources with renewables. By the end of the year, new reduction targets will be set to include emissions from our entire value chain

Lundbeck contributes to AMR Action Fund (AntiMicrobial Resistance) to fight antibiotic resistance

Lundbeck continues to provide support to patients and communities with respect to COVID-19

Category	H1 2020	H1 2019	Δ% y/y
Energy (MWh) *	49,857	48,535	3%
CO2 (tonnes) *	8,164	8,539	(4%)
Work related accidents *	5.4	6.1	(11%)
No. of employees (FTE)	5,843	5,458	7%

*) This data only covers our headquarters and larger affiliates with research, development and manufacturing activities

Recent ratings in H1 2020

ISS ESG rating of B- in (up from C+)



CDP Climate A Score

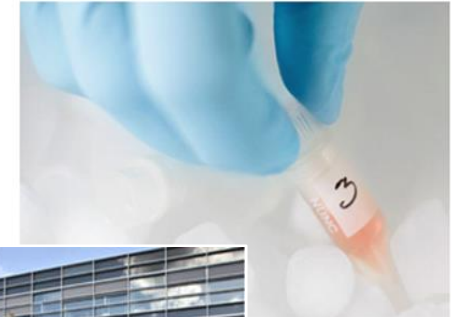


Sustainalytics ESG Risk Rating Score 23.2 (up from 29.4)



Near-term priorities

- Manage the impact from COVID-19 internally and externally
- Secure supply of medicines to patients
- Ensure strong continued momentum for the strategic brands
- Vyepti launch in the U.S., regulatory submissions and indication expansion
- Regaining momentum and accelerate clinical activities
- Continue to execute on our strategy



Thank you

Lundbeck

