

# H. LUNDBECK A/S



*(incorporated with limited liability under the laws of The Kingdom of Denmark)*

**EUR 2,000,000,000**

## **Euro Medium Term Note Programme**

### **FIRST SUPPLEMENT DATED 1 OCTOBER 2020**

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This first supplement (the "**First Supplement**") is supplemental to, and must be read in conjunction with, the base prospectus dated 24 February 2020 (the "**Base Prospectus**") prepared in relation to the EUR 2,000,000,000 Euro Medium Term Note Programme (the "**Programme**") of H. Lundbeck A/S ("**Issuer**"). Under the Programme, the Issuer, subject to compliance with all relevant laws, regulations and directives, may from time to time issue Euro Medium Term Notes (the "**Notes**"). Terms defined in the Base Prospectus have the same meaning when used in this First Supplement.

The Base Prospectus constitutes a base prospectus for the purpose of Article 8 of Regulation (EU) 2017/1129 (the "**Prospectus Regulation**") and was approved in Ireland by the Central Bank of Ireland (the "**Central Bank**") in its capacity as competent authority under the Prospectus Regulation. This First Supplement constitutes a supplement to the Base Prospectus for the purpose of Article 23 of the Prospectus Regulation. This Supplement has been approved by the Central Bank as competent authority under the Prospectus Regulation. The Central Bank only approves this First Supplement as meeting the standards of completeness, comprehensibility and consistency imposed by the Prospectus Regulation. Such approval should not be considered as an endorsement of the Issuer or the quality of the Notes. Investors should make their own assessment as to the suitability of investing in the Notes.

To the extent there is any inconsistency between (a) any statement in this First Supplement, and (b) any other statement in or incorporated by reference in the Base Prospectus, the statements in this First supplement shall prevail.

The Issuer accepts responsibility for the information contained in this First Supplement. To the best of the knowledge of the Issuer the information contained in this First Supplement is in accordance with the facts and does not omit anything likely to affect the import of such information.

This First Supplement has been prepared for the following purposes:

- a. to add a section entitled "*Recent Developments*" to the Base Prospectus;
- b. to incorporate by reference the Issuer's unaudited financial statement for the period ended 30 June 2020 which was published on 13 August 2020;
- c. to amend condition 13(d) of the section of the Base Prospectus entitled "*Terms and Conditions of the Notes*";
- d. to update the section of the Base Prospectus entitled "*Description of the Issuer - Legal Arbitration & Proceedings*"; and

- e. to update the no significant change and no material adverse change statements contained in the “*General Information*” section of the Base Prospectus.

Save as disclosed in this First Supplement, there has been no other material new factor, material mistake or material inaccuracy relating to information included in the Base Prospectus which may affect the assessment of the Notes issued under the Programme since the publication of the Base Prospectus.

This First Supplement, the Base Prospectus, and the information incorporated by reference in the Base Prospectus are available on the website of Euronext Dublin ([www.ise.ie](http://www.ise.ie)) and the Issuer’s website (<https://www.lundbeck.com/global>). For the avoidance of doubt, the content of the websites of Euronext Dublin and the Issuer do not form part of this First Supplement or the Base Prospectus, except where that information has been incorporated by reference into this First Supplement or the Base Prospectus.

## RECENT DEVELOPMENTS

### ***IMPACT OF COVID-19***

The COVID-19 pandemic has posed and continues to pose challenges for the Issuer, as it evolves in different regions. Measures such as travel restrictions and working from home were put in place to protect the Issuer's employees and their families and to prevent spreading of the coronavirus. The Issuer's priority during the global pandemic has been and still is the health and safety of its employees and to continue to safely supply all its medicines to the millions of patients who rely on them.

While the Issuer in the first quarter benefitted from stocking of products from both patients and pharmacies due to the COVID-19 pandemic, both revenue and earnings were negatively impacted in the second quarter by slightly lower demand and destocking which offset the positive effect seen in the first quarter of the year. Due to COVID-19, the first half results combined are more representative of the Issuer's underlying performance compared to the figures for the first and second quarter of the year individually. The Issuer's cash collections continue to be according to the Issuer's normal trade terms, and days sales outstanding are at normal levels.

The Issuer's product portfolio has generally been resilient, but products such as the strategic brand Brintellix/Trintellix have been impacted by lower new patient starts, for example in the U.S. and Japan, and significant reductions in patient visits to physicians as well as reduced interaction between company representatives and health care providers due to widespread restrictions on in person meetings with healthcare professionals. The launch of Vyepti™ (eptinezumab), the strategic product acquired by the Issuer in connection with acquiring Alder Bio Pharmaceuticals, Inc. ("Alder") (see page 106, 'Recent Acquisitions' of the Base Prospectus), in April 2020 has been impacted by the COVID-19 pandemic's negative influence on HCP-administered medicines.

The COVID-19 pandemic also continues to impact clinical and regulatory activities causing, as at the date of this First Supplement, manageable disruptions. Currently, the most significant impact is the potential delays to existing clinical studies or new clinical study starts. The impact on each trial has been different and the timelines will be assessed once the situation stabilises.

### ***RESEARCH AND DEVELOPMENT PIPELINE***

In 2020, the Issuer has received headline results on:

- a. a clinical phase IIa study on foliglurax (mGluR 4 PAM) for Parkinson's disease. The study did not show statistically significant reduction in OFF time (primary endpoint) nor an improvement of dyskinesia (secondary endpoint) and the development programme of Foliglurax will be terminated, as publicly announced by the Issuer on 27 March 2020. The Issuer has no significant financial obligations under the clinical study.
- b. a clinical phase IIa study on Lu AG06466 (MAGLi)(formerly ABX-1431) for Tourette Syndrome, a compound added to the Issuer's pipeline as a result of the acquisition of Abide Therapeutics Inc.(as described on page 107 of the Base Prospectus). The study showed insufficient efficacy to proceed with development of Lu AG06466 (MAGLi) in Tourette Syndrome, but the safety and tolerability of the agent was such that further investigational studies in additional indications will proceed, as publicly announced by the Issuer on 27 March 2020. The Issuer has no significant financial obligations under the clinical study.
- c. the parallel group, double-blind, randomised, placebo-controlled RELIEF study that assessed the efficacy and tolerability of Vyepti (Eptinezumab) when initiated during a migraine attack in patients who are candidates for preventive therapy. As publicly announced in a press release on 31 August 2020, the study met statistical significance on the co-primary endpoints demonstrating that patients receiving 100 mg Vyepti infusion during migraine attack achieved earlier time to freedom from headache pain and absence of their most bothersome symptom compared to patients receiving placebo. The most bothersome symptom was the individual patient's choice between photophobia, phonophobia, and nausea.

The key secondary endpoints of proportion of patients with pain freedom and proportion of patient with absence of their most bothersome symptom at 2 hours after the start of infusion, also met statistical significance. All other secondary endpoints were also statistically significant.

Vyepti was well-tolerated as a preventive treatment when initiated during a migraine attack, consistent with the previous phase III studies with no new safety signals identified. The most common adverse reactions (greater than 2% and at least 2% or greater than placebo) in the clinical trials for the preventive treatment of migraine were nasopharyngitis and hypersensitivity.

The Issuer plans to share the full data at upcoming scientific meetings and will submit the study for publication in a peer-reviewed journal.

Further, on 5 August 2020, the Issuer announced the decision to discontinue the phase II proof of concept clinical study of Lu AF11167 (PDE10 inhibitor) in patients with schizophrenia, who are experiencing negative symptoms. The decision to stop the trial is based on the results of a futility interim analysis, which concluded that the trial is unlikely to achieve statistical significance on its primary endpoint. The recommendation to stop the trial was not based on safety concerns.

The Issuer has initiated a phase I clinical study with the compound Lu-AG06479, a compound acquired in connection with the Issuer's acquisition of Abide Therapeutics Inc. The purpose of this study (n = ~66) is to investigate the safety, tolerability and pharmacokinetic of Lu AG06479 after single dose administration to healthy volunteers (NCT04473651).

### ***IMPAIRMENT***

In 2015, the Issuer recognised an impairment of the Rexulti® product rights. The Issuer is periodically re-assessing the basis for this impairment. The Danish Business Authority (*Erhvervsstyrelsen*) has requested a new impairment assessment for 2017. As at the date of this First Supplement, it is not possible to conclude on the outcome of this discussion.

## MODIFICATIONS TO THE BASE PROSPECTUS

With effect from the date of this First Supplement, the information appearing in, or incorporated by reference into, the Base Prospectus shall be amended and/or supplemented in the manner described below. References to page numbers are to the pages of the Base Prospectus.

1. On page 29 of the Base Prospectus, the section entitled “INFORMATION INCORPORATED BY REFERENCE” shall be amended by the insertion of new paragraph 3 as follows:

“3. The half year earnings release for the period 1 January 2020 to 30 June 2020 of the Issuer containing unaudited financial information, as set out on pages 6 to 17 and pages 21 to 29 of the half year earnings release. The half year earnings release can be found on the Issuer’s website: <https://investor.lundbeck.com/static-files/69683107-7797-4ec8-8c82-00a7d77a9b87>

2. On page 21 of the Base Prospectus, the last paragraph of the risk factor titled “*The Issuer operates in more than 50 countries and any deterioration of the political, socio-economic and financial situation globally or in individual countries may adversely affect the Issuer’s supply and distribution chain and customers’ ability to purchase its products*” shall be deleted, and the following new risk factor shall be added:

***The spread of COVID-19 may have a material negative effect on the Issuer’s business as a whole***

The impact of COVID-19 on the Issuer as at the date of this First Supplement is described in the section ‘Recent Developments’. The future risks and impact of COVID-19 on the Issuer’s business remains uncertain and as at the date of this First Supplement, it is difficult to assess the impact and the risks. The pandemic, any potential new ‘waves’ of COVID-19 and long-term effects may potentially have a material negative effect on the Issuer’s business as a whole and on its financial performance.

Such negative impacts could, for example, include the following:

- The pressure on the global economy, including the increase in unemployment, and a continued deterioration in the political, socio-economic and financial situation globally may have a significant negative impact on the Issuer.

The pandemic could lead to a realisation of the risks set out in the risk factor titled: “*The Issuer operates in more than 50 countries and any deterioration of the political, socio-economic and financial situation globally or in individual countries may adversely affect the Issuer’s supply and distribution chain and customers’ ability to purchase its products.*”

The pandemic could also lead to pricing pressure for the Issuer’s products driven by, for example, restrictive reimbursement policies, changes in the insurance environment and cost control. This could impose pressure on the Issuer to lower its prices or entail a significantly lower sale of the Issuer’s products and thereby significantly affect the profitability and financial results of the Issuer. It could also potentially lead to a realisation of the risks described under the risk factor entitled: “*Rising pricing pressure driven by restrictive reimbursement policies and cost control clauses, legislative and regulatory proposals to lower the costs of prescription drugs and other healthcare system reforms worldwide may impose downward pressure on the prices of the Issuer’s products and significantly affect its profitability and financial results.*”

- COVID-19 may further delay or harm the sale of existing key products and/or the launch and sale of new important products, such as the strategic product Vyepi™ (eptinezumab). Such delay or harm in launch and/or sale could significantly negatively affect the financial performance of the Issuer and its future growth.
- The COVID-19 pandemic could have a negative impact on the Issuer’s ability to conduct clinical studies in a timely and expedient manner. Such negative impacts include, but are not limited to, challenges in recruiting patients for studies. COVID-19 could also potentially lead

to a realisation of the risks described under the risk factor titled: “Any failure or delay in the delivery of pipeline or development and launch of new and innovative products may impair the Issuer’s achievement of development targets, and adversely affect the reputation of its research and development capabilities and its ability to reach its business and financial targets”, which would negatively impact the Issuer’s pipeline development, reputation, costs, profitability, future growth and ability to reach its financial targets.

- COVID-19 may potentially lead to delays and/or disruptions in the Issuer's incoming and outgoing supply chain leading to the realisation of the risks set out under the risk factor titled: “Any delay or disruption in the Issuer’s manufacturing and supply processes may lead to product shortage, loss of product sales and adversely affect the Issuer’s reputation, costs, business, profitability and ability to reach its financial targets”. This includes, but is not limited to, the Issuer’s purchase and the Issuer’s delivery of necessary raw materials, goods, medicine and services which, if negatively impacted, could adversely affect the Issuer’s reputation, costs, business, profitability and ability to reach its financial targets.
  - During the pandemic, many companies, including the Issuer, have adjusted to lockdowns and closed borders and have implemented a number of measures to allow e-businesses to move forward. This includes, but is not limited to, work-from-home arrangements and part-time office hours which have increased dependence on and risks related to various IT solutions and security. As a result of the change in patterns of IT use, IT security and risks have changed which could lead to an increase of those risks described in the risk factor titled: “Failure of information security, data protection, cyberattacks or disruption of information technology systems may lead to system down-time, loss of critical or sensitive information (such as patient data, clinical trial records and key scientific research) and harm the Issuer’s business.”
3. The section entitled “Description of the Issuer - The Issuer’s Development Portfolio (Pipeline Overview):” on page 93 to page 94 of the Base Prospectus shall be deleted in its entirety and be replaced with the following wording:

**“The Issuer’s Development Portfolio (Pipeline Overview):**

The table below sets out which phase each project is currently in:

Project	Area	Phase I	Phase II	Phase III	Filing
Eptinezumab (anti CGRP-mAb)	Migraine prevention				Ex-U.S.
Brexpirazole <sup>1)</sup>	Agitation in Alzheimer's disease				
Brexpirazole <sup>1)</sup>	PTSD				
Brexpirazole <sup>1)</sup>	Borderline personality disorder				
Aripiprazole 2-months injectable	Schizophrenia/bipolar I disorder				
Lu AF82422 (alpha-synuclein mAb)	Synucleinopathies				
Lu AF28996 (D <sub>1</sub> /D <sub>2</sub> agonist)	Parkinson's disease				
Lu AG06466 (MAGLI) <sup>2)</sup>	Neurology/psychiatry				
Lu AF88434 (PDE1B inhibitor)	Cognitive dysfunction				
Lu AF87908 (Tau mAb)	Tauopathies				
Lu AG09222 (PACAP mAb) <sup>3)</sup>	Migraine				
Lu AG06479 (MAGLI) <sup>2)</sup>	Neurology/psychiatry				

- 1) Acts as a partial agonist at 5-HT<sub>1A</sub> and dopamine D<sub>2</sub> receptors at similar potency, and an antagonist at 5-HT<sub>2A</sub> and noradrenaline alpha<sub>1B/2C</sub> receptors.  
2) MAGLI: Monoacylglycerol lipase inhibitor (“MAGlipase”).  
3) PACAP: inhibits pituitary adenylate cyclase-activating polypeptide

4. Condition 13(d) of the Terms and Conditions of the Notes on page 73 of the Base Prospectus shall be deleted in its entirety and replaced with the following wording:

*“(d) Security enforced: a secured party takes possession, or a receiver, manager or other similar officer is appointed, of the whole or any part of the undertaking, assets and revenues of the Issuer or any of its Material Subsidiaries having an aggregate value (net of any expropriation or other compensation received or receivable) of EUR 35,000,000 (or its equivalent in any other currency or currencies), unless the relevant petition is disputed by the relevant member of the Group in good faith and is discharged, stayed or dismissed within 45 days of commencement; or”*

5. The section entitled *“Legal and Arbitration Proceedings”* on pages 104 to 106 of the Base Prospectus shall be deleted in its entirety and replaced with the following wording:

***“Legal and Arbitration Proceedings***

Save as disclosed in this section, there are no governmental, legal or arbitration proceedings, (including any such proceedings which are pending or threatened, of which the Issuer is aware), which may have, or have had during the 12 months prior to the date of this Base Prospectus, a significant effect on the financial position or profitability of the Issuer and its subsidiaries.

The Group is involved in a number of legal proceedings, including patent disputes. In the opinion of the Issuer, the outcome of the proceedings specified below will either not have a significant effect on the Group’s financial position beyond the provisions already provided for by the Group in its latest audited annual financial statements, or the outcome is too uncertain to enable the Issuer to make a reliable provision.

- On 19 June 2013, the Issuer received the European Commission’s decision (case AT.39226) that the Issuer’s agreements concluded with four generic competitors concerning citalopram violated competition law. The decision included fining the Issuer EUR 93.8 million (approximately DKK 700 million). The Issuer paid the fine in the third quarter of 2013 despite continuing to appeal. On 8 September 2016, the Issuer announced that the General Court of the European Union had delivered its judgment (case T-472/13) concerning the Issuer’s appeal against the European Commission’s 2013 decision. The Issuer’s appeal was rejected by the General Court. The Issuer appealed the judgment to the European Court of Justice in 2016 (case C-591/16 P). An oral hearing was conducted by the European Court of Justice on 24 January 2019. The Advocate General delivered her opinion to the European Court of Justice on 4 June 2020. In the opinion, the Advocate General proposes that the European Court of Justice should uphold the fine of almost EUR 93.8 million imposed on the Issuer. A final judgment is expected during 2020.

So-called “follow-on claims” for reimbursement of alleged losses, resulting from alleged violation of competition law, often arise when decisions and fines issued by the European Commission are upheld by the European Court of Justice. UK health authorities (more specifically the Secretary of State for Health and Social Care, the National Health Service Business Services Authority and NHS Wales) and health authorities of the Netherlands have taken formal protective steps against the Issuer with the principal purpose of preventing potential claims from being time-barred under the applicable statutes of limitation. The Issuer expects no further material development in regard hereto until after the European Court of Justice has issued its final judgment.

- In Canada, the Issuer and its subsidiary Lundbeck Canada Inc. are involved in three product liability class-action lawsuits relating to Ciprallex®/Celexa® (two cases allege various Celexa® induced birth defects and one case against several SSRI manufacturers (including the Issuer) alleges that SSRI (Celexa®/Lexapro®) induced autism birth defects); three cases relating to Abilify Maintena® (alleging, inter alia, a failure to warn about compulsive behavior side effects); and one relating to Rexulti® (also alleging, inter alia, a failure to warn about compulsive behavior side effects). The cases are in the preliminary stages and as such there is significant

uncertainty as to how these lawsuits will be resolved. The Issuer strongly disagrees with the claims raised.

- In June 2018, the Issuer announced that its U.S. subsidiary Lundbeck LLC had reached an agreement in principle to resolve the U.S. Department of Justice (the “DOJ”) investigation related to Lundbeck LLC’s relationship with and donations to independent patient assistance charitable foundations, which called for a payment of USD 52.6 million. In April of 2019, the Issuer finalised this settlement, executed a Settlement Agreement, and made a payment of USD 52.6 million. The Settlement Agreement does not include any admission by Lundbeck LLC that it violated any law. The resolution of this matter will allow Lundbeck LLC to continue its focus on providing innovative medications to patients.
- In 2018, the Group entered into settlements with three of the four generic companies involved in an Australian federal court case in which the Issuer was pursuing patent infringement and damages claims over the sale of escitalopram products in Australia. The Issuer received AUD 51.7 million (DKK 242 million) in 2018. In the Issuer’s case against the final generic company, Sandoz Pty Ltd (“Sandoz”), the Federal Court found that Sandoz had infringed the Issuer’s escitalopram patent between 2009 and 2012 and awarded the Issuer AUD 26.3 million in damages. Sandoz’ appeal of the decision was heard on 8 to 10 May 2019 and the Full Federal Court has on 4 August 2020 allowed Sandoz’ appeal and decided that Sandoz is not liable for damages. The Issuer may seek special leave to appeal the decision to the High Court.
- The Issuer has, together with Takeda, instituted patent infringement proceedings against 16 generic companies that have applied for marketing authorisation for generic versions of Trintellix® in the U.S. Two counterparties have now withdrawn and the Issuer has settled with four counterparties. The cases against the remaining 10 parties continue. Decisions are expected shortly before the end of March 2021. The Issuer has strong confidence in its vortioxetine patents. The FDA cannot grant marketing authorisations to the generic companies unless they receive a decision in their favour. The compound patent, including patent term extensions, will expire in the U.S. on 17 December 2026. The Issuer has other patents relating to vortioxetine with expiry in the period until 2032.
- The Issuer has, together with Otsuka instituted patent infringement proceedings against several generic companies that have applied for marketing authorisation for generic versions of Rexulti® in the U.S. The Issuer has strong confidence in the Rexulti® patents. The FDA cannot grant marketing authorisation in the U.S. to the generic companies before the patents expire unless the generic companies receive decisions in their favour.
- In February 2019, Alder terminated a Development and Manufacturing Services Agreement (“DMSA”) with Lonza Ltd. (“Lonza”), based on material breaches of that agreement by Lonza. In April 2019, Lonza filed a claim for arbitration with the American Arbitration Association (“AAA”), asserting claims for breach of contract and declaratory judgment arising from the termination. Lonza disputed the material breaches asserted by Alder, denying that Alder is entitled to terminate the DMSA without further payment, and is seeking monetary damages representing Lonza’s calculation of the fee due upon termination for convenience. In May 2019, Alder filed an answer to Lonza’s claim with the AAA, in which Alder disputed Lonza’s claims and asserted counterclaims arising from Lonza’s breach of the DMSA. In June 2019, Lonza filed its reply to the counterclaims. The date of the arbitration hearing, previously scheduled for September 2020, is currently set for April 2021.
- The Issuer has received a Civil Investigative Demand (“CID”) from the U.S. Department of Justice (“DOJ”) on 9 March 2020. The CID seeks information

regarding the sales, marketing, and promotion of Trintellix. The Issuer is cooperating with the DOJ.”

6. The section of the Base Prospectus entitled “*General Information*” on pages 118 to 120 shall be amended as follows:

Item “3. Significant/Material Change” shall be deleted in its entirety and replaced as follows:

**“3. Significant/Material Change**

“Except as disclosed in the section headed “*Recent Developments*” and “*Risk Factors – The spread of COVID-19 may have a material negative effect on the Issuer’s business as a whole*”, there has since 31 December 2019 been no material adverse change in the prospects of the Issuer or the Issuer and its Subsidiaries (taken as a whole).

There has since 30 June 2020 been no significant change in the financial position or financial performance of the Issuer or the Issuer and its Subsidiaries (taken as a whole).”