UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 6-K

REPORT OF FOREIGN PRIVATE ISSUER
PURSUANT TO RULE 13a-16 OR 15d-16
OF THE SECURITIES EXCHANGE ACT OF 1934

Date of Report: June 28, 2022

(Commission File No. 001-39308)

CALLIDITAS THERAPEUTICS AB

(Translation of registrant's name into English)

Kungsbron 1, D5
SE-111 22
Stockholm, Sweden
(Address of registrant's principal executive office)

Indicate by check mark whether the registrant files or will file annual reports under cover of Form 20-F or Form 40-F.

Form 20-F ☒ Form 40-F ☐

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(1): ☐

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(7): ☐

INCORPORATED BY REFERENCE

This Report on Form 6-K (the "Report") shall be deemed to be incorporated by reference into the Company's registration statement on Form S-8 (File No. 333-240126) and to be a part thereof from the date on which this Report is filed, to the extent not superseded by documents or reports subsequently furnished.

COMPANY ANNOUNCEMENT AND ENTRY INTO A MATERIAL DEFINITIVE AGREEMENT

On June 28, 2022, Calliditas Therapeutics AB (the "Company") entered into a U.S. At-the-Market Offering Program pursuant to an Open Market Sale Agreement℠ (the "Sale Agreement") with Jefferies LLC ("Jefferies"), under which the Company may issue and sell American Depositary Shares, each representing two common shares with a quota value SEK 0.04 per share (the "ADSs"), having an aggregate offering price of up to $75,000,000, to be sold in the United States from time to time, in such share amounts and prices as the Company may specify by notice to Jefferies in accordance with the terms and conditions set forth in the Sale Agreement (the "ATM Program"). The foregoing description of the Sale Agreement is not complete and is qualified in its entirety by reference to the full text of such agreement, a copy of which is filed herewith as Exhibit 1 to this Report on Form 6-K and is incorporated herein by reference. Filed as Exhibit 2 to this Report on Form 6-K is an announcement published by the Company on June 28, 2022 announcing that the Company has entered into the Sale Agreement.

This Report on Form 6-K shall not constitute an offer to sell, or the solicitation of an offer to buy, the ADSs discussed herein, nor shall there be any offer, solicitation, or sale of securities in any state in which such offer, solicitation or sale would be unlawful prior to registration or qualification under the securities laws of any such state.

SUPPLEMENTAL RISK FACTORS AND INTELLECTUAL PROPERTY DISCLOSURE

The Company is filing (i) select risk factors describing risks and uncertainties that may affect the Company and the market price of its securities and (ii) updated disclosure of the Company's intellectual property portfolio with this Report for the purpose of amending and supplementing certain disclosures contained in the Company's prior filings with the SEC, including the Company's Annual Report on Form 20-F filed by the Company with the SEC on April 27, 2022. The updated risk factors and intellectual property disclosure are filed to this Report on Form 6-K as Exhibits 3 and 4, respectively, and are incorporated herein by reference and are intended to be read in conjunction with the remainder of the risk factors and business disclosure included in such previously filed reports.

EXHIBIT INDEX

Exhibit	Description
1	Open Market Sale Agreement[SM], dated June 28, 2022, by and between Calliditas Therapeutics AB and Jefferies LLC (incorporated by reference to Exhibit 1.2 to the registrant's Registration Statement on Form F-3 (File No. 333-265881) filed with the Securities and Exchange Commission on June 28, 2022).
2	Company announcement dated June 28, 2022
3	Supplemental risk factors
4	Supplemental intellectual property disclosure

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

CALLIDITAS THERAPEUTICS AB

Date: June 28, 2022

By:/s/ Fredrik Johansson
Fredrik Johansson
Chief Financial Officer

Exhibit 2

Stockholm, Sweden June 28, 2022

Calliditas Therapeutics establishes a U.S. At-the-Market Program

Calliditas Therapeutics AB (publ) (Nasdaq: CALT, Nasdaq Stockholm: CALTX) ("Calliditas" or "the Company") today announced that it has filed with the U.S. Securities and Exchange Commission (the "SEC") a registration statement including a prospectus ("Prospectus") relating to a U.S. At-the-Market framework of up to an aggregate amount of $75,000,000, pursuant to which the Company may, at its option, sell American Depositary Shares ("ADSs") in the United States at market price, from time to time, in "at the market" transactions on The Nasdaq Global Select Market (the "ATM Program"). If the Company chooses to use the ATM Program, the ADSs will be sold pursuant to an Open Market Sale Agreement (the "Sale Agreement") with Jefferies LLC ("Jefferies"). The timing of any potential sales under the ATM Program will depend on a variety of factors and Calliditas is not under any obligation to utilize the ATM Program in a specified amount or at all.

The ADSs intended to be sold under the Sale Agreement, if any, will be issued and sold by methods deemed to be an "at the market offering" as defined in Rule 415(a)(4) promulgated under the Securities Act of 1933, as amended, pursuant to a shelf registration statement on Form F-3 (the "Registration Statement"), once declared effective by the SEC. The number of ADSs sold pursuant to the Sale Agreement will be limited to the number of underlying common shares approved for transfer pursuant to the shareholder authorization obtained at the annual general meeting held on May 19, 2022 in respect of maximum 5,908,019 shares being valid up until the annual general meeting 2023. Such transfers, if any, may be made effective at a price in cash which corresponds to the market price at the time of the transfer of the Calliditas shares transferred as the Board of Directors finds appropriate. No assurance can be made that sales under the ATM Program will take place. No transactions under the ATM Program will take place on Nasdaq Stockholm. As of today, Calliditas does not hold any of its own shares, but has issued 5,908,018 class C shares to Aktieinvest which the Company intends to repurchase. All C shares are pending conversion into ordinary shares before they are transferred under the ATM Program.

To the extent that ADSs are sold pursuant to the ATM Program, the Company expects to use the net proceeds primarily to fund the development of candidates from the Company's NOX inhibitor platform, including setanaxib, in indications for which they may have therapeutic potential, including PBC and squamous carcinoma of the head and neck, or for any indications which are in early development, to fund commercial activities for TARPEYO, to fund the development of Budenofalk in AIH, and to fund the acquisition, development and commercialization of product candidates that the Company may acquire or in-license and for working capital and other general corporate purposes.

For additional information, please contact:

Marie Galay, IR Manager, Calliditas

Tel.: +44 79 55 12 98 45, email: marie.galay@calliditas.com

The information was sent for publication, through the agency of the contact persons set out above, on June 28, 2022 at 11:15 p.m. CEST.

The Registration Statement was filed with the SEC on June 28, 2022 and has not yet been declared effective. Any sales under the ATM Program will be made pursuant to the Prospectus relating to the ATM Program once the Registration Statement has been declared effective. Before purchasing ADSs in the offerings, prospective investors should read the Prospectus, together with the documents incorporated by reference therein. A copy of the Prospectus may be obtained on the SEC's website at www.sec.gov. Alternatively, a copy of such Prospectus may be obtained from Jefferies LLC, Attention: Prospectus Department, 520 Madison Avenue, New York NY 10022, or by telephone at 1-877-821-7388, or by email at Prospectus_Department@Jefferies.com.

This company announcement does not and shall not constitute an offer to sell or a solicitation to buy the securities mentioned and no sale of such securities will be made in the United States, any state or province in which such offer, solicitation or sale would be unlawful until the securities are registered or their distribution is permitted under the securities laws of that state or province. In particular, no public offering of the ADSs will be made in Europe.

About Calliditas

Calliditas Therapeutics is a commercial stage biopharma company based in Stockholm, Sweden focused on identifying, developing and commercializing novel treatments in orphan indications, with an initial focus on renal and hepatic diseases with significant unmet medical needs. Calliditas' lead product, TARPEYO™ (budesonide) delayed release capsules, has been approved by the FDA. This drug product is awaiting European Commission (EC) approval following a positive CHMP opinion. Additionally, Calliditas is conducting a Phase 2b/3 trial with its NOX inhibitor product candidate setanaxib in primary biliary cholangitis and is initiating a head and neck cancer Phase 2 trial with setanaxib. Calliditas' common shares are listed on Nasdaq Stockholm (ticker: CALTX) and its American Depositary Shares are listed on the Nasdaq Global Select Market (ticker: CALT).

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, as amended, including as to any potential sales under the ATM Program and the application of net proceeds therefrom. The words "may," "will," "could," "would," "should," "expect," "plan," "anticipate," "intend," "believe," "estimate," "predict," "project," "potential," "continue," "target," and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. Any forward-looking statements in this press release are based on management's current expectations and beliefs and are subject to a number of risks, uncertainties, and important factors that may cause actual events or results to differ materially from those expressed or implied by any forward-looking statements contained in this press release, including, without limitation, any related to Calliditas' business, operations, clinical trials, supply chain, strategy, goals and anticipated timelines, competition from other biopharmaceutical companies, and other risks identified in the section entitled "Risk Factors" in Calliditas' reports filed with the Securities and Exchange Commission. Calliditas cautions you not to place undue reliance on any forward-looking statements, which speak only as of the date they are made. Calliditas disclaims any obligation to publicly update or revise any such statements to reflect any change in expectations or in events, conditions, or circumstances on which any such statements may be based, or that may affect the likelihood that actual results will differ from those set forth in the forward-looking statements. Any forward-looking statements contained in this press release represent Calliditas' views only as of the date hereof and should not be relied upon as representing its views as of any subsequent date.

Disclaimer

This announcement does not, and shall not, in any circumstances constitute a public offering nor an invitation to solicit the interest of the public in Sweden, the United States or in any other jurisdiction, in connection with any offer.

The distribution of this document may, in certain jurisdictions, be restricted by local legislation. Persons into whose possession this document comes are required to inform themselves about and to observe any such potential local restrictions.

This announcement is not an advertisement and not a prospectus within the meaning of Regulation (EU) 2017/1129 of the European Parliament and of the Council of 14 June 2017 (the "Prospectus Regulation").

With respect to the member States of the European Economic Area, including Sweden no action has been undertaken or will be undertaken to make an offer to the public of the securities referred to herein requiring a publication of a prospectus in any relevant member State. As a result, the securities may not and will not be offered in any relevant member State except in accordance with the exemptions set forth in Article 1(4) of the Prospectus Regulation or under any other circumstances which do not require the publication by the Company of a prospectus pursuant to Article 3 of the Prospectus Regulation and/or to applicable regulations of that relevant member State.

This announcement is only being distributed to and is only directed at (i) persons who are outside the United Kingdom or (ii) within the United Kingdom, to "qualified investors" (as defined in the UK Prospectus Regulation) who are (a) investment professionals falling within Article 19(5) of the UK Financial Services and Markets Act 2000 (Financial Promotion) Order 2005 (the "Order") or (b) high net worth entities falling within Article 49(2)(a) – (d) of the Order (the persons described in (i) and (ii) above together being referred to as "relevant persons"). The securities are only available to, and any invitation, offer or agreement to subscribe, purchase or otherwise acquire such securities will be engaged in only with, relevant persons. Any person who is not a relevant person should not act or rely on this announcement or any of its contents. The "UK Prospectus Regulation" means Regulation (EU) 2017/1129 as it forms part of domestic law in the United Kingdom by virtue of the European Union (Withdrawal) Act 2018.

Exhibit 3

RISK FACTORS

The following risk factors should be read in conjunction with, and amends and supplements, those included in the Annual Report on Form 20-F filed by the Company on April 27, 2022 (the "Form 20-F"). Investing in the Company's ADSs and common shares involves a high degree of risk. You should carefully consider the risk described below, and all other information contained in or incorporated by reference in the Form 20-F, before making an investment decision regarding the Company's securities. The terms "we," "us" and "our" refer to the Company.

The regulatory approval processes of the FDA, EMA, European Commission and comparable foreign regulatory authorities are lengthy, time consuming and inherently unpredictable, and if we are ultimately unable to obtain acceptance for filing and regulatory approval for our products, product candidates or future product candidates, our business will be substantially harmed.

The time required to obtain approval by the FDA, EMA, European Commission and comparable foreign regulatory authorities is unpredictable but typically takes many years following the commencement of clinical trials and depends upon numerous factors, including the substantial discretion of the regulatory authorities. In addition, approval policies, laws or regulations or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions. Although Nefecon has been approved under accelerated approval by the FDA (marketed in the United States under the brand name TARPEYO), it is possible that we and our licensees may not be able to obtain full marketing approval in the United States, approval for Nefecon outside of the United States, or approval for setanaxib or other product candidates we may seek to develop in the future.

Any of our product candidates, including setanaxib and Nefecon, could fail to receive regulatory approval for many reasons, including the following:

- to the extent that we seek approval for any additional product candidates based on evaluation of a surrogate marker, as we did for Nefecon, we may be unable to utilize the accelerated approval pathway under Subpart H of the FDA's New Drug Application, or NDA, regulations and comparable regulations promulgated in the European Union if the appropriate regulatory authorities do not accept the proposed surrogate marker as the basis for an accelerated/conditional approval;

- the data collected from clinical trials of our product candidate may not be sufficient to support the submission of an NDA to the FDA or other submission or to obtain regulatory approval in the United States, the European Union or elsewhere;

- the scientific advice and regulatory feedback provided by the FDA and EMA, or comparable foreign regulatory authorities, as applicable, during the drug development phase, including at meetings at the end of each phase of clinical development, is not legally binding, and the FDA or EMA may depart from such advice and feedback on the basis of justified grounds during assessment of future marketing authorization applications;

- we may be unable to demonstrate to the satisfaction of the FDA, the EMA and the European Commission or comparable foreign regulatory authorities that a product candidate is safe or effective for its proposed indication;

- the results of clinical trials may not be sufficiently statistically significant or clinically meaningful as required by the FDA, the EMA or comparable foreign regulatory authorities for approval;

- we may be unable to demonstrate that the product candidate's clinical and other benefits outweigh its safety risks;

- the FDA, the EMA or comparable foreign regulatory authorities may disagree with our interpretation of data from clinical trials;

- the FDA, the EMA or comparable foreign regulatory authorities may find deficiencies with or fail to approve the manufacturing processes, quality control procedures or facilities of third-party manufacturers with which we contract for clinical and commercial supplies; and

- the approval policies or regulations of the FDA, the European Commission, or comparable foreign regulatory authorities or the laws they enforce may significantly change in a manner rendering our clinical data insufficient for approval.

This lengthy process towards approval as well as the unpredictability of future clinical trial results may result in our failing to obtain regulatory approval to market any of our product candidates, which would significantly harm our business, financial condition and results of operations. The FDA, EMA, European Commission and other comparable foreign regulatory authorities have substantial discretion in the approval process and determining when or whether regulatory approval will be obtained for any of our product candidates. Even if we believe the data collected from clinical trials of our product candidates are promising, such data may not be sufficient to support approval by the FDA, the European Commission or other comparable foreign regulatory authorities.

Additionally, disruptions at the FDA and other comparable foreign regulatory authorities and agencies may lengthen the time necessary for new drugs to be reviewed and/or approved by necessary government agencies, which could adversely affect our business. For example, in recent years, including in 2018 and 2019, the U.S. government shut down several times and certain regulatory agencies, such as the FDA, had to furlough critical employees and stop critical activities. Separately, many foreign and domestic inspections by the FDA and foreign regulatory authorities have been delayed due to the COVID-19 pandemic. If a prolonged government shutdown occurs in the future, or if the COVID-19 pandemic continues to affect the operations of regulatory authorities, our ability to obtain approval of our product candidates may be adversely impacted.

Accelerated approval by the FDA, and conditional approval by the European Commission, even if pursued for any future product candidates, may not lead to a faster development process or regulatory review and does not increase the likelihood that our product candidates will receive marketing approval. If we are not successful with this process, the development or commercialization of such product candidates could be delayed, abandoned or become significantly more costly.

In certain circumstances, the FDA and EMA selectively allows the use of surrogate endpoints to permit a faster development and an accelerated approval path.

For setanaxib, our ongoing Phase 2b/3 trial utilizes alkaline phosphatase (ALP) and total bilirubin (TBR) as a composite surrogate endpoint for accelerated approval in PBC. Even if the clinical data from the trial show an impact on the primary endpoint there is no guarantee that the FDA considers this to be clinically relevant or that the FDA would otherwise regard the clinical trial results as sufficient to support accelerated approval. If this is the case we may have to conduct additional clinical trials to support a marketing application for setanaxib in such indication.

As a condition of accelerated or conditional approval, regulatory agencies may impose specific obligations, including the performance of confirmatory, post marketing clinical trials to verify the clinical benefit of a drug. Following accelerated approval or conditional approval, we may therefore not ultimately receive full approval from the regulatory agencies should the additional data generated through post-marketing clinical trials not confirm that the benefit-risk balance of Nefecon, setanaxib or any other future product candidate is positive, or the burden to complete the obligations becomes too high.

In the European Union, the conditional marketing authorization is valid for one year and must be renewed annually until all specific obligations have been fulfilled. Once all pending study results are provided, the conditional marketing authorization can be converted into a traditional marketing authorization. However, if the obligations are not fulfilled within the timeframe set by the European Commission, EMA can take regulatory action, such as suspending or revoking the marketing authorization. Complying with the conditions of the marketing authorization may require financial resources and time. In addition, we may not be able to comply with all required conditions and may need to withdraw the marketing authorization. The European Commission may decide not to renew the conditional marketing authorization, although such measure is rarely applied in practice. An analysis of reimbursement decisions by the competent authorities of the individual EU Member States for conditionally authorized medicines in the European Union has shown some delays in the timeline for reaching a positive health technology recommendation. If this happens for Nefecon or any other future product candidate, it may delay the timing and success of the commercialization of such product.

Clinical trials are difficult to design and implement, and they involve a lengthy and expensive process with uncertain outcomes. We may experience delays in completing, or ultimately be unable to complete, the development and commercialization of our current and future product candidates.

To obtain the requisite regulatory approvals to commercialize any product candidates, we must demonstrate through extensive clinical trials that our product candidates are safe and effective in humans. Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Successful completion of clinical trials is a prerequisite to submitting an NDA to the FDA, a Marketing Authorization Application, or MAA, to the EMA and similar marketing applications to comparable foreign regulatory authorities for each product candidate and, consequently, the ultimate approval and commercial marketing of any product candidates. Failure can occur at any time during the clinical trial process and our future clinical trial results may not be successful.

Differences in trial design between early-stage clinical trials and later-stage clinical trials make it difficult to extrapolate the results of earlier clinical trials to later clinical trials. Moreover, clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in clinical trials have nonetheless failed to obtain marketing approval of their products. Where a randomized, placebo-controlled clinical trial is designed to allow enrolled subjects to cross-over from the placebo cohort to the treatment cohort, there may be a risk of inadvertent unblinding of subjects prior to cross-over, which may limit the clinical meaningfulness of those data and may require the conduct of additional clinical trials.

In addition, we may experience delays in initiating or completing clinical trials. We may also experience numerous unforeseen events during our clinical trials that could delay or prevent our ability to receive marketing approval or commercialize the product candidates we develop, including:

- delays in or failure to obtain institutional review board, or IRB, or ethics committee approval for each site;
- delays in or failure to recruit a sufficient number of suitable patients to participate in a trial;
- failure to have patients complete a trial or return for post-treatment follow-up;
- clinical sites deviating from trial protocol or dropping out of a trial;
- failure to manufacture sufficient quantities of product candidate for use in clinical trials in a timely manner or shipping delays and interruptions;
- safety or tolerability concerns that could cause us or our collaborators, as applicable, to suspend or terminate a trial if we or our collaborators find that the participants are being exposed to unacceptable health risks;
- changes in regulatory requirements, policies and guidelines, or their application regarding recommendations or guidance provided by regulatory authorities;
- evolution in the standard of care during the development of a product candidate that require amendments to an ongoing clinical trial or the conduct of additional safety studies or clinical trials;
- failure of our third-party research contractors to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;

- the FDA, EMA or other regulatory authorities may require us to submit additional data or impose other requirements before accepting a trial as being registrational;

- delays in establishing the appropriate dosage levels in clinical trials; and

- the quality or stability of the product candidate falling below acceptable standards.

Disruptions caused by the COVID-19 pandemic may increase the likelihood that we encounter such difficulties or delays in initiating, enrolling, supplying, conducting or completing our planned and ongoing clinical trials. For example, we experienced a reduced enrollment rate in our ongoing NefIgArd trial over the last several months of 2020 due to the impact of the COVID-19 pandemic, and we hence completed full enrollment in January 2021, which was later than we originally had anticipated. We could encounter delays if a clinical trial is suspended or terminated by us, by the IRBs or ethics committees of the institutions in which such trials are being conducted, or by the FDA or other comparable foreign regulatory authorities, or recommended for suspension or termination by the Data Review Committee, or DRC, or Data Safety Monitoring Board, or DSMB, for such trial. Such authorities may impose such a suspension or termination due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA or other comparable foreign regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, including those relating to the class to which our product candidates belong, failure to demonstrate a benefit from using a product candidate, or changes in governmental regulations or administrative actions.

If we experience delays in the completion of, or if we terminate, any clinical trial of our product candidates, the commercial prospects of our product candidates will be harmed, and our ability to generate product revenues from any of these product candidates will be delayed. In addition, any delays in completing our clinical trials will increase our costs, slow down our product candidate development and approval process and jeopardize our ability to commence product sales and generate revenues. From time to time, we may interact with regulatory agencies with the aim of facilitating the development of our product candidates by achieving alignment on an efficient trial design, a modest number of enrolled patients or a relatively expedient timeline. However, there can be no assurances that such alignment will be reached and, even if achieved, that we will realize the intended benefits from these interactions.

Moreover, if we make changes to our product candidates, we may need to conduct additional studies to bridge our modified product candidates to earlier versions, which could delay our clinical development plan or marketing approval for our product candidates. Significant clinical trial delays could also allow our competitors to bring products to market before we do or shorten any periods during which we have the exclusive right to commercialize our product candidates and impair our ability to commercialize our product candidates.

Any of these occurrences may harm our business, financial condition and results of operations significantly. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates or result in the cessation of development of our product candidates.

Exhibit 4

SUPPLEMENTAL INTELLECTUAL PROPERTY DISCLOSURE

The following disclosure should be read in conjunction with, and amends and supplements, the disclosure in Item 4.B, "Business Overview—Intellectual Property—Patents" included in the Annual Report on Form 20-F filed by the Company on April 27, 2022 (the "Form 20-F"). The terms "we," "us" and "our" refer to the Company.

Patents

The patent positions for biotechnology companies like us are generally uncertain and can involve complex legal, scientific and factual issues. In addition, the coverage claimed in a patent application can be significantly reduced before a patent is issued, and its scope can be reinterpreted and even challenged after issuance. As a result, we cannot guarantee that any of our technologies and product candidates will be protectable or remain protected by enforceable patents. We cannot predict whether the inventions and patent applications we are currently pursuing will issue as patents in any particular jurisdiction or whether the claims of any issued patents will provide sufficient proprietary protection from competitors. Any patents that we hold may be challenged, circumvented or invalidated by third parties.

With regards to Nefecon, we co-own one patent family with Kyowa Kirin Services Ltd., f/k/a Archimedes Development Ltd., to which we have a sole and exclusive global license, even in relation to the other co-owner, in any field of use. This patent family protects a formulation for the oral delivery of budesonide and the medicinal use thereof. The patents in this patent family expire in 2029 provided all renewal fees are paid within the prescribed period, which we intend to do. The patents in this family include a United States patent, a patent in each of China, Hong Kong and Japan and a European patent that has been validated in 15 countries (Austria, Belgium, Switzerland, Germany, Denmark, Spain, Finland, France, the United Kingdom, Italy, the Netherlands, Norway, Poland, Sweden and Turkey). The patents in this family are not eligible for extension in the United States because the active ingredient is used in existing approved drugs. In Europe, extension of the patents is not likely subject to the recent judgement of litigation in the European Union, CJEU C-443/17, related to the degree to which it is possible to obtain a Supplementary Protection Certificate for a previously authorized active ingredient.

With regards to the NOX estate, there are three patent families covering various aspects of the setanaxib asset derived from three PCT applications. The composition of matter and certain methods of therapy are covered in two of these patent families. The third covers the use of setanaxib in certain oncology indications, including head and neck cancer. There is one further patent family that covers other NOX inhibitors and one that covers the use of setanaxib and other NOX inhibitors in a kidney disease indication. As these patents and applications cover new chemical entities, the territorial coverage is generally quite wide, and as the compounds do not yet form part of an approved drug product, patent life may potentially be extended in countries where legislation provides for patent term extension. The two families covering setanaxib's composition of matter have projected expiry dates in 2028 and 2029, excluding potential extensions.