UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

SCHEDULE TO

Tender Offer Statement Pursuant to Section 14(d)(1) or 13(e)(1)
of the Securities Exchange Act of 1934

ALDER BIOPHARMACEUTICALS, INC.
(Name of Subject Company)

VIOLET ACQUISITION CORP.
(Offeror)
A Wholly Owned Subsidiary of

LUNDBECK LLC
(Offeror)
An Indirect Wholly Owned Subsidiary of

H. LUNDBECK A/S
(Offeror)

COMMON STOCK, $0.0001 PAR VALUE
(Title of Class of Securities)

014339 105
(CUSIP Number of Class of Securities)

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CALCULATION OF FILING FEE

Transaction Valuation	Amount of Filing Fee
N/A*	N/A*

* A filing fee is not required in connection with this filing as it relates solely to preliminary communications made before the commencement of the tender offer.

☐ Check the box if any part of the fee is offset as provided by Rule 0-11(a)(2) and identify the filing with which the offsetting fee was previously paid. Identify the previous filing by registration statement number, or the Form or Schedule and the date of its filing.

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☒ Check the box if the filing relates solely to preliminary communications made before the commencement of a tender offer.

Check the appropriate boxes below to designate any transactions to which the statement relates:

- ☒ third-party tender offer subject to Rule 14d-1.
- ☐ issuer tender offer subject to Rule 13e-4.
- ☐ going-private transaction subject to Rule 13e-3.
- ☐ amendment to Schedule 13D under Rule 13d-2.

Check the following box if the filing is a final amendment reporting the results of the tender offer: ☐

If applicable, check the appropriate box(es) below to designate the appropriate rule provision(s) relied upon:

- ☐ Rule 13e-4(i) (Cross-Border Issuer Tender Offer)
- ☐ Rule 14d-1(d) (Cross-Border Third-Party Tender Offer)

This filing relates solely to preliminary communications made before the commencement of a tender offer by Violet Acquisition Corp., a Delaware corporation ("Purchaser"), a wholly owned subsidiary of Lundbeck LLC, a Delaware limited liability company ("Payor"), and an indirect wholly owned subsidiary of H. Lundbeck A/S, a Danish *aktieselskab* ("Parent"), for all of the outstanding shares of common stock, par value $0.0001 per share ("Shares"), of Alder BioPharmaceuticals, Inc., a Delaware corporation ("Alder"), at a price of (x) $18.00 per Share, net to the seller in cash, without interest and less any applicable withholding taxes, plus (y) one contractual contingent value right per Share, which represents the right to receive a contingent payment of $2.00 in cash if a specified milestone is achieved, pursuant to an Agreement and Plan of Merger, dated as of September 16, 2019, by and among Parent, Purchaser, Payor and Alder.

Notice to Investors

The tender offer (the "Offer") for the outstanding common stock of Alder referred to in this filing and related exhibits has not yet commenced. The description contained in this filing and related exhibits is neither an offer to purchase nor a solicitation of an offer to sell any securities, nor is it a substitute for the tender offer materials that Parent will file with the U.S. Securities and Exchange Commission (the "SEC"). The solicitation and offer to buy the common stock of Alder will only be made pursuant to an offer to purchase and related tender offer materials. At the time the Offer is commenced, Parent will file a tender offer statement on Schedule TO and, thereafter, Alder will file a solicitation/recommendation statement on Schedule 14D-9 with the SEC with respect to the Offer. THE TENDER OFFER MATERIALS (INCLUDING AN OFFER TO PURCHASE, A RELATED LETTER OF TRANSMITTAL AND CERTAIN OTHER OFFER DOCUMENTS) AND THE SOLICITATION/RECOMMENDATION STATEMENT ON SCHEDULE 14D-9 WILL CONTAIN IMPORTANT INFORMATION. ANY HOLDERS OF SHARES ARE URGED TO READ THESE DOCUMENTS CAREFULLY WHEN THEY BECOME AVAILABLE BECAUSE THEY WILL CONTAIN IMPORTANT INFORMATION THAT HOLDERS SHOULD CONSIDER BEFORE MAKING ANY DECISION REGARDING TENDERING THEIR SHARES. The offer to purchase, the related letter of transmittal and the solicitation/recommendation statement will be made available for free at the SEC's website at www.sec.gov. Free copies of the offer to purchase, the related letter of transmittal and certain other offering documents will be made available by Parent and when available may be obtained by directing a request to the Information Agent for the tender offer which will be named in the Schedule TO. Copies of the documents filed with the SEC by Alder will be available free of charge on Alder's internet website at http://investor.alderbio.com/financial-information/sec-filings or by contacting Alder's investor relations contact at +1 (212) 362-1200.

In addition to the offer to purchase, the related letter of transmittal and certain other tender offer documents filed by Parent, as well as the solicitation/recommendation statement filed by Alder, Alder will also file annual, quarterly and current reports with the SEC. You may read and copy any reports or other information filed by Parent or Alder at the SEC public reference room at 100 F Street, N.E., Washington, D.C. 20549. Please call the SEC at 1-800-SEC-0330 for further information on the public reference room. Alder's filings with the SEC are also available to the public from commercial document-retrieval services and at the website maintained by the SEC at http://www.sec.gov.

EXHIBIT INDEX

Exhibit No.	Description
99.1	Transcript of H. Lundbeck A/S Investor/Analyst Conference Call, dated September 16, 2019.

Exhibit 99.1

Teleconference – 16 September 2019
Lundbeck to acquire Alder BioPharmaceuticals

Safe Harbor/Forward-Looking Statements

This transcript contains forward-looking information related to Lundbeck, and the proposed acquisition of Alder by Lundbeck that involves substantial risks and uncertainties that could cause actual results to differ materially from those expressed or implied by such statements. Forward-looking statements in this document include, among other things, statements about the potential benefits of the proposed acquisition, the anticipated contingent value right payment, anticipated royalties, earnings dilution and accretion, and growth, Lundbeck's plans, objectives, expectations and intentions, the financial condition, results of operations and business of Lundbeck and Alder, Alder's product pipeline and portfolio assets, Alder's ability to achieve certain milestones that trigger the contingent value right payment, the anticipated timing of closing of the proposed acquisition and expected plans for financing the proposed acquisition. Risks and uncertainties include, among other things, risks related to the satisfaction or waiver of the conditions to closing the proposed acquisition (including the failure to obtain necessary regulatory approvals) in the anticipated timeframe or at all, including uncertainties as to how many of Alder's stockholders will tender their shares in the tender offer and the possibility that the acquisition does not close; the possibility that competing offers may be made; risks related to obtaining the requisite consents to the acquisition, including, without limitation, the timing (including possible delays) and receipt of regulatory approvals from various governmental entities (including any conditions, limitations or restrictions placed on these approvals and the risk that one or more governmental entities may deny approval); risks related to the ability to realize the anticipated benefits of the proposed acquisition, including the possibility that the expected benefits and accretion from the proposed acquisition will not be realized or will not be realized within the expected time period; the risk that the businesses will not be integrated successfully; disruption from the transaction making it more difficult to maintain business and operational relationships; negative effects of this announcement or the consummation of the proposed acquisition on the market price of Lundbeck's common stock, Lundbeck's credit ratings and/or Lundbeck's operating results; significant transaction costs; unknown liabilities; the risk of litigation and/or regulatory actions related to the proposed acquisition; other business effects, including the effects of industry, market, economic, political or regulatory conditions; changes in reimbursement rules and governmental laws and related interpretations thereof; delay or failure of development projects, production problems, unexpected contract breaches or terminations; future exchange and interest rates; changes in tax and other laws, regulations, rates and policies, including government-mandated price decreases for Lundbeck's products; future business combinations or disposals; the uncertainties inherent in research and development, including the ability to meet anticipated clinical endpoints, commencement and/or completion dates for clinical trials, regulatory submission dates, regulatory approval dates and/or launch dates, as well as the possibility of unfavorable new clinical data and further analyses of existing clinical data; the uncertainty that the milestones for the CVR payment may not be achieved in the prescribed timeframe or at all; the risk that clinical trial data are subject to differing interpretations and assessments by regulatory authorities; whether regulatory authorities will be satisfied with the design of and results from Lundbeck's and Alder's clinical studies; whether and when drug applications may be filed in any jurisdictions for any potential indication for any of Lundbeck's and Alder's pipeline assets; whether and when any such applications may be approved by regulatory authorities, which will depend on myriad factors, including making a determination as to whether the product's benefits outweigh its known risks and determination of the product's efficacy and, if approved, whether any such products will be commercially successful; decisions by regulatory authorities impacting labeling, manufacturing processes, safety and/or other matters that could affect the availability or commercial potential of any such products; and competitive developments. Lundbeck does not undertake any obligation to update these forward-looking statements (whether as a result of new information, future events or otherwise) except to the extent otherwise required by law.

A further description of risks and uncertainties relating to Alder can be found in Alder's Annual Report on Form 10-K for the fiscal year ended December 31, 2018, and in its subsequent Quarterly Reports on Form 10-Q and Current Reports on Form 8-K, all of which are filed with the SEC and available at www.sec.gov and https://www.alderbio.com/.

These forward-looking statements are based on numerous assumptions and assessments made by Lundbeck in light of its experiences and perception of historical trends, current conditions, business strategies, operating environment, future developments and other factors it believes are appropriate. By their nature, forward-looking statements involve known and unknown risks and uncertainties because they relate to events and depend on circumstances that will occur in the future. The factors described in the context of such forward-looking statements in this transcript could cause Lundbeck's plans with respect to Alder, actual results, performance or achievements, industry results and developments to differ materially from those expressed in or implied by such forward-looking statements. Although it is believed that the expectations reflected in the forward-looking statements in this transcript are reasonable, no assurance can be given that such expectations will prove to have been correct and persons reading this transcript are therefore cautioned not to place undue reliance on these forward- looking statements which speak only as at the date of this transcript.

Certain assumptions made by Lundbeck are required by Danish Securities Law for full disclosure of material corporate information. Some assumptions, including assumptions relating to sales associated with product that is prescribed for unapproved uses, are made considering past performances of other similar drugs for similar disease states or past performance of the same drug in other regions where the product is currently marketed. It is important to note that although physicians may, as part of their freedom to practice medicine in the US, prescribe approved drugs for any use they deem appropriate, including unapproved uses, at Lundbeck, promotion of unapproved uses is strictly prohibited.

Operator

Ladies and gentlemen, welcome to the H. Lundbeck conference call. For the first part of the call, all participants will be in listen-only mode and afterwards, there will be a question and answer session. Today I am pleased present Deborah Dunsire, President and CEO, and Anders Götzsche, Executive Vice President and CFO, and Johan Luthman, Executive Vice President of Research and Development. Speakers, please begin your meeting.

Deborah Dunsire

Thank you very much, operator, and thank you for joining us to discuss the announcement today of our agreement to acquire Alder BioPharmaceuticals. I hope you have received our press release and can see the presentation which is located on the investor section of the Lundbeck website. As you have heard, I am joined by our CFO Anders Götzsche and our EVP of R&D Johan Luthman. Following our presentation, we will open the call for your questions.

On slide 2, you can see the company's updated disclaimer. Please review this when you have the time. Please also refer to the cautionary statements regarding the transaction detailed in the press release. They are also listed here on slide 3 of the presentation. I urge you to read it thoroughly.

Let us go to slide 4. When I became the CEO of Lundbeck last year, I worked together with the management team to define our corporate strategy to establish Lundbeck's path to future growth. We announced our Expand and Invest to Grow strategy in February. The strategy is firmly rooted in our more than 70-year heritage and our competitive strength in bringing forward transforming medicines for brain diseases. Two key pillars of the strategy were to expand our therapeutic breadth in the range of brain diseases we will address and to rebuild our pipeline through both our internal discovery as well as through accessing external innovation. In May of 2019, Lundbeck acquired Abide, now Lundbeck La Jolia Research Centre providing us with the very exciting discovery platform. Today's announcement of the agreement to acquire Alder is a further very exciting leap forward on our path to deliver long-term sustainable growth and value to our shareholders.

Next slide, please. With this, we expand our reach in therapies for brain disease bringing the opportunity to build a migraine franchise addressing a large market with substantial unmet medical needs. The lead asset in Alder's portfolio is eptinezumab or epti for short. A potential best-in-class anti CGRP monoclonal antibody which is filed with the FDA and we believe will launch in early 2020. This provides near-term growth with blockbuster potential over time. Additionally, Alder's strong antibody capability accelerates Lundbeck's ability to delivery future biologics in other brain diseases. We believe this transaction has the potential to create compelling, long-term value for all our stakeholders including our shareholders.

Next slide, please. Migraine is a serious neurological disease and according to several organisations, including the UN's Global Burden of Disease, it is the most disabling of all diseases for people under the age of 50. Every attack lasts between 4 and 72 hours and not only brings incapacitating pain, but also the burden of disabling sensitivity to light and sound with attendant nausea, vomiting and cognitive impairment.

Next slide, please. There is a high unmet need for new effective and well tolerated prevention options. According to the Chronic Migraine in America survey, 9 out of 10 patients don't use preventive therapy or discontinue its use within 6 months to 1 year because they experience a lack of efficacy or develop side effects. And even for those patients where the treatment is effective, it can take weeks or months to achieve a meaningful clinical benefit.

Next slide, please. Migraine is an enormous problem by any standard. As migraine frequency increases, the susceptibility to future migraine also increases. The biggest risk for chronic migraine is suffering frequent episodic migraines. Migraine is a disease that begins early in life and continues for decades worsening over time. There is a spectrum of severity in migraine. Relatively infrequent migraine or episodic migraine includes people having less than four migraine days per month. Frequent episodic migrainers have between 4 and 14 attacks per month. People facing over 15 attacks per month are referred to as having chronic migraine. Remember each migraine attack can last up to 48 hours. People with episodic migraine progress to chronic migraine at varying rates. The most recent estimate is that approximately 2.5% of people with episodic migraine will progress to chronic migraine each year. It is estimated that over 134 million people suffer from migraine in the major world markets. Almost all patients with migraine will treat that episode with acute therapy to limit the individual attack. Preventive therapies are treatments that are intended to reduce the frequency and severity of headache. It is estimated that 43% of the diagnosed patients or approximately 18 million people have attacks that are so frequent and disabling that they need preventive treatments.

Next slide, please. CGRP has been explored as a target for migraine since the 1980s giving abundant evidence demonstrating CGRP's role in driving migraine attacks. We now know that blocking CGRP's activity provides effective preventive treatment. With the launch of the CGRP inhibitors in the past year along with the expected launch of epti and possibly other molecules in the coming years, the market is expected to reach more than USD 7 billion by 2027.

Next slide, please. Johan will dive deeper into some of the clinical results that epti has achieved in a minute. I assume that many of you have had the opportunity to familiarise yourselves with Alder's substantial pivotal trial programme, including the PROMISE 1 trial that enrolled 888 patients and the PROMISE 2 trial that enrolled 1,072 patients. Patients in these trials have suffered with migraine for an average of 15-20 years. The results of those trials clearly demonstrated a powerful, fast and sustained response to epti. Additionally, the patients' reported outcomes were significantly improved. With that I will turn the presentation over to Johan.

0.08.46

Johan Luthman

Thank you, Deborah. Please turn to slide 11. So as Deborah mentioned, Alder ran two successful phase III studies in adult patients. PROMISE 1 in episodic migraine patients included patients having between 4 to 14 migraine days per month. The second trial, PROMISE 2, sought to prevent migraine in people with more severe disease, chronic migraine, and included people experiencing 15 or more migraine attacks per month. What you see here is that in both trials after even the first 30-minute IV infusion, a clinically meaningful benefit was seen in terms of change from Baseline in monthly migraine days MMD which was the primary end point for both studies. The two studies also consistently demonstrated a very high response rate with 60% of patients achieving better than 50% reduction in migraine days. 40% of patients reaching a 75% reduction and a rather amazing 15-20% of patients having 100% response rates. That is to say, no migraine days in the 3-month dosing in both of these trials.

Next slide, please. The achievement of prevention of day 1, 24 hours post dosing, was a pre-specified secondary end point in the studies. Epti demonstrated a significant ability to achieve prevention of migraine by 24 hours in both the PROMISE 1 and PROMISE 2 studies. It was also noted that efficacy was maintained throughout the period between doses.

Next slide, please. Across the two studies, epti treatment was well tolerated with an adverse event incidence that was similar across all doses when compared to placebo. The only adverse event that exceeded the placebo rate by 2% or more was nasopharyngitis which is the swelling of the nasal passage. In

patients treated with 100 mg, the rate was 6% and in patients treated with 300 mg, the rate was 8% while the placebo rate was 6%. The nasopharyngitis was also transient. So epti has an encouraging tolerability profile.

Next slide, please. Turning now to how epti will fit into the migraine prevention landscape. We believe epti will offer a unique and differentiated value proposition to patients and those that care for them. It is our belief that symptom relief and quality of life measures are extremely important to migraine patients. And that most patients would choose a product based on its effectiveness and speed of prevention effect.

Market research in migraine sufferers suggests that they prioritise depth ??? 0.11.47 and sustainability release when choosing a therapy. Even at this clinical profile, IV administration would not be a barrier for them. We also note that in the US, most of the specialists treating migraine patients have ready access to IV delivery capabilities.

Next slide, please. Another near-term potentially significant opportunity for epti is in the acute treatment of migraine in those patients eligible for prevention. Alder has communicated plans to initiate a phase III clinical trial evaluating epti in this so-called treatment prevent indication in the second half of 2019. The trial will seek to leverage epti 100% by availability and rapid onset of prevention as demonstrated in clinical testing to date. The objective of the planned study is to secure an indication for the acute treatment of migraine for patients who are candidates for preventive therapy. If successful, the trial might be used to seek approval to expand the label positioning epti as the first anti CGRP monoclonal antibody to both treat and prevent migraine.

The anti CGRP mechanism has also potential in several other pain syndromes. Addressing additional indications is under consideration.

Next slide, please. Through Alder, Lundbeck is also getting access to an additional phase I ready product, namely ALD1910. This molecule has the potential to address a subset of migraine patients who may not respond well to anti-CGRP therapy. ALD1910 is a highly specific, high affinity neutralising monoclonal antibody against the pituitary adenylate cyclase-activating peptide or PACAP for short.

PACAP has emerged as an important signalling pathway in the pathophysiology on migraine and pre-clinical data have shown its role in migraine is distinct from that of CGRP. As such, we believe PACAP represents an attractive, novel target and we are very encouraged by the pre-clinical data to date which suggest that ALD1910 prevents the signalling of PACAP through its receptors. The pre-clinical programme has been completed to support the phase I trial start before the end of 2019.

I will now hand over to Anders Götzsche to expand on the financial aspects of the transaction.

0.14.30

Anders Götzsche

Thanks, Johan. Please turn to slide 17. Just a few details on the transaction. We have agreed to acquire Alder for an upfront payment of USD 18 per share along with a CVR of USD 2 per share based upon regulatory approval of epti in the EU based on the data from PROMISE 1 and PROMISE 2.

This represents a total transaction value of USD 1.95 billion or approximately DKK 13 billion at current exchange rate adjusted for Alder's net cash. The upfront cash consideration represents a 79% premium to Alder's shareholders based on the closing price on 13 September 2019 and an approximate 3% discount based on the 52-week high share price. We will commence a tender offer for the shares in Alder within the next 5 business days.

We will finance the deal through existing cash reserves plus bank financing. I think it is important to note that we expect to be core EPS accretive in 2023 and that we expect to stay within our current financial policy of a remaining investment grade ??? 0.16.04. Additionally, we expect to maintain our current dividend policy. We expect the transaction to close in Q4 2019 pending anti-trust regulatory review and other customary conditions.

Please turn to slide 18. I expect you are all aware of the financial guidance we provided for 2019 at our half- year earnings call in August. The guidance we provided then remains unchanged at this time. Upon closure of the transaction, there will be an impact on our EBIT and core EBIT guidance and we will clarify the change upon successful closing the tender offer. Transaction costs are expected to reach around DKK 200 million and there will also be integration and retention costs which we expect to reach DKK 400-500 million. Additionally, based on Alder's financial guidance for the year and assuming that the transaction is completed by 1 November, we anticipate recognition of two months of operating expenses totalling DKK 325-400 million. The transaction represents a significant long-term investment in Lundbeck's future growth and we plan to resource it appropriately to ensure that we have the right clinical data and commercial capabilities in place to support the global launch and long-term maximising of epti as well as investment in the pipeline we are also acquiring.

Given that driving faster revenue growth will take time, the investments we believe are necessary will result in a short-term dilution over the next couple of years. The short-term dilution is expected to diminish rapidly with the acquisition becoming accretive to core EPS by 2023 and increasing thereafter. Overall, we believe this transaction represents a compelling opportunity to accelerate the build of our pipeline and establish a commercial capability in migraines, ultimately improving our performance and generating long- term sustainable growth for Lundbeck. With that now back to Deborah.

0.18.35

Deborah Dunsire

Thanks Anders. Alder provides Lundbeck the opportunity to build a migraine franchise with the expected launch of eptinezumab in the US in the first half of next year thereby contributing to revenue growth starting in 2020. Additionally, we expect submission in the EU during 2020 followed by submissions for approval in other regions around the world. Epti is patent protected through the mid-2030s, which allows for further development in a number of additional pain syndromes where there is high unmet need. Finally, Alder will provide us with technical capabilities in the antibody field for future pipeline candidates. With that I would like to thank you all for your interest and open for the Q&A session. Operator?

0.19.34

Operator

Thank you and ladies and gentlemen if you do wish to ask a question, please press 01 on your telephone keypad now. The first question is from James Gordon from J.P. Morgan. Please go ahead. Your line is now open.

James Gordon

Hello, good morning. James Gordon from J.P. Morgan. Thanks for taking the questions. Two questions please. One about epti ramp ??? 0.19.55 so you guided EPS accretion in 2023 but what does that assume about the pace of epti uptake and I can see consensus as 2023 sales of almost 600 million but do you think that is plausible if that is the third year of US launch and second year of the EU launch? That is the first question, please. And then the second question is on cost savings so the release, in the presentation just now there is talk about strategic benefits but I did not see a comment on synergies or specifically on cost savings. What does the 2023 guidance assume for the ability to take cost out or what the company would

do stand alone. Is there much central cost you can take out? And is there a synergy maybe that you can use the Northera sales force to sell it ??? 0.20.35 or some other synergy that would allow cost savings please?

0.20.39

Deborah Dunsire

Okay. I will start and then Anders will add commentary so you have asked about the pace of epti uptake and we cannot comment on what the consensus guidance is. We are anticipating the launch in early 2020 in the US but we are only submitting in the EU during 2020 so obviously the EU launch is a little bit further out and so we have made our forecast based on those two time lines. Anders, do you want to comment?

0.21.14

Anders Götzsche

Yes. But it is a fact to add to what Deborah just said this we believe will be a blockbuster of course and there will be.. we will be in a launch phase in 2020 and 2021 and 2022 and that is why we also say we will be – we can promise that it will be core EPS accretive in 2023 and what we need to finalise first is we need all the shareholders to accept the tender offer and when that has been done, then we will start to look into how can we get the best out of the companies? How can we secure that we combine the strengths of Lundbeck and Alder and secure the best possible launch? And then of course we will look into what kind of synergies can we take between the companies? But it is a bit too early to go into these details before we have made final closing.

0.22.12

Deborah Dunsire

I think when we think about the strategic benefits, one of those benefits, James, is being able to leverage the strengths we have. First of all, we have a global commercial infrastructure that we can build upon to launch epti around the world. There certainly will be some overlap but we will also be reaching some new target audiences, headache specialists or migraine specialists are not an audience we currently call on and there is not a complete overlap with the neurology market that our sales force in Northera calls on, but of course, we can get some synergy and leverage out of being in those two neurology areas so we will be working through that but as you know, these transactions require HSR clearance and other regulatory clearance so we will be thinking through the planning going forward. What I can say is that we would on the whole be spending less than a stand-alone company would have to spend.

0.23.31

James Gordon

Thank you.

Operator

And next question is from the line of Trung Huynh from Credit Suisse. Please go ahead, your line is now open.

0.23.41

Trung Huynh

Thanks for taking my questions. I have a few if I can. Just touching on your comments on overlaps between some of these prescribers. Just how does Lundbeck intend to position epti with neurologists and non- neurologists? And then could you just say what relationships you do have with these prescribers and perhaps the number that you are going to need to hire? And then just on future M&A, what is your strategy following this deal and then I've got a few financing ones, hopefully they are quick. You know, the two- month operating costs for Alder between DKK 325-400 million, can you give us an idea of these operating costs going forward? And then just finally on financing, is 3% a reasonable expectation? Thanks very much.

0.24.34

Deborah Dunsire

Okay, so talking about the overlap in prescribers, there are a lot of chronic – remember, this is preventive therapy for frequent episodic and chronic migraine so these are patients that are going to be in a specialist neurology audience and there are some general neurologists who will be treaters and then the most severe patients will be in the migraine or headache clinics. So we certainly address neurologists fairly broadly today with Northera and outside the US with some of our other products. Specifically in the headache clinics, we have not, if they are dedicated to those, to treating migraine and other pain syndromes, we would not be calling on those neurologists at this time for Northera so that would be an expansion of the audience for us. Does that answer your question there?

0.25.40

Trung Huynh

Yes, that sounds great, thanks.

Deborah Dunsire

And then with respect to our M&A strategy going forward, we have said that we will be building our pipeline through both our internal discovery and development as well as selectively looking externally for not only M&A but licensing and partnership and so that process will continue and we will over the years ahead be looking to continue to supplement Lundbeck's pipeline in a way that gives us a long-term future growth profile. Financing, do you want to comment, Anders?

0.26.21

Anders Götzsche

And maybe also, you had a question around how many people do we need to hire, you know, what we have said all the time with the new strategy is that of course, where we know we have been extremely good at creating growth for the strategic products we have is that we are a specialist company and this is a specialist product where we need 100-125 reps in the US and we anticipate the same in Europe and other markets so this is for specialists, that we have shown with Xenazine, Onfi, with Sabril and other products that we are maybe one of the best companies in the world to work with patient associations, get out to these specialists and securing double digit growth numbers and it is definitely our intention. If this deal is closing, we anticipate that we will be doing that again. And for the two months operating costs, we have not given our own specific guidance to what we anticipate of cost because we think that is too early. So what we have done is we have used the guidance that Alder has in the marketplace today and then we have taken two months of that cost and then we have also taken into account that they are going into a launch phase or building up the pre-launch activities so it is a pure straightforward calculation of what they have guided. The financing, you should expect us to have a cost around 1% for our debt.

0.28.00

Trung Huynh

Great, thanks very much Anders.

Operator

And next question is from the line of Michael Novod from Nordea Markets. Please go ahead, your line is now open.

0.28.12

Michael Novod

Yes hello it's Michael from Nordea. Just a few questions. Maybe just going back to the differentiated profile. Can you try to talk a bit more to how you in real life see the differentiation? I fully understand the strength of the data and also that it's an IV every quarter but bearing in mind that you could also have a Sub-Q every quarter, you will see orals likely coming into the market. How is the real differentiation of this product? Is there anything on the launch or in compliance ??? 0.28.51 that you think will be better? Things like that would be very helpful at least for me to understand the full differentiation. And then secondly again on the consensus, we see these numbers initial uptake around 3-400 million in the first 2-3 years, I know you are not using consensus but can you comment whether you see that this is realistic or whether there is say upside or downside to those numbers because you are paying 100% premium so I would assume that you see upside, not downside to those numbers or maybe you can just elaborate on it.

0.29.37

Deborah Dunsire

Okay, thanks for the questions, Michael. First on the differentiation. When we look at the delivery of this IV product, it achieves a very, very – first of all, that is a 100% bioavailable and one of the benefits of that is that you get speed and epti is unique in the fact that it achieves migraine prevention as early as day 1 following the infusion so that we get a great reduction in patients who will have a migraine the next day after dosing and that is across both trials and for people with chronic and frequent episodic migraine, that is enormously important. Additionally, that effect is sustained throughout the full 3 months and with subsequent doses even tends to improve. So as patients get more and more recovery time between migraines, the benefits get better and better. One of the issues with frequent episodic and chronic migraine is that they tend to worsen because one headache is layered on top of another and so breaking that cycle is absolutely critical. Additionally, since the product, the patients are seen roughly every quarter by their physicians, this can be easily administered at the time that they are normally seen and then you have got the therapy, the preventive therapy on board for a full quarter and so we do see the potential for compliance being very strong and that we certainly observed during the clinical trials so we see this fast, deep response that is sustained over time. This is the only product that is administered through the medical benefit in the US so that is a bit different in how it will be dealt with within the US market. We also know that the neurologists who are treating this condition have very easy access to IV capabilities and so we don't anticipate that being a barrier for uptake. There are also patients who indicate a lack of willingness to self-inject and there are some people who can manage it if it is done for them but are not well able to do that to themselves so there is all kinds of reasons that I think patients could have a preference for this agent.

0.32.47

Anders Götzsche

And to the consensus, Michael, you know, we are of course – we have made thorough market research and we definitely believe that the consensus numbers are not out of reach.

Michael Novod

Okay. Just a follow-up to the differentiation. Is there any risk that you see patients using this agent for immediate relief and then over time, do you risk to see a switching over to the Sub-Qs? Because I can understand that some patients prefer IV and of course, I see all the presentations and they have surveys for preference of IV but if you take all the Sub-Q companies, they have surveys showing preference for Sub-Q. So I don't really know how much you can count on that. So is there any risk that you will see this being used as an immediate relief and then over time, patients are switching? And then to the Medicare Part B, have you assumed in your forecast that this will be differently priced? I know there are different discounts in Medicare Part B compared to Part D but have you assumed that it will be differently priced because it is in the medical benefit scheme?

Deborah Dunsire

I think – dealing with your second question first, we are assuming a similar level of pricing and that is all I will say about that. With respect to will patients switch between drugs – you know, frequently in this category, there is back and forth and I think when a patient achieves relief with the administration of epti and that relief is sustained for 3 months, they don't have to make that change and particularly when at the second dose, the improvement actually increases, so will patients move back and forth? It certainly does happen in the market places but we think that this has a compelling profile. Johan, would you like to comment?

0.35.02

Johan Luthman

No, I think that is very correct so once you have a good response, the willingness to shift may go down but also obviously many of those patients come back at the regular intervals so they may fit very well with the 3-month dosing interval so that will be also the prescribing physician that basically will offer the same treatment if it has worked well. So that may also increase the compliance to this particular product because it is within a doctor setting where the administration happens.

0.35.35

Anders Götzsche

Yeah and then I think it's important to emphasise we are talking about patients that might have had severe migraine for more than 15-20 years so this is a disease where it has been pretty disabling for the quality of life so if you compare that to having 30 minutes infusion 4 times a year, then if you have relief, then it will be a game changer for these patients' lives and therefore, I don't think it's a big barrier getting this 30 minutes infusion if you get to the clinic and you get a Sub-Q by the physician, then you also need to be in the waiting room for these allergic reactions so in principle, the time of treatment, the difference is pretty limited. So yeah, that was just to add.

0.36.32

Michael Novod

Thank you. Congratulations with the acquisition.

Operator

Next question is from Rushee Jolly from Bernstein. Please go ahead, your line is now open.

0.36.43

Hi, Rushee Jolly, Bernstein. Two questions please. Firstly, does this reflect a bit of a shift towards biologics for yourselves and if you could provide a bit of colour on your manufacturing capabilities and given that launch isn't too far off an impact on COGS and my second question is really a follow-up from what Michael was saying on the speed of onset. Could you give me a sense of how you see the market evolving, whether people with such a fast onset product would be willing to take it for acute treatment if they have maybe one migraine a year and how you see the market splitting up between people who have taken prophylaxis or more acute treatment? Thank you.

0.37.23

Deborah Dunsire

Okay, so commenting on whether this is a shift to biologics. Lundbeck has been talking about for quite a number of years moving more of its pipeline to biologics to have a balanced approach between small molecules and biologics and so this fits with that strategy. This is, as you correctly point out, right in filing at the FDA now so the manufacturing is well advanced, it is all done through external manufacturer, there is

no, Alder does not own a factory of its own so the manufacturers are well known and well experienced. The COGS, as you point out, are certainly higher on a monoclonal, any monoclonal, than a small molecule and that we have taken into account. Any other comments from Anders or Johan?

0.38.29

Johan Luthman

Yeah, I would just like to add that obviously, we already have biologics programmes in our portfolio early stage so this is just a further step into that arena and I always say that we should go for the drug entities where the biology is strong and where the path of physiology link is established so this is a good example where we have a very strong biology and in this case, the monoclonal offers a lot of advantages, cell activity avoiding some of the liver tox issues that early programmes with small molecules had etc. so this is really a way to just build on what we are already doing in the pipeline.

0.39.09

Deborah Dunsire

And then your second question went to speed of onset and would people with say one migraine take this acutely. You know, the trials have been done in these more severe patients who are candidates for prevention so I don't think that would be the first place it would go. I think that for people who have very few migraines in a year, the standard acute therapy will still be used. But for people who are candidates for prevention, it makes all the sense in the world to give this to the person when they have the migraine and gain the benefit of the fact that they will already the next day not have as many migraines and for the next 3 months, they are experiencing the benefits of prevention.

0.40.09

Rushee Jolly

That's great, thank you very much.

Operator

And next question is from the line of Peter Sehested from Handelsbanken. Please go ahead, your line is now open.

Peter Sehested

Yeah, it's Peter from Handelsbanken, thank you for taking my questions. I have two. The first one relates to the clinical profile, just trying to understand it a bit better. Looking at the absolute, let's say the two figures, the end points of multi migraine days and the more than 50% responders. I mean the absolute numbers look impressive but let's say the placebo adjusted numbers appear slightly lower than what you see with the competing products. Just some flavour on that. And to the patent expiry, you said mid 30s, I believe that all the documents, 10K etc. say 2032 so I guess you are assuming some kind of patent term extension. Those were the questions. Thank you very much.

0.41.11

Deborah Dunsire

Okay, I will start the comment on the clinical profile and Johan can comment. The monthly migraine days, there is a very important reduction that was highly significant across doses, the 100 mg and the 300 mg doses in both PROMISE 1 and PROMISE 2. The 50% responder profile is very strong as well as the 75% and indeed the 100% responder and placebo adjustment is an interesting one given the effect that being managed by migraine specialists and being given intravenous therapy has on the placebo. So we know that that will increase the placebo response but when patients are treated, they get the full benefit versus their baseline. Johan, do you want to comment?

0.42.15

Johan Luthman

I would just like to add of course the ultimate is the effect the patients perceive and the combination here is of course a procedural and a strong drug effect so obviously with this kind of administration, we have as you can see comparing to other studies a higher placebo effect but that makes it also extremely harder to compare it between the studies. But overall, of course, it is a strong effect which of course the patient at the end probably doesn't care really what it is coming from but we of course don't have any direct comparison data.

0.42.53

Deborah Dunsire

With respect to the patent, we are considering in that mid 30s the total globe. So there is the US which obviously is the US patent and its extensions and then as we think about the EU and beyond where post- launch, we would have 10 years of data exclusivity.

0.42.24

Peter Sehested

Okay, so just to follow up on the response rate, so you are pretty confident that these absolute numbers will also pan out in real life clinical practice or let's say there might be some kind of inflation related to the clinical trial settings, its design implementation etc.?

0.43.44

Deborah Dunsire

Yeah I think Johan is probably best suited to comment on that.

Johan Luthman

Well, I mean as you know, phase III trials are trying to mimic real life as much as possible but there is continuously debate how close that is to real life and clinical practice but this is a pretty sort of established field, established caregivers, we have some experience with the old drugs, triptans etc. and obviously are gaining experience now with this novel very interesting class. So I think we are actually in some manner a little closer to reality here because it's such an established field, it's not that we are creating a completely new treatment, clinical network or anything like that so yeah, that's the best we can say at this stage. Obviously, we are going to have long-term follow-ups, we are going to have additional studies, we are going to gain more and more data including more on the patient perspective, patient insights data that we will gather over time so we can probably come back and really tell you how this phase III data translates properly to real clinical practice.

0.44.53

Deborah Dunsire

Then I would say that applies to all studies in every indication, particularly in neurology and psychiatry so every drug going through this is influenced by the expectation of benefit that patients have when they participate in a clinical trial and epti is certainly not unique in that regard.

0.45.17

Peter Sehested

Thank you very much.

Johan Luthman

I would just like to add that you know obviously we have very strong data here and we are talking about measures that are not so prone to patient variability. Of course, it is patients reporting, but it is a pretty

robust experience of the patient, it is not the usual psychometric scales that we have in some other indications so this is real life benefit that the patients are reporting.

Peter Sehested

Thank you

0.45.52

Operator

And there are currently no further questions registered so I will hand the call back to the speakers. Please go ahead.

Deborah Dunsire

Well, we are very excited today about the opportunity to bring in the Alder portfolio addressing and transforming migraine therapy and we are looking forward to being able to put the tender offer forward and close after regulatory review of that tender offer. So thank you for joining us today and we look forward to talking with you about this much more in the future.