425 1 f425_080421.htm 425

Filed by Acasti Pharma Inc.
Pursuant to Rule 425 under the Securities Act of 1933
and deemed filed pursuant to Rule 14a-6
under the Securities Exchange Act of 1934
Subject Company: Acasti Pharma Inc.
Commission File No.: 001-35776

CRESCENDO COMMUNICATIONS, LLC

To: Acasti and Grace Management

From Crescendo Communications

Subject: Acasti/Grace Acquisition Call

Date: August 4, 2021

I. Introduction – David Waldman

Thank you. Good afternoon everyone and welcome to this investor conference call to discuss Acasti's proposed acquisition of Grace Therapeutics. On the call with us from Acasti are Jan D'Alvise, president and CEO, Pierre Lemieux, chief operating officer, chief scientific officer and co-founder, and Brian Ford, chief financial officer. Also joining us from the Grace team are George Kottayil, co-founder and CEO and Prashant Kohli, vice president of commercial operations.

I'd also like to remind everyone that statements on this conference call that are not statements of historical or current fact constitute "forward-looking information" within the meaning of Canadian securities laws and "forward-looking statements" within the meaning of the U.S. Private Securities Litigation Reform Act of 1995, the Securities Act of 1933 and the Securities Exchange Act of 1934. Such forward-looking statements involve known and unknown risks, uncertainties, and other unknown factors that could cause the actual results of Acasti, Grace and the combined company to be materially different from historical results or from any future results expressed or implied by such forward-looking statements. In addition to statements which explicitly describe such risks and uncertainties, readers are urged to consider statements labeled with the terms "believes," "belief," "expects," "intends," "anticipates," "potential," "should," "may," "will," "plans," "continue," "targeted" or other similar expressions to be uncertain and forward- looking. Listeners are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date of this conference call. Forward-looking statements during this conference call may include, but are not limited to, the expected timetable for completing the proposed acquisition of Grace and benefits to Acasti of the proposed acquisition of Grace; future product development plans and projected timelines for the initiation and completion of preclinical and clinical trials; the potential for the results of ongoing preclinical or clinical trials and the efficacy of drug candidates; the potential market opportunities and value of drug candidates; other statements regarding future product development and regulatory strategies, including with respect to specific indications; the combined company's plans, objectives, and future opportunities; future financial performance and operating results; sufficiency of capital resources to fund operating requirements; and any other statements regarding Acasti's and Grace's future expectations, beliefs, plans, objectives, financial conditions, assumptions or future events or performance.

The forward-looking statements contained in this conference call are expressly qualified in their entirety by this cautionary statement, the "Cautionary Statements Regarding Forward-Looking Statements" in Acasti's registration statement on Form S-4 relating to the proposed merger (including the prospectus and proxy statement included therein), the "Cautionary Note Regarding Forward-Looking Information" section contained in Acasti's latest annual report on Form 10-K and most recent management's discussion and analysis, which are available on SEDAR at www.sedar.com, on EDGAR at www.sec.gov, and on the investor section of Acasti's website at www.acastipharma.com. All forward-looking statements in this conference call are made as of the date of this conference call. Acasti does not undertake to update any such forward-looking statements whether as a result of new information, future events or otherwise, except as required by law. The forward-looking statements contained herein are also subject generally to assumptions and risks and uncertainties that are described from time to time in Acasti's public securities filings with the Securities and Exchange Commission and the Canadian securities commissions, including Acasti's registration statement on Form S-4 relating to the proposed merger (including the prospectus and proxy statement included therein), its latest annual report on Form 10-K and most recent MD&A. In addition, any forward-looking statements represent Acasti's views as of today and should not be relied upon as representing our views of any subsequent date. While Acasti might update forward-looking statements at some point in the future, unless legally required under applicable securities laws, Acasti specifically disclaims any obligation to do so.

I'd now like to turn the call over to Jan D'Alvise – please go ahead, Jan.

II. Transaction Overview – Jan D'Alvise

Thank you, David and I'd like to welcome everyone on the call today to discuss what we believe is an exciting new direction for Acasti and our shareholders. On May 7th we announced the signing of a definitive agreement to acquire Grace Therapeutics, in an all-stock transaction. And now as we get closer to our annual shareholder meeting to be held on August 26th, we thought it would be helpful to review the key attributes of the transaction, and share what we see as the key benefits for our shareholders, and ultimately the patients who will benefit most from the medicines that we plan to develop. I will provide an overview of the Grace product pipeline on today's call, and I plan to highlight our near-term development plans and key milestones. Finally, we'll wrap up by answering the numerous questions that we have received from shareholders ahead of today's call.

So let me start by saying how excited we are about the planned acquisition, which both the Acasti and Grace teams believe will be truly transformative for the newly combined company and for our shareholders. We believe this transaction will create new and exciting opportunities for us in sizable markets, with substantial unmet medical needs. We believe that the successful development of Grace's pipeline drugs could provide new treatment options for patients who are suffering from rare diseases, and their physicians and families who support and care for them.

Grace is a rare and orphan disease specialty pharmaceutical company that has developed novel drug delivery technologies. Grace is applying these technologies to already approved and marketed pharmaceutical compounds with proven safety profiles and clinical efficacy, often for indications different from the ones Grace is pursuing.

Grace's technologies enable them to customize the formulation of these marketed drugs in new ways, that have the potential to address significant unmet medical needs by achieving faster onset of action, enhanced efficacy, reduced side effects, and more convenient drug delivery – all which can help to increase compliance and improve patient outcomes.

The proposed acquisition of Grace represents a unique opportunity for Acasti and our shareholders to build a new, late-stage specialty pharma company focused on rare diseases, by combining Acasti's drug development, manufacturing, and commercialization expertise, along with our strong balance sheet, with Grace's chemistry expertise, drug delivery technologies, and their deep clinical and preclinical product pipeline. Based on the valuations set in the merger agreement, Acasti's shareholders will own on a proforma basis not less than 55% but expected to be as high as 58% of the common shares, and Grace's stockholders will own between 42 - 45% of the common shares, in each case calculated on a fully-diluted basis, and after cash and working capital adjustments are made at closing.

Following the merger, and based on management's current forecasts, we expect to have more than $60 million in cash on our balance sheet at closing, which should provide at least two years of operating runway. This cash should enable us to achieve meaningful value catalysts, including the completion of the clinical development and filing of a New Drug Application, or NDA, for Grace's lead clinical asset GTX-104, as well as advancing other drug candidates in the pipeline to additional key, value-enhancing milestones.

The first three products in Grace's clinical pipeline have already received Orphan Drug Designation from the FDA, and if approved, will give us access to addressable markets in the U.S. that are currently valued at more than $2 billion. The market opportunities in Europe and Asia are also attractive, with significant additional revenue potential. We expect to address these international markets through future marketing and distribution partnerships, that we plan to put in place as our drugs complete clinical trials and get closer to market approval.

Rare diseases represent an attractive area for drug development, as getting an Orphan Drug Designation from the FDA provides seven years of marketing exclusivity post-launch in the U.S., provided that the appropriate conditions are met at approval. In our case, exclusivity could potentially be extended well beyond those seven years based on Grace's large and growing patent portfolio, which we expect will provide exclusivity beyond 2036. In addition to extended market exclusivity, a focus on developing orphan drugs can bring other benefits. They typically require smaller, shorter and less expensive clinical trials to obtain regulatory approval, and usually a much smaller, more targeted commercial infrastructure is required to address these markets. Orphan drug indications also typically benefit from a more favorable pricing and reimbursement environment. This is a way for the government to attract investment in rare disease conditions where there are limited or no currently approved therapies.

In the case of the first three products in Grace's pipeline, each chemical entity is currently approved for different indications from what Grace is pursuing, with the exception of GTX-104, which will provide a different and potentially improved delivery method for nimodipine, a drug commonly used to treat patients with subarachnoid hemorrhage – I'll tell you more about that in a minute. These marketed drugs all have safety profiles that are well known and well understood. In each case, the Grace team has leveraged their chemistry and drug delivery expertise to reformulate these compounds in novel ways that we believe could enhance efficacy and/or safety. This approach could give us the ability to use the Section 505(b)(2) regulatory pathway under the Federal, Food, Drug and Cosmetic Act for clinical development and approval, which states that if sufficient support of a product's safety and efficacy already exists, either through previous FDA experience or sufficiently within the scientific literature, some of the preclinical and clinical studies that might otherwise be required of an NCE drug candidate, could be waived. Consequently, this regulatory pathway is commonly utilized when repurposing existing compounds, and the resulting less complex development programs can significantly reduce time to market, as well as cost and risk. These accelerated programs for the first three drug candidates in Grace's pipeline create the opportunity for near-term milestones that we believe can be achieved over the next 6 to 12 months. I plan to highlight those key milestones as I briefly describe each of Grace's three most advanced clinical programs, and our current development plans and timelines:

So, with that introduction, I'll start by telling you more about GTX-104, which is an intravenous or IV formulation of nimodipine, designed to treat subarachnoid hemorrhage or "SAH". SAH is a condition that causes acute bleeding in the brain due to a ruptured aneurysm. It is estimated to affect about 50,000 patients each year in the United States alone. SAH typically requires immediate surgery, and on average, about two weeks in a neuro-intensive care unit to try to prevent death and reduce the risk of long-term disability. Consequently, SAH is very expensive to treat, and third-party market research study conducted for Grace estimated that the average inpatient hospital cost is about $250,000. Nimodipine is currently available in the U.S., only in an oral dosage form. Many of these patients are unconscious or have a hard time swallowing during their hospital stay, so GTX-104 as an IV infusion, could be a much more convenient and efficient way to deliver nimodipine, and importantly, it could potentially provide physicians with a more effective tool for hypotension management.

GTX-104 was previously evaluated by Grace in a randomized safety and dose-ranging study in over 80 healthy subjects designed to assess the pharmacokinetics, bioavailability, and safety of GTX-104 administered via an IV infusion as compared to oral nimodipine. The results of this study were highly encouraging, as no serious adverse events were reported, and the incidence of non-serious adverse events was much lower for GTX-104 as compared to nimodipine delivered orally.

These positive results support the next step in clinical development, which is now to conduct a small PK Bridging Study in about 60 patients. We expect to start this study this fall, shortly after our proposed acquisition of Grace closes, and we expect to report results in the second quarter of 2022. The goal of this study is to achieve blood levels with our GTX-104 IV nimodipine formulation, that are comparable to the oral form of the drug that is in routine use today. Positive results would likely advance us directly into a Phase 3 clinical safety trial for SAH, in about 100 patients. Provided we see a similar safety profile to oral nimodipine upon completion of the Phase 3 study, we could then expect to proceed with filing an NDA using the Orphan Drug Designation and the 505(b)(2) pathway.

We believe that GTX-104 could represent an important advancement in the care of patients with SAH, as approximately 70% of them either die, or require dependent care for the rest of their lives. Of this 70%, about half die within one month of experiencing the brain hemorrhage. While physicians have been using oral nimodipine for decades, it comes with serious dose-limiting side effects such as hypotension and poor absorption. In fact, only about 13% of nimodipine is actually absorbed when delivered orally. Additionally, oral nimodipine must be dosed frequently, approximately every 4 hours.

Grace's IV formulation of nimodipine allows for continuous therapy, and therefore gives physicians the ability to tightly control the administration to achieve better blood pressure control. This advantage is important, as GTX-104 could help to reduce the incidence of vasospasm, which requires immediate, aggressive and costly intervention, and can lead to worse outcomes for the patient. The IV formulation of GTX-104 also eliminates the difficulties experienced by the nursing staff in having to deliver oral nimodipine via a nasogastric tube to an unconscious patient who can't swallow, and it may also reduce drug-drug interactions that are occasionally seen with oral nimodipine.

With a total estimated addressable market of approximately $300 million in the U.S. alone, following FDA approval we believe we can bring GTX-104 to market very quickly, with a relatively small and focused sales force, as our target customers will be the roughly 400 major stroke centers in the U.S. This strategy simplifies and reduces our commercialization costs and could shorten the revenue ramp with our first marketed drug. Opportunistically, we also plan to evaluate licensing partnerships for both the U.S. and major ex-U.S. markets.

The second drug in Grace's clinical pipeline is GTX-102, which is an oral-mucosal betamethasone spray for the treatment of ataxia telangiectasia, also known as "A-T". A-T is a complex, genetic neurodegenerative orphan disorder usually diagnosed in young children. Children with A-T begin to experience balance and coordination problems as toddlers, they become wheelchair-bound, and then often develop compromised immune systems as they get older, putting them at an increased risk of respiratory infections and cancers, including lymphomas, leukemia, and brain cancer.

Unfortunately, no FDA-approved treatment exists today for A-T, and these patients typically die in their 20s from complications of lung disease or cancer.

Looking ahead, GTX-102 would follow a clinical development plan that is very similar to GTX-104, as we expect to utilize the 505(b)(2) NDA pathway for regulatory approval. Based on input that Grace has already received from the FDA, the next step in our development plan would be to conduct a pharmacokinetic bridging study, comparing blood levels of GTX-102 with oral betamethasone. Assuming this trial is successful, we would then move forward quickly to conduct a confirmatory Phase 3 safety and efficacy trial in patients with A-T.

This expedited development path for GTX-102 is important, because while current treatment options help to alleviate symptoms in some of these patients, they only seem to do so for a short period of time. Previous trials of oral betamethasone conducted in Italy have shown the potential to provide significant clinical benefit by decreasing the symptoms of A-T with minimal adverse events.

Based on these data, we believe that a decrease in symptoms is possible with GTX-102, and could lead to fewer complications, which may in turn prolong these patients' lives, and at the same time improve their quality of life.

So, our hope, and the goal of this program, is to show that GTX-102 could potentially provide a better solution for this devastating condition that currently has no known cure or treatment to help slow disease progression, and improve the lives of these children and their families.

A-T is estimated to affect about 4,300 patients per year in the U.S. alone, representing an estimated addressable market of approximately $150 million. About half of the patients who have been diagnosed with A-T in the U.S., are currently being treated at Johns Hopkins Medical Center, which is the world's leading center of excellence for A-T. Grace has been collaborating with the clinical thought leaders at Johns Hopkins for several years, and they have indicated a strong interest in participating in our clinical efficacy and safety trial. Again, assuming a successful clinical program outcome, we believe we can rapidly penetrate the A-T market with a small, targeted sales force, and a focused patient support and advocacy strategy.

Finally, the third clinical stage product in the Grace pipeline is GTX-101, a topical, bio-adhesive, film-forming bupivacaine spray for postherpetic neuralgia, or PHN. PHN is caused by the varicella zoster virus – this is the same virus that causes chickenpox. This virus can reactivate decades after the initial infection to cause what is commonly known as shingles. GTX-101 is intended to be administered to patients after the blisters or rash associated with shingles have healed, to treat the severe and often difficult to manage neuralgia, or nerve pain, that is often associated with the disease. This nerve pain can become quite debilitating, and it may persist for many months or even years. The multiple issues associated with chronic pain are well documented in terms of quality of life and emotional well-being. In fact, PHN is the number one cause of intractable, debilitating pain in the elderly, and has been identified as a leading cause of suicide in chronic pain patients over the age of 70.

Current treatments for PHN include lidocaine patches that can be difficult to apply to the skin and remain in place, and the onset of action can take up to a week or more post-application. Oral gabapentin is an anti-epileptic, anti-convulsant that is also frequently used to treat PHN, but it can cause uncomfortable side-effects such as dizziness, sleepiness and water retention. Both these treatments are often found to be unsatisfactory because of the poor management of pain. Consequently, to get adequate pain relief, patients often progress to the use of stronger pain medications such as opioids, which come with a significant risk of psychological and physical addiction.

We believe GTX-101 could solve these significant problems. It will be packaged in a convenient spray bottle, and when applied, it forms a thin, bioadhesive film of bupivacaine on the patient's skin. Phase 1 single dose clinical studies that have already been completed by Grace, have shown that GTX-101 may provide potentially faster onset of action, sustained pain relief for up to 8-hours with possibly lower dosing, and increased convenience when compared to the lidocaine patch. Importantly, patients using GTX-101 will not develop physical dependence, and therefore it could be opioid sparing, providing a key advantage to patients and the healthcare system. We are highly encouraged by these data, and we are currently planning additional pre-clinical and clinical dose-ranging studies in 2022 as an important next step towards regulatory approval.

PHN affects about 150,000 patients per year in the United States, representing a total addressable market of approximately $400 million for PHN pain alone. In addition to helping patients suffering from PHN, the opportunity in the broader pain market is significant. Grace's market research indicates that there could also be an opportunity to tap into the larger U.S. market for non-PHN pain, which is currently estimated at $1.2 billion. So, you can see why we are so excited about GTX-101, and we plan to do everything possible to accelerate its development.

While I have focused my comments today on Grace's three leading clinical assets, it's important to mention that the transaction would also provide Acasti with a large pipeline of additional preclinical drug candidates based on Grace's novel drug delivery and formulation technologies. Post-merger, we plan to more fully assess the market potential and the clinical, regulatory and manufacturing plans required to develop, and commercialize each of these assets. We then plan to prioritize them for future clinical development to maximize value for our shareholders. I look forward to sharing more about Grace's impressive pipeline and our development plans in the months to come.

A key aspect of drug commercialization is manufacturing and scale-up. Grace has already done a great job of establishing a network of third-party contract manufacturers, or CMOs, who are making the active pharmaceutical ingredients as well as the finished drug products for clinical use. Outsourcing to separate CMOs was a very smart strategy on Grace's part, as it helps to mitigate the risk of a single manufacturing location for all products. Based on the extensive diligence conducted by Acasti to date, we also believe that the manufacturing processes for GTX-104, 102 and 101 are all well advanced, and have relatively low risk remaining as we begin to plan the scale up for larger clinical trials, and if successful, eventually commercial launch and global commercialization.

I should also mention that Grace has done an excellent job protecting their intellectual property and know-how. Grace's extensive patent estate includes more than 40 granted and pending patents around the world, including four issued U.S. patents and seven additional filed U.S. patent applications. These patents include both composition of matter and method-of-use claims, which we believe will provide long-term protection, and extend exclusivity beyond the 7 years that is granted through the FDA's orphan drug designation. In fact, many of these patents and patent applications will have terms that extend well beyond 2036, with planned additional patents still to be filed.

The acquisition of Grace would not only bring an exciting pipeline to Acasti, but we would also be getting a highly skilled management team and staff with skills in many cases, that are complementary to our own. As I've mentioned, Grace brings significant experience in drug formulation and drug delivery research, and they will be additive to the strong team that we have assembled over the last 10 years at Acasti. Grace's team has collectively been involved in the clinical development, approval and commercial launch of several successfully marketed drugs at other companies, and we believe their skills will synergize well with Acasti's expertise in running large-scale clinical trials, commercial-scale manufacturing and product commercialization, as well as with the depth of our experience in finance, corporate and business development.

Finally, many of you have been asking about the status of CaPre and our plans for our Phase 3 asset. Despite not meeting the primary endpoint in our TRILOGY 1 and TRILOGY 2 trials, and as we have disclosed, the triglyceride reduction seen for CaPre was one of the highest seen among previously conducted hypertriglyceridemia studies, particularly in the large subset of patients on statins. Consequently, we have received strong interest, and continue to evaluate a variety of strategic options for CaPre. While we can't provide additional details at this time, CaPre remains an important focus of management and our Board, and we promise to provide additional information as soon as practical.

In closing, I would like to emphasize again how enthusiastic we are about this proposed acquisition of Grace, and the bright future it can create for Acasti. We therefore strongly encourage all of our shareholders to vote in favor of the transaction at our upcoming shareholder meeting on August 26th. You should already have received the proxy materials electronically, by mail or through your broker to vote your shares. Please take the time to follow the link provided in the proxy materials at investorvote.com, and enter your control number, or you can send it back by mail. It will only take you a couple minutes, but it is so important that all of our shareholders vote, so that we can secure the required quorum for shareholder approval for the transaction. If you have any questions, please contact our investor relations team at Crescendo at 212-671-1021, or you can call our proxy solicitors at D.F. King & Co, and their toll-free number is (800) 884-4725.

Finally, I would like to thank all of our shareholders for your patience and support during this lengthy, but productive transition process. We remain as encouraged as ever about the outlook for our company, and we believe the Grace transaction has the potential to create significant value for all of our shareholders in the future.

That concludes our prepared remarks, and I'll now turn the call over to David Waldman for Q&A.

IV. Q&A

DAVID WALDMAN:

Thank you, Jan.

The company received many questions from investors for today's call, and we thank you all for your interest, feedback and continued support as shareholders. Many of these questions were repetitive and so on today's call we will be addressing the most frequently asked questions. If you have any questions after the call or would like any additional information about Acasti, please contact Crescendo Communications at 212-671-1021.

Additionally, the company has received multiple questions seeking information about things that have not been disclosed by the company or that are forward-looking, as well as several questions regarding share price fluctuations and the trading activities of the company's shares. As a matter of policy and regulatory compliance, the company does not offer interim operational or financial updates, forward-looking guidance or capital markets strategies, nor does Acasti comment on the performance of the company's shares in the market.

With that, the first set of questions come from Leland Gershell, the biopharma analyst from Oppenheimer.

First, in terms of GTX-104:

1) **DAVID: What is the nanoparticle shell composed of?**

JAN: The nano-micelle is comprised primarily of the non-ionic surfactant Polysorbate 80, which is an excipient that is commonly used to stabilize aqueous formulations of medications for parenteral administration.

2) **DAVID: In what animal were the PK data shown derived?**

JAN: The PK data were derived using a Rat model

3) **DAVID: How many subjects do you expect to be needed for the Ph 3 safety study?**

JAN: Based on preliminary discussions with the FDA to date, we believe about 100 patients will be adequate for this study, but that will of course, need to be confirmed by the FDA once we have our final protocol drafted.

4) **DAVID: With respect to current nimodipine use, to what extent could GTX-104 expand the scope of this pharmacotherapy in SAH?**

JAN: This is a great question and again is another reason why we are so excited about the potential for GTX-104. We believe that GTX-104 could really benefit a majority of patients with SAH who are unconscious when admitted to the hospital, and consequently are not able to swallow a large capsule. Additionally, we believe that nimodipine blood levels achieved with an IV infusion are expected to be more consistent when compared to oral nimodipine. This could give physicians the ability to more tightly control the administration of nimodipine to achieve better blood pressure control. This advantage is important, as GTX-104 could help to reduce the incidence of vasospasm, which requires immediate, aggressive and costly intervention, and can also lead to worse outcomes for the patient.

5) **DAVID: Where would you expect to price GTX-104 in the US?**

JAN: The generic oral nimodipine is currently priced at around $500/day. And we know that in general, IV products are typically priced higher than oral products, and so we expect the price of GTX-104 could probably be set at a modest premium over the liquid nimodipine currently on the market. Ultimately the pricing will depend on the results of our clinical studies and the perceived benefits of the IV over the oral.

6) **DAVID: Would pharmacoeconomic studies be needed to support market access, or would the advantages to current Standard of Care stand on their own?**

JAN: We are actually planning to include some important pharmacoeconomic endpoints in our Phase 3 safety study so that we can begin to quantify the cost/benefit impact of GTX-104 IV therapy over the oral nimodipine standard of care. So, depending on the outcome, we may decide to conduct a larger follow-on pharmacoeconomic study post-approval, but that decision will be made once we see our Phase 3 results.

7) **DAVID: Do you have an outlook on what would be needed for EU approval?**

JAN: Yes, we believe that a small clinical study in SAH patients would be required, but this will need to be confirmed with the EMA, the European regulatory agency.

The next set of questions from Mr. Gershell involve GTX-102:

1) **DAVID: Are steroids currently used to manage A-T, and if so, to what extent? Is there support for this approach apart from the Zannolli data?**

JAN: Yes, steroids are currently being utilized in some cases to help manage these A-T patients. In fact, several investigators have utilized oral betamethasone in Europe, and their experience, which has been promising, has been reported in the published literature.

2) **DAVID: With no therapies approved by FDA, this indication may be new regulatory ground. What endpoints, and how long a treatment duration, would expect to be needed for the Phase 3? Would ICARS be a putative primary endpoint?**

JAN: We expect that the treatment duration will be about 6 months, and yes, based on discussions to date with the FDA, we expect that the standard ICARS scoring system would be the primary endpoint.

The next set of questions revolve around GTX-101:

1) **DAVID: Given cheap generic anesthetic patches, how will you position this product in the marketplace?**

JAN: We hope to demonstrate superior clinical outcomes both in terms of faster onset of action and longer lasting analgesic effects over the standard of care. In addition, the ease of use of the GTX-101 spray and the better aesthetic appeal over the patch could be strong market differentiators. As I stated earlier, PHN pain can be very debilitating, especially in seniors who are disproportionately affected by it. We believe GTX-101 has the potential to transform PHN treatment and become the new standard of care.

2) **DAVID: What is your expected market exclusivity?**

JAN: As I mentioned earlier, we expect to see 7 years of market exclusivity based on our orphan designation for GTX-101, and then we have patents that should extend our exclusivity beyond 2036.

DAVID WALDMAN: Thank you Leland for your questions. Now I will turn to the questions that were submitted by shareholders ahead of today's meeting. The first question goes to Jan – what was the process that you went through to select Grace?

JAN D'ALVISE: Thank you for that question, and it gets at some of the key reasons we made the decision to acquire Grace. With the tremendous support of our bankers at Oppenheimer, Acasti pursued a thorough strategic process to evaluate a wide range of value-creating alternatives. Through this rigorous process, more than 100 companies were screened by Oppenheimer, and we conducted diligence on more than 20 companies in total. We ultimately selected Grace, primarily based on the strength of their technology platforms and IP, the market opportunity and the potential for expedited clinical development and commercialization of their first 3 assets, as well as their scientific talent, which as I mentioned earlier are highly synergistic with Acasti's expertise. This positions us well to build a portfolio of innovative therapeutics that we believe will address significant unmet medical needs in these targeted orphan indications.

DAVID WALDMAN: When does Acasti expect to commence Phase 3 Trials for Grace's products?

JAN D'ALVISE: We expect to begin Phase 3 enrollment for GTX-104, Grace's IV formulation of nimodipine, in the second half of next year, and in first half of 2023 for GTX-102, which again is an oral spray form of betamethasone for treating children with A-T. Importantly, we expect to complete additional near-term milestones in the form of smaller but very important, pivotal pharmacokinetic studies for GTX-104 in the first half of 2022, and in the second half of next year for GTX-102.

DAVID WALDMAN: Upon approval, what is the go-to-market strategy? Would you be looking to partner or what kind of sales organization would you need to put in place?

JAN D'ALVISE: As GTX-104 and GTX-102 complete their clinical development programs, our current plan is to build a small and focused commercial organization in the U.S. to market and sell these drugs upon FDA approval. We believe the treatment centers and medical specialists who manage these patients are fairly concentrated geographically. This allows us to cost-effectively promote these products with a small commercial team following approval. In contrast, for GTX-101 we will be targeting a larger primary care and pain specialist market, so we will likely seek commercial partnerships in the U.S. and other major countries to fully exploit the market potential of this drug.

DAVID WALDMAN: When do you expect to close the merger?

JAN D'ALVISE: We previously announced that the special shareholder meeting to approve the transaction will occur on August 26th. The proposed transaction is expected to close very shortly after we receive approval from Acasti shareholders, subject to any stock exchange approvals, as well as satisfaction of other closing conditions as specified in the definitive merger agreement. These conditions should be met within a few business days of the shareholder meeting, assuming we are able to reach a quorum, and a positive vote in favor of the transaction. Again, I'd like to take this opportunity to say how extremely important it is that our shareholders vote **FOR** this transaction, and we thank you in advance for your participation and support.

DAVID WALDMAN: Will Grace shareholders be locked up after the merger?

JAN D'ALVISE: Yes – they will be locked up for 12 months, subject to certain customary exceptions. Again, I would refer shareholders to the prospectus and proxy statement related to the merger for further details on this.

DAVID WALDMAN: How much of the combined companies will Acasti shareholders own after the merger?

JAN D'ALVISE: I will turn this question over to Brian Ford, our chief financial officer. Brian?

BRIAN FORD: Thank you Jan. With regard to the shareholder composition after the merger is complete, Acasti's security holders, on a pro forma basis after the transaction, would own not less than 55%, but expected to be as high as 58% of the company's common shares, and Grace's security holders would own between 42% and 45% of the company's common shares, subject to upward adjustments in favor of Acasti based on each company's capitalization and net cash balance, as set forth in the definitive merger agreement, with more details available in the prospectus and proxy statement related to the merger.

DAVID WALDMAN: How was the exchange ratio for Grace stockholders determined?

BRIAN FORD: David, I'll take this one as well. The equity exchange ratio is calculated using a formula intended to allocate Grace's existing stockholders an ownership percentage of Acasti post-closing, and as adjusted based on changes to cash and capitalization for each entity at the time of the merger, with more details available in the prospectus and proxy statement relating to the merger. As previously mentioned, Acasti's shareholders, on a pro forma basis, would own at least 55%, but expected to be as high as 58% of the company's common shares, and Grace's securityholders would own 42% to 45% of the company's common shares. The final exchange ratio at closing will vary a little depending on net cash and capitalization for each company at the effective date of the transaction.

DAVID WALDMAN: Can you say more about how the valuation of Grace and the combined company was determined?

JAN D'ALVISE: David – I'll take this one. I'd like to first direct shareholders to the section of the prospectus and proxy statement that describes the merger transaction, and emphasize the depth and breadth of analysis that was conducted by the Company as part of our diligence process, as well as by Oppenheimer to support their Fairness Opinion. Acasti management conducted deep dive diligence activities that focused on the development programs and IP for Grace's first three products, as well as the market potential for these products, including conducting in-depth interviews with leading physician thought leaders to validate the market opportunity, and the unmet medical needs that could be addressed by Grace's products. Oppenheimer utilized management's product and market diligence and supplemented it with an analysis of other publicly traded specialty pharma companies. They also looked at a range of recent specialty pharma transactions, as well as a discounted cash flow analysis to conclude in each case, that the value being ascribed to Grace in this transaction, and the percentage of the resulting company that will be held by Acasti shareholders, are well supported by these different analytical approaches that were considered by Oppenheimer in delivering its fairness opinion, and by our board in approving the transaction. Therefore, we believe that this proposed acquisition represents an attractive deal for our shareholders, and that with a successfully completed transaction, both companies will be worth more together than as a sum of their parts, since there are great synergies between the two companies that will bring the potential for significant value creation going forward.

DAVID WALDMAN: Great – thanks for that explanation. I have a question now related to the Proxy. What is the rationale behind the proposed amendments to the equity incentive plans?

BRIAN FORD: I can take this question. The equity incentive plan proposals are standard proposals that are typically put forward to shareholders on an annual basis and are not directly related to the Grace transaction. The central element of the proposals relating to our equity incentive plans is that their size will now be limited to 10% of our issued and outstanding shares from time to time. Keep in mind that in the past several years, our pool was limited to a fixed 15% of our issued and outstanding shares at the time of approval by shareholders, so this proposal will bring our plan in line with what is generally considered to be the market standard approach for equity incentive plans. I should also mention that our plans are subject to other insider participation and ancillary limits to comply with applicable securities law and stock exchange requirements.

DAVID WALDMAN: How does Acasti plan to deploy the $60 million of cash on hand across the various programs?

JAN D'ALVISE: Thanks David – I'll take this one. At this time, it is difficult to precisely estimate the costs and time required to develop these products. Factors that could affect both the eventual cost and timing of these programs include the final design of the clinical study programs and protocols as finally authorized by the FDA, the pace at which we are able to enroll patients, the time it takes to complete the clinical trials, the timing of marketing approvals, and the timing of the various activities that will be required to scale up manufacturing. That being said, we currently project that our cash on hand will provide **at least** two years of operating runway and enable us to complete development and file an NDA for GTX-104. It will also enable us to significantly advance clinical development of GTX-102 and GTX-101, and advance other drug candidates to key milestones.

DAVID WALDMAN: Does Acasti plan to raise additional capital?

JAN D'ALVISE: Given that we expect to have at least two years of capital at closing, we currently have no plans for a material capital raise, but as always, we will continue to be opportunistic if market conditions and the potential to create shareholder value warrant.

DAVID WALDMAN: Grace shows $13 million of liabilities; will Acasti be responsible for paying off all of that Grace debt?

BRIAN FORD: No – and let me clarify how this will work. A majority of these liabilities, roughly $10 million are in the form of convertible debt and will be converted into Grace shares prior to the share exchange, and are already accounted for in the share exchange ratio. Other components of the Grace debt will also be converted into shares of Grace prior to the transaction. Note that for any cash deficiency or accounts payable that remain and are assumed by Acasti, there will be an adjustment in favor of current Acasti shareholders to reduce the shares issued to Grace stockholders to account for the liabilities assumed in an equitable manner.

DAVID WALDMAN: What is the status of discussions with Nasdaq to maintain Acasti's listing? Will there be a reverse split? If so, when, and what is the expected share ratio?

BRIAN FORD: I know that there has been some confusion on this topic, so I am happy to try to clarify the situation. Acasti has been in close contact with Nasdaq to ensure that the steps to regain compliance with its minimum bid price requirements are being appropriately taken. We intend to effect a reverse split **only if it is required** to regain compliance with the $1 minimum bid rule, and then we would effect it in connection with the closing of the transaction following the August 26th shareholder meeting. Again, it would only be done if it is absolutely necessary to regain compliance with the minimum bid price rule in connection with the transaction, and, if so, the share consolidation would likely be within a 1 to 6 to 1 to 8 range.

DAVID WALDMAN: Thank you Brian, that is very helpful. Jan, this question comes back to you. What is the company's position regarding these shareholder lawsuits that have been filed regarding the transaction?

JAN D'ALVISE: We strongly believe that the allegations in these complaints are frivolous and without merit, and we plan to vigorously defend against them. The complaints generally allege that our public disclosures pertaining to the transaction, omit material facts purportedly in violation of applicable securities laws, which frankly we believe is clearly not the case if anyone takes the time to read through our very extensive and comprehensive disclosures.

Unfortunately, these types of frivolous lawsuits are common in the U.S. and are expected with any merger or acquisition transaction. As stated earlier, we believe that our transaction with Grace represents a very good deal for our shareholders, and again we plan to vigorously defend against these claims. For additional information on these complaints, we refer you to our public disclosures on this topic, and we will continue to keep our shareholders informed as practical.

DAVID WALDMAN: What are the company's plans for CaPre and are you considering conducting additional trials for the compound?

JAN D'ALVISE: No, and as we have stated previously, we do not plan to proceed with an NDA filing, nor do we plan to conduct any additional clinical trials for CaPre. However, as I mentioned earlier, we have received strong interest and continue to evaluate several strategic options for our CaPre assets, and we will keep the market apprised as this process progresses.

DAVID WALDMAN: Jan, here are some general questions that we received. First, what are the benefits of gaining orphan drug status?

JAN D'ALVISE: I appreciate this question, as it was one of many key factors in our decision to acquire Grace. There are many benefits for a drug candidate that has received orphan drug designation from the FDA. As I mentioned earlier, the first is 7 years of marketing exclusivity once the product has received NDA approval. We could also receive a significant federal tax credit for up to 50% of the expenses incurred in conducting clinical research within the United States. Another nice benefit is that the FDA grants a waiver of their Prescription Drug User Fee Act or PDUFA fee for orphan drugs – for which the average cost in 2020 was approximately $3 million – so this could be a significant cost savings to us in the future. Finally, as an incentive to encourage pharma companies to make investments in treatments and cures for rare diseases, a drug that has been granted orphan status can often be priced significantly higher than more widely prescribed drugs. Data shows that orphan drugs are approximately 25x more expensive than non-orphan drugs, and the average annual orphan drug cost rose from about $7,000 in 1997 to more than $185,000 in 2017. Today, 88% of orphan drugs cost more than $10,000 per year / per patient, and in 2017, 7 out of the 10 best-selling drugs were for orphan indications.

DAVID WALDMAN: One last question here, can you clarify what is the 505(b)(2) development pathway?

JAN D'ALVISE: Sure…the Section 505(b)(2) regulatory pathway under the Federal Food, Drug and Cosmetic Act can provide for a lower cost, lower risk, and potentially faster path to regulatory approval than the more common 505(b)(1) or new chemical entity (NCE) pathway. Under Section 505(b)(2), if sufficient support of a product's safety and efficacy exists either through previous FDA experience or if it can be sufficiently established within the scientific literature, the FDA may eliminate the need to conduct some of the preclinical and clinical studies that NCE candidates might otherwise require.

DAVID WALDMAN: Thank you Jan and Brian. This concludes the Q&A portion of our call and I return it to Jan D'Alvise for closing remarks.

V. Concluding Remarks – Jan D'Alvise

Thank you, David. Once again, I would like to thank everyone for joining us on the call today, and I would especially like to thank our shareholders for your support and patience through this transition period. We truly believe this acquisition of Grace can be transformative for Acasti, and we could not be more excited. We remain highly encouraged by the outlook for our overall business prospects, and we look forward to providing further updates to shareholders on our strategic processes as it relates to both the Grace acquisition as well as our plans for CaPre. Should you desire further information, we encourage you to visit our website and review the documents posted there, including the FAQ document and our filings with securities regulators.

And finally, when you receive your proxy materials, please take the time to vote your shares, as it is extremely important that we get the necessary votes to meet our quorum requirement and get the deal approved. It will only take you a couple minutes to go online and vote or send back your votes by mail.

That concludes our call today. Thank you very much for listening in, and we look forward to providing further updates as soon as possible.

Additional Information and Where to Find It

In connection with the Merger, Acasti filed with the SEC a registration statement on Form S-4 on June 30, 2021 (as amended on July 13, 2021) that includes the preliminary Prospectus/Proxy Statement. On July 15, 2021, the registration statement was declared effective by the SEC and Acasti filed the final Prospectus/Proxy Statement in connection with the Merger with the SEC, which contains important information about the Merger and related matters. The Prospectus/Proxy Statement will be mailed to Acasti shareholders and is accessible on Acasti's EDGAR and SEDAR profiles. INVESTORS AND SECURITY HOLDERS OF ACASTI ARE URGED TO CAREFULLY READ THE ENTIRE PROSPECTUS/PROXY STATEMENT (INCLUDING ANY AMENDMENTS OR SUPPLEMENTS TO SUCH DOCUMENTS) BEFORE MAKING ANY VOTING DECISION WITH RESPECT TO THE MERGER BECAUSE IT CONTAINS IMPORTANT INFORMATION ABOUT THE MERGER AND THE PARTIES TO THE MERGER.

Acasti shareholders can obtain a free copy of the Prospectus/Proxy Statement, as well as other relevant filings containing information about Acasti and the Merger, including materials incorporated by reference into the Prospectus/Proxy Statement, without charge at the SEC's website (www.sec.gov) or from Acasti by contacting Acasti's Secretary at 3009 boul. de la Concorde East, Suite 102 Laval, Québec, Canada H7E 2B5, telephone: (450) 686-4555.

No Offer or Solicitation

This document is not intended to and shall not constitute an offer to buy or sell or the solicitation of an offer to buy or sell any securities, or a solicitation of any vote or approval, nor shall there be any sale of securities in any jurisdiction in which such offer, solicitation or sale would be unlawful prior to registration or qualification under the securities laws of any such jurisdiction. No offering of securities shall be made, except by means of a prospectus meeting the requirements of Section 10 of the U.S. Securities Act of 1933, as amended.

Participants in the Solicitation

Acasti and Grace and certain of their respective directors, executive officers and employees may be deemed to be participants in the solicitation of Acasti proxies in respect of the Merger. Information regarding the persons who may, under SEC rules, be deemed participants in the solicitation of proxies to Acasti shareholders in connection with the Merger is set forth in the Prospectus/Proxy Statement. Copies of the Prospectus/Proxy Statement may be obtained free of charge from the SEC or Acasti, as described in the preceding paragraph.

Cautionary Statement Regarding Forward-Looking Statements

This document contains "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995, as amended, Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, and may be forward-looking information as defined under applicable Canadian securities legislation (collectively, "forward-looking statements"). These statements may discuss goals, intentions and expectations as to future plans, trends, events, results of operations or financial condition, or otherwise, based on current beliefs of the management of Acasti, as well as assumptions made by, and information currently available to, management. Forward-looking statements generally include statements that are predictive in nature and depend upon or refer to future events or conditions, and include words such as "may," "will," "should," "would," "expect," "estimate," "plan," "believe," "anticipate," "intend," "look forward," and other similar expressions among others. Statements that are not historical facts are forward-looking statements. Forward-looking statements are based on current beliefs and assumptions that are subject to risks and uncertainties and are not guarantees of future performance.

Forward-looking statements contained in this document may include, without limitation, statements regarding the proposed merger between Acasti and Grace; the timing and financial and strategic benefits thereof; the expected impact of the transaction on the cash balance of Acasti following the merger; Acasti's future strategy, plans and expectations after the merger; and the anticipated timing of clinical trials and approvals for, and the commercial potential of, Acasti's products and pipeline product candidates and those of its subsidiaries (including Grace, if the merger is completed). Actual results could differ materially from those contained in any forward-looking statement as a result of various factors, including the failure to receive, on a timely basis or otherwise, the required approvals by Acasti shareholders or Grace stockholders, as applicable, in connection with the merger; the risk that a condition to closing of the merger may not be satisfied; the possibility that the anticipated benefits of the proposed merger may not be fully realized or may take longer to realize than expected; the possibility that costs or difficulties related to the integration of the businesses of Acasti and Grace will be greater than expected; the ability of the companies following the merger to commercialize drug candidates in line with the companies' expectations; the ability to retain and hire key personnel and maintain relationships with customers, key opinion leaders, suppliers or other business partners; the impact of legislative, regulatory, competitive and technological changes; and other risk factors relating to the companies' businesses and the biopharmaceutical industry, as detailed from time to time in Acasti's reports filed with the SEC and the Canadian Securities Administrators, which you are encouraged to review. Investors should not place undue reliance on forward-looking statements.

For a discussion of the factors that may cause Acasti's, Grace's or the combined company's actual results, performance or achievements to differ materially from any future results, performance or achievements expressed or implied in such forward-looking statements, and for a discussion of risks associated with the ability of Acasti and Grace to complete the merger and the effect of the merger on the business of Acasti, Grace and the combined company, see the section titled "Risk Factors" in the Prospectus / Proxy Statement.

The forward-looking statements reflect management's current knowledge, assumptions, beliefs, estimates and expectations and express management's current view of future performance, results and trends. If any of these risks or uncertainties materializes or any of these assumptions proves incorrect, the results of Acasti, Grace or the combined company could differ materially from the forward-looking statements. All forward-looking statements in this document are current only as of the date on which the statements were made, or in the case of a document incorporated by reference, as of the date of that document. Except as required by applicable law, neither Acasti nor Grace undertakes any obligation to update publicly any forward-looking statements for any reason after the date of this document or to conform these statements to actual results or to changes in expectations.