Acerus and Aytu Bioscience to Co-promote Natesto® in the United States

Acerus Pharmaceuticals to launch U.S. specialty sales force of at least 25 representatives
Combined effort expected to optimize resources and execution to accelerate sales
Investor conference call Tuesday, July 30, 2019 at 4:30 PM ET

TORONTO--(BUSINESS WIRE)-- Acerus Pharmaceuticals Corporation (TSX:ASP, OTCQB:ASPCF) today announced that it will be taking an expanded role in the commercialization of NATESTO® in the U.S. The company has entered into an amended and restated licensing agreement with Aytu BioScience, Inc. (NASDAQ: AYTU), which will, upon closing, move the partnership from an out-license model to a co-promotion arrangement that the companies believe will leverage their collective product, marketplace and Men's Health experience to capture a significant share of the U.S. market for NATESTO®.

Under the terms of the new agreement, Aytu returns the NDA for NATESTO® in the U.S. back to Acerus. Going forward Acerus will assume all regulatory and clinical responsibilities and costs for the product in the U.S. Acerus will take on a more expansive role in matters such as U.S. marketing, reimbursement and medical strategy as part of the companies' joint commercialization committee, and will launch a specialist sales force focused on urologists and endocrinologists (Acerus Sales Channel). Aytu will retain its primary care sales force (Aytu Sales Channel) and will continue to book all product net revenue while serving as the exclusive U.S. supplier of NATESTO® to wholesalers, pharmacies and other customers that receive a direct shipment. Financial payments will be based upon a tiered level of net revenue, post cost of goods sold (COGS), based on annual sales performance in the respective Acerus and Aytu Sales Channels.

"Based on the year-over-year growth we have seen in NATESTO® sales in Canada, we believe that the performance of NATESTO® in the U.S. will benefit from Acerus employing a similar specialist-driven model focused in urology and endocrinology," said Ed Gudaitis, President and Chief Executive Officer of Acerus. "There continues to be a need for an effective testosterone replacement therapy that does not have the same transference and safety concerns associated with topical products. With its unique nasal gel formulation and delivery method, NATESTO® is ideally suited to meet this need and the revised partnership with Aytu gives us the scale and reach needed to increase awareness and adoption among physicians and patients."

To establish a high performing commercial footprint in the U.S., Acerus has engaged Syneos Health (NASDAQ: SYNH), a leading integrated biopharmaceutical solutions organization including the industry's largest Contract Commercial Organization (CCO), to be its commercialization partner. Syneos Health has extensive experience in Men's Health and with NATESTO®, and offers an end-to-end model that will enable Acerus to rapidly stand up a U.S. commercial team; to scale across all aspects of commercialization, including medical and regulatory affairs, managed markets, marketing and sales; and will provide greater flexibility and effectiveness in resource deployment.

Low testosterone is estimated to affect approximately 39% of men over 45 years old in the U.S.; however, because the condition is underdiagnosed the overall prevalence is uncertain[1]. While patients have access to other treatment options, NATESTO® is unique in that it is administered in seconds via a convenient and simple nasal gel applicator, addressing the risk of testosterone transference associated with other topical products, which carry "black box" warnings on their product labels.

NATESTO® remains fully available and accessible to patients in the U.S.

Financial Terms of Amended and Restated Agreement

As part of the amended and restated partnership agreement, Acerus did not pay Aytu to regain the marketing authorization for NATESTO® in the U.S. The royalty structure currently in place will be replaced with a pay-for-performance incentive structure intended to drive NATESTO® revenue growth in both Sales Channels. The revised agreement extends the partnership to the later of 2027, the launch of an FDA approved, AB-rated generic equivalent to NATESTO®, or the expiration or invalidation of the last to expire NATESTO® patent.

Aytu will now pay Acerus a variable rate commission for sales made in the Acerus Channel as per the following schedule:

- Up to the current status quo of NATESTO® net sales ($0 – 5.5M), Acerus will receive a commission equivalent to 25% of net revenue generated;
- For the next $4.5M in net revenue ($5.5M – 10M), Acerus will receive a commission equivalent to 50% of

net revenue generated; and
- Above $10M in net revenue, Acerus receives a commission equivalent to the combination of 90% of urologists and endocrinologists related net revenues and 10% of Aytu's sales channel net revenue generated.

By investing into the commercialization effort behind NATESTO® in the U.S. and continuing to work in partnership with Aytu BioScience, Acerus should realize increased financial value as growth in prescription volume and net revenue is accelerated. While Acerus will receive a higher blended percentage of net revenue as it grows to $10M to offset its increase in commercial investment, in the long run both companies will benefit as improved sales will drive an increase in net revenue that will be split more equally.

Closing is conditioned upon Acerus raising capital, whether by way of equity or debt, of at least USD $10 million on or before January 29, 2020.

Conference Call on Tuesday, July 30 @ 4:30 PM Eastern Time

To access the call live, please dial the toll-free number 1-866-215-0058 (Canada/US) or International/Local dial-in number 416-204-1547. Listeners are encouraged to dial in 10 minutes before the call begins to avoid delays.

A replay of the conference call will be available until 11:59 PM ET on Tuesday, August 6, 2019 by dialing the toll-free number 1-800-408-3053 (Canada/US), or International/Local dial-in number 905-694-9451, using access code: 7881826#.

The Investor Slide Deck that will be shared during the call will be available for download on the Acerus website (www.aceruspharma.com) as of Tuesday July 30 @ 9:00 AM ET.

About NATESTO® (Testosterone) Nasal Gel

NATESTO® is a nasal gel formulation of testosterone developed by Acerus Pharmaceutical Corporation and indicated as a replacement therapy for men diagnosed with conditions associated with a deficiency or absence of endogenous testosterone (hypogonadism). It is the first and only nasally-administered testosterone product approved by the U.S. Food and Drug Administration, Health Canada and South Korea Ministry of Food and Drug Safety (MFDS), available in a 'no-touch' dispenser with a metered dose pump. A copy of the NATESTO® Canadian product monograph can be found at: http://www.aceruspharma.com/English/products-and-pipeline/NATESTO®/default.aspx. For further information, specific to the U.S. product dosing and administration, please visit: www.NATESTO.com.

About Acerus

Acerus Pharmaceuticals Corporation is a Canadian-based specialty pharmaceutical company focused on the commercialization and development of innovative prescription products that improve patient experience, with a primary focus in the field of men's health. The Company commercializes its products via its own salesforce in Canada, and through a global network of licensed distributors in the U.S. and other territories.

Acerus' shares trade on TSX under the symbol ASP and on OTCQB under the symbol ASPCF. For more information, visit www.aceruspharma.com and follow us on Twitter and LinkedIn.

Notice Regarding Forward-Looking Statements
Information in this press release that is not current or historical factual information may constitute forward looking information within the meaning of securities laws. Implicit in this information are assumptions regarding our future operational results. These assumptions, although considered reasonable by the company at the time of preparation, may prove to be incorrect. Readers are cautioned that actual performance of the company is subject to a number of risks and uncertainties, including with respect to the commercial performance of NATESTO® in the United States, and could differ materially from what is currently expected as set out above. For more exhaustive information on these risks and uncertainties you should refer to our annual information form dated March 4, 2019 which is available at www.sedar.com. Forward-looking information contained in this press release is based on our current estimates, expectations and projections, which we believe are reasonable as of the current date. You should not place undue importance on forward-looking information and should not rely upon this information as of any other date. While we may elect to, we are under no obligation and do not undertake to update this information at any particular time, whether as a result of new information, future events or otherwise, except as required by applicable securities law.

No Offer

This press release is not intended to and does not constitute an offer of securities for sale in the United States or

any other jurisdiction.

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[1] Mulligan T, Frick MF, et al. Prevalence of hypogonadism in males aged at least 45 years: the HIM study. Int J Clin Pract. 2006 Jul 1; 60(7): 762–769

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