Investor Relations - SWK Holdings

## Acerus Reports First Quarter 2019 Financial Results

TORONTO--(BUSINESS WIRE)-- Acerus Pharmaceuticals Corporation (“Acerus” or the “Company”) (TSX:ASP; OTCQB:ASPCF) today reported its financial results for the three-month period ended March 31, 2019 (“Q1-2019). Unless otherwise noted, all amounts are in US dollars and are prepared in accordance with International Financial Reporting Standards (“IFRS”).

Q1-2019 Highlights

- Total revenues in Q1-2019 of $2.2 million, an increase of $0.5 million or 33% compared to the first quarter of 2018 (“Q1-2018”).
- Natesto® revenue growth to $1.4 million representing increased sales traction in both Canadian and U.S. markets.
- Filing of New Drug Submission (“NDS”) for avanafilwith Health Canada.
- C$4.5 million private placement in quarter to strengthen balance sheet.

“We continue to see positive growth in the Natesto® business as we and our US partner, Aytu Bioscience, expand our programs to reach more US and Canadian physicians and patients”, said Ed Gudaitis, President and Chief Executive Officer of Acerus. “At the same time, we look forward to being able to leverage our existing Men’s Health sales force in Canada to effectively launch avanafil once it is approved by Health Canada.”

Summary of Results for the Three Months Ended March 31, 2019 (compared to the Three Months Ended March 31, 2018 unless otherwise noted)

Total Q1-2019 revenue was $2.2 million compared with $1.6 million of revenue in Q1-2018. Revenue comprised the following products:

- A $0.7 million increase in Natesto® revenue to $1.4 million reflecting both increased Canadian and US Natesto® revenues as well as a one-time top-up of Tier 2 revenue on Natesto® units held in inventory by our US partner Aytu Bioscience;
- A $0.3 million decline in Estrace® revenue to $0.6 million reflecting the impact of the anticipated shortage and the resulting allocation of product to preserve availability (see Estrace® update below); and
- Urivarx revenues in Q1-2019 of $0.2 million compared with less than $0.1 million in Q1-2018 reflecting the fact that Urivarx was first introduced in Q1-2018.

Q1-2019 gross margin was $1.5 million compared with negative $1.8 million in Q1-2018. The prior year quarter reflecting a $2.4 million royalty buyout charge for the nasal gel dispenser technology. When comparing direct cost of sales, the prior year quarter’s gross margin was $0.6 million. The improved gross margin reflects the Tier 2 revenue on Natesto US shipments as non-inventory revenue has no cost of sales associated with such product.

Research and development ("R&D") expenses increased by $0.6 million to $1.0 million for the current quarter compared to Q1-2018 reflecting a $0.3 million accrual for the filing fee to Health Canada for the avanafil New Drug Submission and increased clinical trial costs for Natesto®, principally in the US.

Selling, general and administrative expenses (“SG&A”) increased by $2.5 million to $4.2 million in the first quarter of 2019. This increase in expenses is principally due to a non-cash impairment charge of $2.5 million on the value of the Estrace® intangible asset. This charge reflects management’s estimate of the impact of the potential shortage of Estrace® on the carrying value of the underlying asset (see additional discussion below).

Q1-2019 Earnings before interest, tax, depreciation and amortization (“EBITDA”)[1] was a loss of $3.3 million compared to a loss of $3.8 million for the prior year quarter. Adjusted EBITDA[1], was a loss of $0.8 million for the quarter compared to a loss of $1.0 million for the prior year period.

The Company incurred a net loss of $4.4 million or $(0.02) per share for the quarter compared to a loss of $4.5 million or $(0.02) per share for the first quarter of 2018.

Cash as of March 31, 2019 was $5.0 million compared with $3.8 million on December 31, 2018, reflecting a C$4.5 million private placement that closed in March of 2019.

ESTRACE ® UPDATE

On January 11, 2019, the Company announced that it had reported an anticipated shortage of certain dosages of Estrace® on the Drug Shortages Canada website in relation to supply issues arising from the GMP compliance issues at the Company’s contract manufacturer. The Company had met with the contract manufacturer as well as health authorities in Canada and the UK regarding the anticipated restart of Estrace® production.

At that time, the manufacturer expected to be in a position to deliver Estrace® to Acerus by September 2019. As a result of the possible shortage and the potential impact on the future revenue stream of Estrace®, the Company recorded a $2.6 million non-cash impairment charge against the carrying value of the Estrace® intangible asset in Q4 of 2018.

The manufacturer has now revised their anticipated next delivery date to the end of 2019. In addition, the Company was advised by Health Canada that the contract manufacturer should be removed from the Company’s Drug Establishment License, requiring a resubmission for ultimate approval. Accordingly, it does not appear that the Company will receive a shipment of Estrace® until mid-2020. As a result, the Company recorded a further $2.5 million non-cash impairment charge in Q1 of 2019.

The Company is currently looking at various strategies to accelerate delivery timelines, one of which includes contracting with an alternative manufacturer. A potential manufacturer has been identified and the Company is working towards a final agreement.

Conference Call

Shareholders are reminded that the conference call to discuss the Company’s results for the three months ended March 31, 2019 will be held on Monday, May 13, 2019 at 8:30 a.m. Eastern Time. To access the call live, please dial 647-484-0475 or 1-888-882-4478. 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 p.m. Eastern Time on Tuesday, May 21, 2019 by dialing 905-694-9451 or 1-800-408-3053, using access code: 7327615#.

About Acerus

Acerus Pharmaceuticals Corporation is a Canadian-based specialty pharmaceutical company focused on the commercialization and development of innovative, branded products, with a primary focus in the fields of urology (men’s health) and andrology. 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.

[1] Non-IFRS Financial Measures - EBITDA and Adjusted EBITDA

The non-IFRS measures included in this press release are not recognized measures under IFRS and do not have a standardized meaning prescribed by IFRS and may not be comparable to similar measures presented by other issuers. When used, these measures are defined in such terms as to allow the reconciliation to the closest IFRS measure. These measures are provided as additional information to complement those IFRS measures by providing further understanding of our results of operations from our perspective. Accordingly, they should not be considered in isolation nor as a substitute for analysis of our financial information reported under IFRS. Despite the importance of these measures to management in goal setting and performance measurement, we stress that these are non-IFRS measures that may have limits in their usefulness to investors.

We use non-IFRS measures, such as EBITDA and Adjusted EBITDA to provide investors with a supplemental measure of our operating performance and thus highlight trends in our core business that may not otherwise be apparent when relying solely on IFRS financial measures. We also believe that securities analysts, investors and other interested parties frequently use non-IFRS measures in the valuation of issuers. We also use non-IFRS measures in order to facilitate operating performance comparisons from period to period, prepare annual operating budgets, and to assess our ability to meet our future debt service, capital expenditure and working capital requirements.

The definition and reconciliation of EBITDA and Adjusted EBITDA used and presented by the Company to the most directly comparable IFRS measures follows below:

EBITDA is defined as net (loss)/income adjusted for income tax, depreciation of property and equipment, amortization of intangible assets, interest on long-term debt and other financing costs, interest income, licensing revenue and changes in fair values of derivative financial instruments. Management uses EBITDA to assess the Company's operating performance.

Adjusted EBITDA is defined as EBITDA adjusted for, as applicable, royalty expenses associated with triggering events, milestones, share based compensation, impairment of intangible asset, foreign exchange (gain)/loss and gain on extinguishment of payables. We use Adjusted EBITDA as a key metric in assessing our business performance when we compare results to budgets, forecasts and prior years. Management believes Adjusted EBITDA is an alternative measure of cash flow generation than, for example, cash flow from operations, particularly because it removes cash flow fluctuations caused by extraordinary changes in working capital. A reconciliation of net (loss)/income to EBITDA (and Adjusted EBITDA) is set out below.

| | For the three months ended | |
|---|---|---|
| | March 31, | |
| | 2019 | 2018 |
| Net (loss) | $ (4,431) | $ (4,454) |
| Adjustments: | | |
| Amortization of intangible assets | 289 | 425 |
| Depreciation of property and equipment | 64 | 65 |
| Depreciation of right of use asset | 12 | - |
| Interest on long-term debt and other financing costs | 647 | 191 |
| Interest income | (1) | (5) |
| Change in fair value of derivative | 132 | (39) |
| EBITDA | $ (3,288) | $ (3,817) |
| | | |
| Royalty expense/Buyout | - | 2,414 |
| Share based compensation | 80 | 141 |
| Foreign exchange loss/(gain) | (90) | 235 |
| Impairment loss on intangible asset | 2,471 | - |
| Adjusted EBITDA | $ (827) | $ (1,027) |

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 ability of Acerus to obtain regulatory approval for Avanafil, Lidbree™, Elegant™ and Gynoflor™, to continue to successfully commercialize Natesto®, UriVarx® and Estrace®, and to be successful in its early stage R&D initiatives (including its cannabinoid initiative), 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 ("AIF") 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.

Acerus Pharmaceuticals Corporation
Condensed Interim Consolidated Statement of Financial Position
As at March 31, 2019 and December 31, 2018
Unaudited
(expressed in thousands of U.S. dollars)

| | March 31, 2019 | December 31, 2018 |
|---|---|---|
| ASSETS | | |
| Current assets | | |

| | | |
|---|---|---|
| Cash | $ 4,991 | $ 3,829 |
| Trade and other receivables | 1,097 | 1,113 |
| Contract asset | 694 | - |
| Inventory | 2,296 | 2,506 |
| Prepaid and other assets | 248 | 176 |
| Total current assets | 9,326 | 7,624 |
| Property and equipment, net | 1,219 | 1,267 |
| Right of use asset | 291 | - |
| Intangible assets, net | 5,397 | 7,933 |
| Total assets | $ 16,233 | $ 16,824 |
| LIABILITIES AND SHAREHOLDERS' EQUITY (DEFICIT) | | |
| Current liabilities | | |
| Accounts payable and accrued liabilities | $ 7,926 | $ 5,619 |
| Current portion of deferred lease inducement | - | 46 |
| Current portion of lease liability | 83 | - |
| Total current liabilities | 8,009 | 5,665 |
| Accrued liabilities | - | 2,462 |
| Deferred lease inducement | - | 254 |
| Lease liability | 570 | - |
| Long-term debt | 8,369 | 8,287 |
| Derivative financial instruments | 364 | 227 |
| Total liabilities | 17,312 | 16,895 |
| Shareholders' equity (deficit) | | |
| Share capital | $ 158,083 | $ 154,737 |
| Warrants | 1,420 | 1,420 |
| Contributed surplus | 11,580 | 11,500 |
| Accumulated other comprehensive loss | (13,795) | (13,851) |
| Deficit | (158,367) | (153,877) |
| Total shareholders' equity (deficit) | (1,079) | (71) |
| Total liabilities & shareholders' equity (deficit) | $ 16,233 | $ 16,824 |

Acerus Pharmaceuticals Corporation
Condensed Interim Consolidated Statement of Loss and Comprehensive Loss
For the three months ended March 31, 2019 and 2018
Unaudited
(expressed in thousands of U.S. dollars, except per share and share data)

| | March 31, 2019 | March 31, 2018 |
|---|---|---|
| Revenue | | |
| Product revenue | $ 2,165 | $ 1,624 |
| | 2,165 | 1,624 |
| Cost of goods sold | 632 | 1,027 |
| Royalty buyout | - | 2,414 |
| Gross margin | 1,533 | (1,817) |
| Expenses | | |
| Research and development | 1,038 | 472 |
| Selling, general and administrative | 4,238 | 1,783 |
| Total operating expenses | 5,276 | 2,255 |
| Operating loss | (3,743) | (4,072) |
| Other expenses/(income) | | |
| Interest on long-term debt and other financing costs | 647 | 191 |
| Interest income | (1) | (5) |
| Foreign exchange (gain)/loss | (90) | 235 |
| Change in fair value of derivative financial instruments | 132 | (39) |
| Total other expenses | 688 | 382 |
| Net loss for the period | $ (4,431) | $ (4,454) |
| Other comprehensive income, net of income tax | | |
| Foreign currency translation adjustment | 56 | 90 |
| Total comprehensive loss for the period | $ (4,375) | $ (4,364) |
| Loss per common share | | |
| Basic and diluted net loss per common share | $ (0.02) | $ (0.02) |
| Weighted average common shares outstanding | | |
| Basic | 235,900,501 | 213,125,705 |

| | | |
|---|---|---|
| Diluted | 235,900,501 | 213,125,705 |

Acerus Pharmaceuticals Corporation
Condensed Interim Consolidated Statement of Cash Flows
For the three months ended March 31, 2019 and 2018
Unaudited
(expressed in thousands of U.S. dollars)

| | March 31, 2019 | March 31, 2018 |
|---|---|---|
| Operating activities: | | |
| Net loss for the period | $ (4,431) | $ (4,454) |
| Items not affecting cash: | | |
| Adjustment for unrealized foreign exchange (loss)/gain | (134) | 214 |
| Amortization of intangible assets | 289 | 425 |
| Depreciation of property and equipment | 64 | 65 |
| Depreciation of right of use asset | 12 | - |
| Amortization of deferred leasehold inducement | - | (12) |
| Interest on long-term debt and other financing costs | 647 | 191 |
| Change in fair value of derivative financial instruments | 132 | (39) |
| Share based compensation | 80 | 141 |
| Impairment on intangible asset | 2,471 | - |
| Net changes in non-cash working capital items related to operating activities: | | |
| Trade and other receivables | 40 | 263 |
| Contract asset | (694) | - |
| Inventory | 229 | (25) |
| Prepaids and other assets | (67) | 81 |
| Accounts payable and accrued liabilities | (436) | 2,582 |
| Licensing fee receivable | - | 300 |
| Net cash used in operating activities | (1,798) | (268) |
| | | |
| Financing activities | | |
| Interest and financing fees paid | (336) | (148) |
| Proceeds from issuance of common shares, net of financing costs | 3,346 | - |
| Proceeds from exercise of stock options | - | 6 |
| Principal elements of lease payments | (20) | - |
| Net cash from/(used in) financing activities | 2,990 | (142) |
| | | |
| Investing activities | | |
| Acquisition of property and equipment, net of deposits | (4) | (53) |
| Acquisition of product rights | (100) | (79) |
| | | |
| Net cash used in investing activities | (104) | (132) |
| | | |
| Net increase/(decrease) in cash for the period | 1,088 | (542) |
| Exchange gain/(loss) on cash | 74 | (66) |
| Cash, beginning of period | 3,829 | 3,156 |
| Cash, end of period | $ 4,991 | $ 2,548 |

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