Investor Relations - SWK Holdings

Acerus Reports Second Quarter and Year to Date Fiscal 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 and six-month period ended June 30, 2019. Unless otherwise noted, all amounts are in US dollars and are prepared in accordance with International Financial Reporting Standards (“IFRS”).

Second Quarter Highlights

- Continued growth of NATESTO® in the Canadian market
- avanafil in active review by Health Canada
- Strengthened balance sheet with US$5 million subordinated secured loan facility in July
- Announced amended and restated NATESTO® licensing agreement with Aytu BioScience to co-promote NATESTO® in the USA

“Our strategy to focus our business on a men’s health portfolio and build the global brand for NATESTO® is now starting to bear fruit”, said Ed Gudaitis, President and Chief Executive Officer of Acerus. “Our Canadian NATESTO® business continues to show positive revenue growth, we are pleased to see the progress being made by our partner in South Korea and we are pleased with the ongoing positive developments in the regulatory process in the European Union. Subsequent to quarter end, we announced the implementation of a voluntary recall of several lots of NATESTO® restricted to both the Canadian and South Korean markets. While there is no safety risk to patients, we did identify instances where the dispenser could clog - potentially causing a lower than expected dosing of the product. At Acerus we are committed to patient safety and product quality. We will always do the right thing and we are committed to replacing the affected product as quickly as possible. Finally, last week we also announced our amended and restated agreement with Aytu BioScience, which, when implemented, should allow for much deeper brand awareness and sales channel penetration in the US market resulting in accelerated sales growth for both companies.”

Summary of Results for the Three Months Ended June 30, 2019 (compared to the Three Months Ended June 30, 2018 unless otherwise noted)

- Total revenue in the quarter was $1.3 million compared to $2.1 million in the second quarter of 2018. This decline is due to the combination of a $0.7 million decline in product revenue and a decline of $0.1 million in licensing and other revenue.
- Product revenue declined $0.7 million to $1.3 million from $2.0 million in the second quarter of 2018 reflected the following changes in product revenue (in US$’000s):

	Q2 2019	Q2 2018	Difference $
NATESTO®			
USA	124	396	(272)
Canada	350	307	43
Rest of World	278	-	278
Total NATESTO®	752	703	49
Estrace®	320	1,019	(699)
UriVarx™	184	230	(46)
Total Q2	1,256	1,952	(696)

  - While the NATESTO® Canadian business reflected healthy quarter over quarter growth from Q2 of 2018, the US declined reflecting a combination of the change in accounting policy regarding revenue recognition on US based revenue announced in the first quarter of 2019 and a shipment of inventory to the US partner in Q2 2018 that was not repeated in Q2 2019.
  - The decline in ESTRACE ® revenue reflects the conservation measures management has implemented due to the previously announced manufacturing license suspension at our contract manufacturer. The Company is working to transition ESTRACE ® production to a new contract manufacturer with the expectation that new shipments and the associated return in revenues to more normalized revenues should begin by the second quarter of 2020.
  - The second quarter of 2019 also reflects the last quarter of revenue related to Urivarx™ as the Company and the manufacturer mutually agreed to terminate the distribution and license agreement for this product for the Canadian market.

- Gross margin increased by $3.1 million to negative $0.1 million from negative $3.2 million in the prior year quarter. The prior year period gross margin included a $4.3 million charge for a buyout of the Mattern royalty obligation related to the nasal gel dispensing technology. The current period also reflects a $0.8 million charge related to a product recall (see below). Absent these two adjustments gross margins in both periods would be at 52% and 51% for the 2019 and 2018 period respectively.
- On August 2, 2019, we announced that we will voluntarily replace certain NATESTO® lots released in the Canadian and South Korean markets, which is expected to cause temporary shortages in those markets. We have identified four commercial lots of NATESTO® released in the Canadian and South Korean markets that were found to be non-conforming during long-term stability studies, even though such lots were fully in-specification at the time of release. This post-release non-conformity is not harmful to the patient, but may result in difficulties in dispensing. The temporary shortage of the product in the Canadian and South Korean markets is expected to continue until the end of October 2019. Acerus has noted this shortage on the Drug Shortages Canada website and will continue to dialogue with Health Canada to identify solutions to try to minimize the disruption to patients in the affected markets. Due to this issue, included in gross margin is a $0.1 million charge to revenue discounts likely required to compensate customers, $0.3 million impairment of inventory and $0.4 million related to replacing product.
- Research and development ("R&D") expense was $0.6 million for the current quarter similar to the prior year period.
- Selling, general and administrative expenses (“SG&A”) remained stable at $2.2 million over the prior year period. The current quarter does reflect a one-time severance cost accrual of $0.4 million that is offset by lower selling, marketing, general and administrative expenses.
- Earnings before interest, tax, depreciation and amortization (“EBITDA”)[1] was a loss of $2.6 million compared to an EBITDA loss of $5.6 million for the prior year quarter (the prior year EBITDA reflecting the royalty accrual discussed previously. Adjusted EBITDA[1], was a loss of $1.8 million for the quarter compared to a loss of $1.3 million for the prior year period.
- The Company incurred a net loss of $3.2 million or $(0.01) per share for the quarter compared to a loss of $6.4 million or $(0.03) per share for the second quarter of 2018.
- Cash as of June 30, 2019 was $1.2 million compared with $3.8 million on December 31, 2018, reflecting the proceeds of a CDN$4.5 million private placement in Q1 of 2019 offset by cash used in operations. Subsequent to quarter end, the company entered into a subordinated debt facility for US$5.0 million provided by First Generation Capital Inc. a company affiliated with the Chairman of the Board of Directors of the Company.

Summary of Results for the Six Months Ended June 30, 2019 (compared to the Six Months Ended June 30, 2018 unless otherwise noted)

- Total revenue for the six months ended June 30, 2019 and 2018 were $3.4 million and $3.7 million, respectively reflecting a slight decline in product revenue of $0.2 million and a decline in licensing and other revenue of $0.1 million.
- Period-over-period product sales decline of $0.2 million is primarily due to a $1.0 million decrease in ESTRACE® sales, offset by a $0.1 million increase in sales of UriVarx® and a $0.7 million increase in NATESTO® sales.
- Gross margin was $1.5 million compared to a negative gross margin of $5.0 million in the prior year period. 2018's negative gross margin reflects the $6.7 million Mattern Pharma AG royalty buyout accrual recorded in the first and second quarter of 2018. Gross margin in the current period includes the following charges related to the NATESTO® recall described above: a $0.1 million charge to revenue discounts likely required to compensate customers, $0.3 million impairment of inventory million and $0.4 million related to replacing product.
- Research and development ("R&D") expenses were $1.7 million in the first half of 2019, an increase of $0.6 million from the $1.1 million from the prior year period and reflect increased clinical trial costs as well as the Health Canada filing fee for avanafil recorded in the first quarter of 2019.
- Selling, general and administrative expenses ("SG&A") were $6.5 million in the first half of 2019, an increase of $2.5 million from the $4.0 million reported in first half of 2018. This increase is principally due to the $2.5 million non-cash impairment charge for the carrying value of the ESTRACE® intangible asset reflected in the first quarter of 2019.
- EBITDA[1] loss for the six months ended June 30, 2019 was $5.9 million compared with an EBITDA loss of $9.4 million for the prior year period reflecting the adjustments noted above. Adjusted EBITDA[1] for the six months ended June 30, 2019 was a loss of $2.6 million compared to loss of $2.4 million for the prior year period.
- The Company incurred a net loss for the six months ended June 30, 2019 of $7.7 million or $(0.03) per share compared to $10.9 million or $(0.05) for the same prior year periods.

NATESTO® USA UPDATE

On July 30, 2019, the Company and Aytu Bioscience jointly announced that they had signed an amended and restated license agreement to allow Acerus to enter the US market directly and co-promote NATESTO®to the specialist (urology and endocrinology) market. 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. Aytu will retain its primary care sales force 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. This transaction is conditional on Acerus raising at least US$10 million in any combination of debt or equity by no later than January 29, 2020. For more details, please refer to the press release entitled "ACERUS AND AYTU BIOSCIENCE TO CO-PROMOTE NATESTO® IN THE UNITED STATES" issued by Acerus on July 30, 2019 and Acerus' Material Change Report dated August 2, 2019 and available at www.sedar.com.

Conference Call
Shareholders are reminded that the conference call to discuss the Company's results for the three- and six-month period ending June 30, 2019 will be held on Wednesday, August 7, 2019 at 8:30 a.m. Eastern Time. To access the call live, please dial 416-204-1547 or 1-866-215-0058. 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 Wednesday, August 14, 2019 by dialing 905-694-9451 or 1-800-408-3053, using access code: 2038837#.

About Acerus
Acerus Pharmaceuticals Corporation is a Canadian-based specialty pharmaceutical company focused on the development, manufacture, marketing and distribution of innovative, branded products that improve patient experience, with a primary focus in the field of men's and women'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 the 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 the impact of charges related to a product recall. 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 June 30,		For the six months ended June 30,	
	2019	2018	2019	2018
Net (loss)	$ (3,203)	$ (6,410)	$ (7,634)	$ (10,864)
Adjustments:				
Amortization of intangible assets	176	428	465	853
Depreciation of property and equipment	63	64	127	129
Depreciation of right of use asset	11	-	23	-
Interest on long-term debt and other financing costs*	519	367	1,166	558
Interest income	-	(4)	(1)	(9)
Change in fair value of derivative	(171)	(51)	(39)	(90)
EBITDA	$ (2,605)	$ (5,606)	$ (5,893)	$ (9,423)
Licensing and other revenue	-	(150)	-	(150)
Royalty expense/Buyout	-	4,266	-	6,680
Share based compensation	26	85	106	226
Foreign exchange loss/(gain)	(95)	70	(185)	305
Charges related to product recall	792	-	792	-
Impairment loss on intangible asset	65	-	2,536	-
Adjusted EBITDA	$ (1,817)	$ (1,335)	$ (2,644)	$ (2,362)

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™, and Elegant™, to continue to successfully commercialize NATESTO® 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 June 30, 2019 and December 31, 2018
Unaudited
(expressed in thousands of U.S. dollars)

	June 30, 2019	December 31, 2018
ASSETS		
Current assets		
Cash	$ 1,231	$ 3,829
Trade and other receivables	863	1,113
Contract asset	601	-
Inventory	1,596	2,506
Prepaid and other assets	727	176
Total current assets	5,018	7,624
Property and equipment, net	1,167	1,267
Right of use asset	285	-
Intangible assets, net	5,224	7,933
Total assets	$ 11,694	$ 16,824
LIABILITIES AND SHAREHOLDERS' EQUITY (DEFICIT)		
Current liabilities		
Accounts payable and accrued liabilities	$ 6,687	$ 5,619
Current portion of deferred lease inducement	-	46
Current portion of lease liability	90	-
Total current liabilities	6,777	5,665
Accrued liabilities	-	2,462
Deferred lease inducement	-	254
Lease liability	557	-
Long-term debt	8,427	8,287
Derivative financial instruments	197	227
Total liabilities	15,958	16,895
Shareholders' (deficit)		
Share capital	$ 158,402	$ 154,737
Warrants	1,420	1,420
	11,291	11,500

Contributed surplus		
Accumulated other comprehensive loss	(13,807)	(13,851)
Deficit	(161,570)	(153,877)
Total shareholders'(deficit)	(4,264)	(71)
Total liabilities & shareholders' (deficit)	$ 11,694	$ 16,824

Acerus Pharmaceuticals Corporation
Condensed Interim Consolidated Statement of Loss and Comprehensive Loss
For the three and six months ended June 30, 2019 and 2018
Unaudited
(expressed in thousands of U.S. dollars, except per share and share data)

	For the three months ended, June 30,		For the six months ended, June 30,	
	2019	2018	2019	2018
Revenue				
Product revenue	$ 1,256	$ 1,952	$ 3,421	$ 3,576
Licensing and other revenue	-	150	-	150
	1,256	2,102	3,421	3,726
Cost of goods sold	1,339	1,029	1,971	2,056
Royalty buyout	-	4,266	-	6,680
Gross margin	(83)	(3,193)	1,450	(5,010)
Expenses				
Research and development	647	604	1,685	1,076
Selling, general and administrative	2,220	2,231	6,458	4,014
Total operating expenses	2,867	2,835	8,143	5,090
Operating loss	(2,950)	(6,028)	(6,693)	(10,100)
Other expenses/(income)				
Interest on long-term debt and other financing costs	519	367	1,166	558
Interest income	-	(4)	(1)	(9)
Foreign exchange (gain)/loss	(95)	70	(185)	305
Change in fair value of derivative financial instruments	(171)	(51)	(39)	(90)
Total other expenses	253	382	941	764
Net loss for the period	(3,203)	(6,410)	$ (7,634)	$ (10,864)
Other comprehensive income, net of income tax				
Foreign currency translation adjustment	(12)	1	44	91
Total comprehensive loss for the period	(3,215)	(6,409)	$ (7,590)	$ (10,773)
Loss per common share				
Basic and diluted net loss per common share	$ (0.01)	$ (0.03)	$ (0.03)	$ (0.05)
Weighted average common shares outstanding				
Basic	260,881,081	213,678,075	248,459,798	213,404,959
Diluted	260,881,081	213,678,075	248,459,798	213,404,959

Acerus Pharmaceuticals Corporation
Condensed Interim Consolidated Statement of Cash Flows
For the six months ended June 30, 2019 and 2018
Unaudited
(expressed in thousands of U.S. dollars)

	June 30, 2019	June 30, 2018
Operating activities:		
Net loss for the period	$ (7,634)	$ (10,864)
Items not affecting cash:		
Adjustment for unrealized foreign exchange (gain)/loss	(211)	360
Amortization of intangible assets	465	853
Depreciation of property and equipment	127	129
Depreciation of right of use asset	23	-
Amortization of deferred leasehold inducement	-	(25)
Interest on long-term debt and other financing costs	1,166	558
Change in fair value of derivative financial instruments	(39)	(90)
Share based compensation	106	226
Gain on disposal of property and equipment	(5)	-
Impairment on intangible asset	2,536	-
Inventory impairment	339	-
Net changes in non-cash working capital items related to operating activities:		
Trade and other receivables	395	(117)
Contract asset	(694)	-
Inventory	593	73
Prepaids and other assets	(543)	96

Accounts payable and accrued liabilities	(1,764)	6,277
Licensing fee receivable	-	300
Net cash used in operating activities	(5,140)	(2,224)
Financing activities		
Interest and financing fees paid	(774)	(390)
Proceeds from issuance of common shares, net of financing costs	3,350	4,369
Principal elements of lease payments	(39)	-
Proceeds from issuance of long-term debt	-	1,571
Net cash from/(used in) financing activities	2,537	5,550
Investing activities		
Proceeds from disposition of property and equipment	5	-
Acquisition of property and equipment, net of deposits	(4)	(60)
Acquisition of product rights	(100)	(156)
Net cash used in investing activities	(99)	(216)
Net increase/(decrease) in cash for the period	(2,702)	3,110
Exchange gain/(loss) on cash	104	(230)
Cash, beginning of period	3,829	3,156
Cash, end of period	$ 1,231	$ 6,036

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