Investor Relations - SWK Holdings

Acerus Reports Fourth Quarter and Full Year 2018 Financial Results

TORONTO--(BUSINESS WIRE)-- Acerus Pharmaceuticals Corporation (“Acerus” or the “Company”) (TSX: ASP) today reported its financial results for the three and twelve-month period ended December 31, 2018. Unless otherwise noted, all amounts are in US dollars and are prepared in accordance with International Financial Reporting Standards (“IFRS”).

2018 Highlights

- Total revenues of $7.4 million for the year, including $7.0 million of product revenues
- Total Q4 product revenues of $1.9 million compared to $1.8 million in the same prior year period
- Solid growth of Canadian Natesto® revenue in the fourth quarter and 2018 fiscal year
- Natesto® is now licensed to more than 70 countries covering approximately 90% of the global testosterone replacement therapy opportunity

“We are pleased with the pace of the growth of the Natesto® business – especially in Canada”, said Ed Gudaitis, President and Chief Executive Officer of Acerus. “We will continue to work with our partners in the US and elsewhere to increase awareness of Natesto® and accelerate growth of prescription volume. In addition, we will continue to leverage our existing relationships with key opinion leaders and to leverage complimentary products to continue to grow revenues in a cost-efficient manner.”

Summary of Results for the Three Months Ended December 31, 2018 (compared to the Three Months Ended December 31, 2017 unless otherwise noted)

- Total revenue in the quarter was $2.1 million compared to $2.4 million in the fourth quarter of 2017. This decline is due to a $0.4 million decline in licensing and other revenue offset by an increase of $0.1 million in product revenue.
- Product revenue growth of $0.1 million to $1.9 million from $1.8 million in the fourth quarter of 2017 was principally driven by strong growth in Canadian Natesto® revenue, which increased by 109% to $0.45 million from $0.21 million in the prior year period. Revenue from US Natesto® sales by our partner Aytu Bioscience Inc. (“Aytu”) declined from $0.4 million to $0.25 million as Acerus inventory shipments to Aytu occurred in Q4 of 2017 but were not repeated in Q4 of 2018.
- Gross margin increased by $0.2 million to $1.3 million from $1.1 million in the prior year quarter, reflecting improved margins on Natesto US shipments as non-inventory revenue has no cost of sales associated with such product.
- Research and development ("R&D") expense declined slightly by $0.1 million to $0.6 million for the current quarter from $0.7 million in the prior year period.
- Selling, general and administrative expenses (“SG&A”) increased by $1.9 million to $5.0 million from $3.1 million in the prior year period. This increase in expenses is principally due to (i) a non-cash charge of $2.6 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), offset by (ii) an accrual in the fourth quarter of 2017 for severance costs for a member of the executive team.
- Earnings before interest, tax, depreciation and amortization (“EBITDA”)[1] was a loss of $4.4 million compared to a loss of $1.0 million for the prior year quarter. Adjusted EBITDA[1], was a loss of $1.3 million for the quarter compared to a loss of $2.1 million for the prior year period.
- The Company incurred a net loss of $5.1 million or $(0.02) per share for the quarter compared to a loss of $1.8 million or $(0.01) per share for the fourth quarter of 2017.
- Cash as of December 31, 2018 was $3.8 million compared with $1.2 million on September 30, 2018, reflecting the net increase in cash from the $9.0 million new debt facility with SWK Funding LLC after reflecting settlement of prior debt.

Summary of Results for the Year Ended December 31, 2018 (compared to the Year Ended December 31, 2017 unless otherwise noted)

- Total revenue for the twelve months ended December 31, 2018 and 2017 were $7.4 million and $6.5 million respectively, reflecting increased product revenue growth of $1.7 million offset by a decline in licensing and other revenue of $0.9 million.
- Year-over-year product growth of $1.7 million in primarily due to increased Natesto® revenues in Canada and the US combined with the introduction of Urivarx® in 2018.
- Gross margin was negative $2.9 million compared with a gross margin of $3.3 million in 2017. 2018’s negative gross margin reflects the $6.7 million Mattern Pharma AG royalty buyout accrual recorded in the second quarter of 2018.
- Research and development ("R&D") expenses were $2.4 million in 2018, an increase of $0.2 million from the $2.2 million in 2017.
- Selling, general and administrative expenses (“SG&A”) were $11.2 million in 2018, an increase of $3.2 million from the $8.0 million reported in 2017. This increase is principally due to the $2.6 million non-cash impairment charge for the carrying value of the Estrace® intangible asset referred to previously.
- EBITDA[1] loss was $15.4 million for the year compared with an EBITDA loss of $6.0 million for the prior year reflecting the adjustments noted above. Adjusted EBITDA[1] was a loss of $5.2 million for the twelve-months ended December 31, 2018 compared to loss of $5.1 million in 2017.
- The Company incurred a 2018 net loss of $18.8 million or $(0.08) per share compared to $8.6 million or $(0.04) for the same prior year periods.

GYNOFLOR™ UPDATE

On January 25, 2019, the Company announced that it had received a Notice of Deficiency – Withdrawal Letter (the “Notice”) from Health Canada related to the Gynoflor™ New Drug Submission. The Company has decided not to file a Request for Reconsideration of the Notice and has informed its licensor, Medinova AG (“Medinova”), that further studies will be needed in order for Gynoflor™ to be approvable by Health Canada. Under the agreement with Medinova, neither the Company nor Medinova is obligated to conduct such further studies. If no further studies are conducted, then Acerus will not resubmit the Gynoflor™ dossier to Health Canada at this time. Acerus and Medinova will continue to work on areas of possible further collaborations.

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 Company’s contract manufacturer.

Since that time the Company has met with the contract manufacturer as well as health authorities in Canada and the UK regarding the anticipated restart of Estrace® production. In addition, the Company is also evaluating options for relocating production to other contract manufacturing facilities.

We have been advised by the manufacturer that they expect to be in a position to deliver Estrace® to Acerus by September 2019. Notwithstanding this timing, the Company may still experience potential shortages of the 0.5 mg and 1.0 mg doses of ESTRACE® before that time as forecasted

demand may exceed in-stock inventory. At this time, the Company does not foresee a shortfall of the 2.0 mg dose prior to September 2019 based on existing inventory in stock.

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 charge against the carrying value of the Estrace® intangible asset.

Conference Call

Shareholders are reminded that the conference call to discuss the Company's results for the three- and twelve-month period ending December 31, 2018 will be held on Tuesday, March 5, 2019 at 8:30 a.m. Eastern Time. To access the call live, please dial 647-484-0475 or 1-888-220-8451. 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, March 12, 2019 by dialing 905-694-9451 or 1-800-408-3053, using access code: 7172777#.

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. 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 December 31,		For the year ended December 31,	
	2018	2017	2018	2017
Net (loss)	$ (5,051)	$ (1,823)	$ (18,786)	$ (8,623)
Adjustments:				
Income tax expense	27	47	29	47
Amortization of intangible assets	394	406	1,694	1,781
Depreciation of property and equipment	47	66	240	264
Interest on long-term debt and other financing costs	497	85	1,773	380
Interest income	-	(3)	(12)	(21)
Change in fair value of derivative	(292)	255	(380)	156
EBITDA	$ (4,378)	$ (967)	$ (15,442)	$ (6,016)
Licensing and other revenue	(184)	(603)	(334)	(1,187)
Royalty expense/Buyout	-	-	6,680	-
Share based compensation	112	372	449	589
Foreign exchange loss/(gain)	676	(930)	1,029	1,521
Gain on extinguishment of payables	(195)	-	(195)	-
Impairment loss on intangible asset	2,641	-	2,641	-
Adjusted EBITDA	$ (1,328)	$ (2,128)	$ (5,172)	$ (5,093)

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 Stendra™, 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
Consolidated Statements of Financial Position
As at December 31, 2018 and 2017 and January 1, 2017
(expressed in thousands of U.S. dollars)

	December 31, 2018	Restated December 31, 2017*	Restated January 1, 2017*
ASSETS			
Current assets			
Cash	$ 3,829	$ 3,156	$ 5,199
Trade and other receivables	1,113	1,542	1,059
Licensing fee receivable	-	300	4,150
Inventory	2,506	2,979	3,770
Prepaid and other assets	176	229	226
Total current assets	7,624	8,206	14,404
Property and equipment, net	1,267	1,487	1,710
Intangible assets, net	7,933	12,561	13,602
Total assets	$ 16,824	$ 22,254	$ 29,716
LIABILITIES AND SHAREHOLDERS' EQUITY			
Current liabilities			
Accounts payable and accrued liabilities	$ 5,619	$ 3,134	$ 3,322
Current portion of deferred lease inducement	46	50	47
Current portion of long-term debt	-	1,026	4,092
Total current liabilities	5,665	4,210	7,461
Accrued liabilities	2,462	178	-
Deferred lease inducement	254	327	352
Long-term debt	8,287	3,543	2,357
Derivative financial instruments	227	307	141
Total liabilities	16,895	8,565	10,311
Shareholders' equity			
Share capital	$ 154,737	$ 151,766	$ 151,766
Warrants	1,420	-	37
Contributed surplus	11,500	11,066	10,440
Accumulated other comprehensive loss	(13,851)	(14,052)	(16,370)
Deficit	(153,877)	(135,091)	(126,468)
Total shareholders' equity	(71)	13,689	19,405
Total liabilities & shareholders' equity	$ 16,824	$ 22,254	$ 29,716

*See note 3(b) in the consolidated statements for the year ending December 31, 2018 for more information regarding the restatement as a result of a change in accounting policy.

Acerus Pharmaceuticals Corporation
Consolidated Statements of Loss and Comprehensive Loss

For the three and twelve months ended December 31, 2018 and 2017
(expressed in thousands of U.S. dollars, except per share and share data)

	For the three months ended,		For the year ended,	
	December 31, 2018	2017*	December 31, 2018	2017*
Revenue				
Product revenue	$ 1,884	$ 1,779	$ 7,043	$ 5,348
Licensing and other revenue	184	600	334	1,187
	2,068	2,379	7,377	6,535
Cost of goods sold	811	1,328	3,644	3,263
Royalty buyout	-	-	6,680	-
Gross margin	1,257	1,051	(2,947)	3,272
Expenses				
Research and development	571	674	2,398	2,166
Selling, general and administrative	5,024	3,070	11,197	7,967
Total operating expenses	5,595	3,744	13,595	10,133
Operating loss	(4,338)	(2,693)	(16,542)	(6,861)

Other expenses/(income)				
Interest on long-term debt and other financing costs	497	85	1,773	380
Interest income	-	(3)	(12)	(21)
Foreign exchange loss	676	(930)	1,029	1,521
Change in fair value of derivative financial instruments	(292)	255	(380)	156
Gain on extinguishment of payables	(195)	(321)	(195)	(321)
Total other expenses	686	(914)	2,215	1,715
Loss for the year before income taxes	(5,024)	(1,779)	(18,757)	(8,576)
Income tax expense	27	47	29	47
Net loss for the period	(5,051)	(1,826)	$ (18,786)	$ (8,623)
Other comprehensive income, net of income tax				
Foreign currency translation adjustment	102	(1,064)	201	2,318
Total comprehensive loss for the period	(4,949)	(2,890)	$ (18,585)	$ (6,305)
*See note 3(b) in the consolidated statements for the year ending December 31, 2018 for more information regarding the restatement as a result of a change in accounting policy.				
Loss per common share				
Basic and diluted net loss per common share	$ (0.02)	$ (0.01)	$ (0.08)	$ (0.04)
Weighted average common shares outstanding				
Basic	235,317,848	213,118,645	224,436,840	213,118,645
Diluted	235,317,848	213,118,645	224,436,840	213,118,645

Acerus Pharmaceuticals Corporation
Consolidated Statements of Cash Flows
For the three and twelve months ended December 31, 2018 and 2017
(expressed in thousands of U.S. dollars)

	For the three months ended December 31,		For the year ended, December 31,	
	2018	2017*	2018	2017*
Operating activities:				
Net loss for the year	$ (5,051)	$ (1,823)	$ (18,786)	$ (8,623)
Items not affecting cash:				
Adjustment for unrealized foreign exchange loss	199	(1,308)	560	1,078
Amortization of intangible assets	394	406	1,694	1,781
Depreciation of property and equipment	63	66	256	264
Amortization of deferred leasehold inducement	(10)	(13)	(47)	(49)
Interest on long-term debt and other financing costs	497	85	1,773	380
Change in fair value of derivative financial instruments	(292)	255	(380)	156
Share based compensation	112	372	449	589
Loss/(gain) on disposal of property and equipment	1	(4)	1	(8)
Gain on extinguishment of payables	(195)	(321)	(195)	(321)
Impairment on intangible asset	2,641	-	2,641	-
Net changes in non-cash working capital items related to operating activities:				
Trade and other receivables	(151)	163	325	(398)
Inventory	203	166	248	641
Prepaids and other assets	151	(11)	38	12
Accounts payable and accrued liabilities	789	1,658	4,992	447
Licensing fee receivable	-	-	300	4,150
Net cash (used in)/from operating activities	(649)	(309)	(6,131)	99
Financing activities				
Interest and financing fees paid	(135)	(347)	(692)	(687)
Proceeds from issuance of common shares and warrants, net of financing costs	2	-	4,376	-
Proceeds from debt issuance, net of financing costs paid	8,659	2,352	10,230	2,352
Payment of long-term debt obligations	(5,064)	(707)	(6,564)	(4,098)
Net cash from/(used in) financing activities	3,462	1,298	7,350	(2,433)
Investing activities				
Proceeds from disposition of property and equipment	-	5	-	10
Acquisition of property and equipment, net of deposits	1	-	(87)	-
Acquisition of product rights	(2)	-	(158)	-
Net cash (used in)/from investing activities	(1)	5	(245)	10
Net increase/(decrease) in cash for the year	2,812	994	974	(2,324)
Exchange (loss)/gain on cash	(214)	14	(301)	281
Cash, beginning of period	1,231	2,148	3,156	5,199
Cash, end of year	$ 3,829	$ 3,156	$ 3,829	$ 3,156
*See note 3(b) in the consolidated statements for the year ending December 31, 2018 for more information regarding the restatement as a result of a change in accounting policy.				

View source version on businesswire.com: https://www.businesswire.com/news/home/20190305005229/en/

Robert Motz
Chief Financial Officer
Acerus Pharmaceuticals Corporation
rmotz@aceruspharma.com
(905) 817-8288

---

https://swkhold.investorroom.com/2019-03-05-Acerus-Reports-Fourth-Quarter-and-Full-Year-2018-Financial-Results