

Press Releases

[<< Back](#)

[View printer-friendly version](#)

Advanced Accelerator Applications Reports 21% Sales Growth for First Quarter 2017

On Track to Resubmit NDA for lutetium Lu 177 dotatate (Lutathera[®]) to FDA in Mid-2017

NETSPOT[®] Unit Sales per Month Jump 140% During First Quarter

First Quarter 2017 Highlights:

- Advanced preparations for resubmission of lutetium Lu 177 dotatate (Lutathera[®]) New Drug Application to FDA
- Results of Phase 3 NETTER-1 study of investigational drug lutetium Lu 177 dotatate (Lutathera[®]) published in *The New England Journal of Medicine*
- Enhanced supply chain for lutetium 177-labeled products through a ten-year exclusive supply agreement with the University of Missouri Research Reactor (MURR[®])
- More than 80 patients and 15 centers in the US and over 1,600 patients and 60 centers in Europe were participating in the lutetium Lu 177 dotatate (Lutathera[®]) Expanded Access and compassionate use and named patient programs at March 31, 2017
- NETSPOT[®] included in the National Comprehensive Cancer Network[®] (NCCN[®]) Clinical Practice Guidelines in Oncology for NETs
- Sales for the first quarter of 2017 increased 21% compared to the first quarter of 2016
- NETSPOT[®] unit sales per month increased 140% (from 232 to 559) between December 2016 and March 2017

SAINT-GENIS-POUILLY, France, May 31, 2017 (GLOBE NEWSWIRE) -- **Advanced Accelerator Applications S.A.** (NASDAQ:AAAP) (AAA or the Company), an international specialist in Molecular Nuclear Medicine (MNM), today announced its financial results for the first quarter ended March 31, 2017.

Stefano Buono, Chief Executive Officer of AAA, commented, *“2017 is off to a strong start. Sales of NETSPOT[®] in the US continue to grow rapidly, as we expand our national network of partner radiopharmacies. More than 100 institutions across the US are already using NETSPOT[®], and we are currently delivering doses at a run rate of approximately 800 per month. We are proud of NETSPOT[®]’s positive impact on the neuroendocrine tumor (NET) community, which was recently recognized by the National Organization for Rare Disorders.”*

“As we look forward to the rest of the year, we are focused on executing a successful launch for SomaKit TOC[™] in Europe, preparing for potential approvals of lutetium Lu 177 dotatate (Lutathera[®]) in Europe and the US, and advancing development of our theragnostic pipeline, including PSMA-R2 and NeoBOMB1. We remain on track for our mid-year resubmission of the New Drug Application for lutetium Lu 177 dotatate (Lutathera[®]) to the US Food and Drug Administration, and believe the European Medicines Agency will complete its review of the marketing authorization in the third quarter. As this process moves forward, we continue to provide access to treatment with lutetium Lu 177 dotatate to qualifying NET patients in the US and Europe through our ongoing Expanded Access and compassionate use programs. To date, more than 100 patients in 17 centers in the US and over 1,640 patients in 60 centers in Europe have already received treatment under these initiatives.”

First Quarter 2017 Financial Results

Total sales for the first quarter of 2017 were €32.6 million (US\$34.9 million⁽¹⁾), a 21% year-on-year increase compared to €26.9 million (US\$28.8 million⁽¹⁾) in the first quarter of 2016. The increase in sales was primarily driven by the PET product category, which increased 41% to €22.4 million (US\$24.0 million⁽¹⁾), compared to €15.9 million (US\$17.0 million⁽¹⁾) in the prior year’s period. US sales of NETSPOT[®] for the first quarter of 2017 were €3.7 million (US\$4.0 million¹); there were no sales of NETSPOT[®] in the first quarter of 2016, as the drug was not yet approved. Therapeutic sales for the first quarter were €5.3 million (US\$5.7 million⁽¹⁾), compared to €5.6 million (US\$6.0 million⁽¹⁾). SPECT sales for the first quarter were €2.3 million (US\$2.5 million⁽¹⁾), compared to €2.2 million (US\$2.4 million⁽¹⁾) for the first quarter of

2016. First quarter sales of other products were €2.6 million (US\$2.8 million⁽¹⁾), compared to €3.2 million (US\$3.4 million⁽¹⁾) for the same period in 2016.

Operating loss for the first quarter was €6.5 million (US\$7.0 million⁽¹⁾), compared to a loss of €1.1 million (US\$1.2 million⁽¹⁾) for the prior year's period. The Company experienced higher research and development and operating costs during the first quarter of 2017, primarily related to the launch of new products and associated increases in compliance requirements, as well as growth in headcount.

Net loss for the quarter was €11.3 million (US\$12.1 million⁽¹⁾), compared to a net loss of €3.0 million (US\$3.2 million⁽¹⁾) for the first quarter of 2016.

Adjusted EBITDA (see corresponding reconciliation exhibit below) for the quarter was a loss of €2.9 million (US\$3.1 million⁽¹⁾) compared to a profit of €2.1 million (US\$2.2 million⁽¹⁾) for the same period in 2016.

Cash and cash equivalents at March 31, 2017 were €212.8 million (US\$227.7 million⁽¹⁾).

(1) Translated solely for convenience into US\$ at the noon buying rate of €1.00=\$1.0698 at March 31, 2017.

Recent Operational Updates

At the end of March, the Company announced a 10-year exclusive supply agreement for lutetium 177 with the University of Missouri Research Reactor (MURR[®]). Through this agreement, MURR[®] will supply AAA with GMP-quality lutetium 177 Chloride, the precursor for production of investigational product lutetium Lu 177 dotatate (Lutathera[®]) and other Lu 177-based therapeutics in development.

In May, the Company received a 2017 Industry Innovation Award from the National Organization for Rare Disorders (NORD[®]) for NETSPOT[®], at the NORD Rare Impact Awards. NORD is a patient advocacy organization dedicated to the 30 million Americans with more than 7,000 known rare diseases, and many more people and organizations working tirelessly to help. Each year, NORD's Rare Impact Awards program recognizes individuals and organizations that have made a positive impact on patients' lives.

In May, the Company entered into a non-exclusive manufacturing agreement and an exclusive distribution agreement with Blue Earth Diagnostics Ltd., a molecular imaging diagnostics company, for the supply of a Blue Earth Diagnostics PET imaging product in France, Germany, Spain, Italy, and Portugal.

About lutetium Lu 177 dotatate (Lutathera®)

Lutetium Lu 177 dotatate (Lutathera®) is an investigational, Lu-177-labeled somatostatin analog peptide currently in development for the treatment of gastroenteropancreatic neuroendocrine tumors (GEP-NETs), including foregut, midgut, and hindgut neuroendocrine tumors in adults. Lutetium Lu 177 dotatate (Lutathera®) belongs to an emerging form of treatments called Peptide Receptor Radionuclide Therapy (PRRT), which involves targeting neuroendocrine tumors with radiolabeled somatostatin analog peptides. This novel, investigational compound has received orphan drug designation from the European Medicines Agency (EMA) and the US Food and Drug Administration (FDA). Currently, lutetium Lu 177 dotatate (Lutathera®) is administered on a compassionate use and named patient basis for the treatment of NETs and other tumors over-expressing somatostatin receptors in ten European countries and in the US under an Expanded Access Program (EAP) for midgut NETs. New Drug Application and Marketing Authorization Application submissions to the FDA and EMA for lutetium Lu 177 dotatate (Lutathera®) are currently under review.

About Advanced Accelerator Applications S.A.

Advanced Accelerator Applications is an innovative radiopharmaceutical company that develops, produces and commercializes Molecular Nuclear Medicine products. AAA's lead investigational therapeutic candidate, lutetium Lu 177 dotatate (Lutathera®), is a novel MNM compound in development for the treatment of Neuroendocrine Tumors, a significant unmet medical need. Founded in 2002, AAA has its headquarters in Saint-Genis-Pouilly, France. AAA currently has 21 production and R&D facilities able to manufacture both diagnostics and therapeutic MNM products, and more than 500 employees in 13 countries (France, Italy, the UK, Germany, Switzerland, Spain, Poland, Portugal, The Netherlands, Belgium, Israel, the US and Canada). AAA reported sales of €109.3 million in 2016 (+23% vs. 2015). AAA is listed on the Nasdaq Global Select Market under the ticker "AAAP". For more information, please visit: www.adacap.com.

About Molecular Nuclear Medicine ("MNM")

Molecular Nuclear Medicine is a medical specialty using trace amounts of active substances, called radiopharmaceuticals, to create images of organs and lesions, and to treat various diseases, like cancer. The technique works by injecting targeted radiopharmaceuticals into the patient's body that accumulate in the organs or lesions and reveal specific biochemical processes. MNM can be divided in two branches: Molecular Nuclear Diagnostics and Molecular Nuclear Therapy. Molecular nuclear

diagnostics employs a variety of imaging devices and radiopharmaceuticals. PET (Positron Emission Tomography) and SPECT (Single Photon Emission Computed Tomography) are highly sensitive imaging technologies that enable physicians to diagnose different types of cancer, cardiovascular diseases, neurological disorders and other diseases in their early stages. Molecular nuclear therapy uses radioactive sources (radionuclides) to treat a range of tumor types. Using short-range particles, this therapy can target tumors with little effect on normal tissues.

Reconciliation of adjusted EBITDA to net loss for the period from continuing operations for the three months ended March 31, 2017 and 2016

	Three months March 31, 2017	Three months March 31, March 31, 2017 2016	
	in USD thousands ⁽¹⁾	In € thousands	
Net loss for the period from continuing operations	(12,065)	(11,278)	(2,976)
Adjustments			
Finance income			
(including changes in fair value of contingent consideration)	(451)	(422)	(1,303)
Finance costs			
(including changes in fair value of contingent consideration)	4,978	4,653	3,481
Income taxes	592	553	(322)
Depreciation and amortization	3,862	3,610	3,199
Adjusted EBITDA	(3,085)	(2,884)	2,079
Sales	34,912	32,634	26,919
Adjusted EBITDA margin	-8.84 %	-8.84 %	7.72 %

(1) Translated solely for convenience into dollars at the noon buying rate of EUR 1.00=USD 1.0698 at March 31, 2017.

Cautionary Statement Regarding Forward-Looking Statements

This press release contains forward-looking statements. All statements, other than statements of historical facts, contained in this press release, including statements regarding the Company's strategy, future operations, future financial position, future revenues, projected costs, prospects, plans and objectives of management, are forward-looking statements. The words "anticipate," "believe," "estimate," "expect," "intend," "may," "plan," "predict," "project," "target," "potential," "will," "would," "could," "should," "continue," and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. Forward-looking statements that appear in a number of places in this press release include the Company's current expectation regarding future events and various matters, including expected timing of filings with the FDA and EMA, approval dates, and expansion of NETSPOT[®]. These forward-looking statements involve risks and uncertainties that may cause actual results, events or developments to be materially different from any future results, events or developments expressed or implied by such forward-looking statements. Such factors include, but are not limited to, changing market conditions, the successful and timely completion of clinical studies, the timing of our submission of applications for regulatory approvals, EMA, FDA and other regulatory approvals for our product candidates, the occurrence of side effects or serious adverse events caused by or associated with our products and product candidates; our ability to procure adequate quantities of necessary supplies and raw materials for lutetium Lu 177 dotatate (Lutathera[®]) and other chemical compounds acceptable for use in our manufacturing processes from our suppliers; our ability to organize timely and safe delivery of our products or product candidates by third parties; any problems with the manufacture, quality or performance of our products or product candidates; the rate and degree of market acceptance and the clinical utility of lutetium Lu 177 dotatate (Lutathera[®]) and our other products or product candidates; our estimates regarding the market opportunity for lutetium Lu 177 dotatate (Lutathera[®]), our other product candidates and our existing products; our anticipation that we will generate higher sales as we diversify our products; our ability to implement our growth strategy including expansion in the US; our ability to sustain and create additional sales, marketing and distribution capabilities; our intellectual property and licensing position; legislation or regulation in countries where we sell our products that affect product pricing, taxation, reimbursement, access or distribution channels; regulatory actions or litigation; and general economic, political, demographic and business conditions in Europe, the US and elsewhere. Except as required by applicable securities laws, we

undertake no obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events or otherwise.

CONDENSED CONSOLIDATED STATEMENTS OF INCOME

THREE MONTHS ENDED MARCH 31, 2017 AND 2016

In € thousands	Three months	
	March 31, 2017	March 31, 2016
Sales	32,634	26,919
Raw materials and consumables used	(8,301)	(5,624)
Personnel costs	(12,334)	(9,679)
Other operating expenses	(16,066)	(10,919)
Other operating income	1,183	1,382
Depreciation and amortization	(3,610)	(3,199)
Operating loss	(6,494)	(1,120)
Finance income (including changes in fair value of contingent consideration)	422	1,303
Finance costs (including changes in fair value of contingent consideration)	(4,653)	(3,481)
Net finance loss	(4,231)	(2,178)
Loss before income taxes	(10,725)	(3,298)
Income taxes	(553)	322
Loss for the year	(11,278)	(2,976)
Attributable to:		

Owners of the Company	(11,278)	(2,976)
-----------------------	-----------	----------

Loss per share

Basic (€ per share)	(0.13)	(0.04)
---------------------	---------	---------

Diluted (€ per share)	(0.13)	(0.04)
-----------------------	---------	---------

Some figures in the three-month period ended March 31, 2016 were reclassified for comparison purposes, without impact to net results.

CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME

THREE MONTHS ENDED MARCH 31, 2017 AND 2016

In € thousands	Three months	
	March 31, 2017	March 31, 2016
Loss for the year	(11,278)	(2,976)
Other comprehensive income / (expense):		
Items that may be reclassified subsequent to profit or loss		
Exchange differences on translating foreign operations	958	(761)
Items that will never be reclassified subsequent to profit or loss		
Remeasurement of defined benefit liability	10	(37)
Other comprehensive income / (expense) net of tax ⁽¹⁾	968	(798)
Total comprehensive loss for the year	(10,310)	(3,774)
Total comprehensive loss attributable to:		
Owners of the Company	(10,310)	(3,774)

(1) Negative tax effect of €3 thousand at March 31, 2017, and €16 thousand at March 31, 2016.

CONDENSED CONSOLIDATED STATEMENTS OF FINANCIAL POSITION

AT MARCH 31, 2017 AND DECEMBER 31, 2016

ASSETS (in € thousands)	March 31, 2017	December 31, 2016
Non-current assets	148,043	149,695
Goodwill	34,378	34,070
Other intangible assets	44,259	45,027
Property, plant and equipment	62,248	63,915
Financial assets	2,130	2,187
Other non-current assets	4,614	3,941
Deferred Tax assets	414	555
Current assets	263,899	269,048
Inventories	8,656	8,100
Trade and other receivables	33,531	31,079
Other current assets	8,902	7,789
Cash and cash equivalents	212,810	222,080
TOTAL ASSETS	411,942	418,743
EQUITY AND LIABILITIES (in € thousands)	March 31, 2017	December 31, 2016
Equity attributable to owners of the Company	293,324	299,461
Share capital	8,818	8,795
Share premium	361,435	360,085
Reserves and retained earnings	(65,651)	(44,125)
Net loss for the year	(11,278)	(25,294)
Total equity	293,324	299,461
Non-current liabilities	78,450	79,540
Non-current provisions	13,812	12,725

Non-current financial liabilities	11,804	12,302
Deferred tax liabilities	4,224	4,649
Other non-current liabilities	48,610	49,864
Current liabilities	40,168	39,742
Current provisions	1,169	1,135
Current financial liabilities	3,618	4,017
Trade and other payables	20,717	20,119
Other current liabilities	14,664	14,471
Total liabilities	118,618	119,282
TOTAL EQUITY AND LIABILITIES	411,942	418,743

Some figures in the three-month period ended March 31, 2016 were reclassified for comparison

purposes, without impact to net results.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

THREE MONTHS ENDED MARCH 31, 2017 AND 2016

In € thousands	Three months	
	March 31, 2017	March 31, 2016
Cash flows from operating activities		
Net loss for the period	(11,278)(2,976
<u>Adjustments:</u>		
Depreciation, amortization and impairment of non-current assets	3,610	3,199
Share based payment expense	2,800	1,306
Loss / (Gain) on disposal of property, plant and equipment	(2) 72
Financial result	4,231	2,178
Income tax expense	553	(322
Subtotal	(86) 3,457

Increase in inventories	(556) (584)
Increase in trade receivables	(2,452) (3,300)
Increase in trade payables	745	1,572	
Change in other receivables and payables	(3,220) (3,524)
Increase in provisions	1,060	81	
Change in working capital	(4,423) (5,755)
Income tax paid	(475) (425)
Net cash used in operating activities	(4,984) (2,723)
Cash flows from investing activities			
Acquisition of property, plant and equipment	(1,111) (3,623)
Acquisition of intangible assets	(423) (577)
Acquisition of financial assets	(7) (221)
Repayment of financial assets	41	760	
Interest received	469	130	
Proceeds from disposal of property, plant and equipment	15	-	
Proceeds from government grants	334	-	
Acquisition of subsidiaries, net of cash acquired	-	(19,959)
Net cash used in investing activities	(682) (23,490)
Cash flows from financing activities			
Payment of deferred and contingent liabilities to former owners of acquired subsidiaries	(1,750) (194)
Exercise of warrants	1,373	-	
Proceeds from borrowings	329	-	
Repayment of borrowings	(1,273) (1,283)
Interests paid	(109) (95)
Net cash used in financing activities	(1,430) (1,572)
Net decrease in cash and cash equivalents	(7,096) (27,785)
Cash and cash equivalents at the beginning of the year	222,080	118,886	

Effect of exchange rate changes on cash and cash equivalents	(2,219) (2,647)
Cash and cash equivalents at the end of the period (1)	212,765	88,454	

(1) The amount of cash and cash equivalents at March 31, 2017, is lower by €45 thousand than the amount in the consolidated statement of financial position, due to the offset of bank overdrafts.

Contacts:

AAA Corporate Communications
 Rachel Levine
 Director of Communications
rachel.levine@adacap.com
 Tel: + 1-212-235-2395

AAA Investor Relations
 Jordan Silverstein
 Director of Investor Relations
jordan.silverstein@adacap.com
 Tel: + 1-212-235-2394

Media inquiries:

Makovsky & Company
 Lee Davies
ldavies@makovsky.com
 Tel: +212-508-9651



Advanced Accelerator Applications

