



## PRESS RELEASE

### **Advanced Accelerator Applications Reports 24.4% Sales Growth in the Second Quarter of 2016**

#### ***Launches First U.S. Product and Continues Momentum with Pipeline***

##### Highlights:

- Sales for the second quarter of 2016 increased 24.4% compared to the second quarter of 2015
- The U.S. Food and Drug Administration (FDA) granted Priority Review for Lutathera, with a Prescription Drug User Fee Act (PDUFA) target action date of December 28, 2016
- First patient was treated with Lutathera under the U.S. Expanded Access Program
- The FDA approved NETSPOT™ (Somakit-TATE) for the localization of somatostatin receptor positive neuroendocrine tumors in adult and pediatric patients using Positron Emission Tomography
- Established first U.S. distribution and future production site
- Expanded theragnostic pipeline with NeoBOMB1, a novel GRPR antagonist in development for gastrointestinal stromal tumors, prostate cancer and breast cancer
- Acquired two F-18 production sites in Germany

August 31, 2016, Saint-Genis-Pouilly, France - 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 second quarter of 2016.

Stefano Buono, Chief Executive Officer of AAA, commented, "We are very excited about the launch of our first FDA approved product in the U.S. We have established national distribution for NETSPOT™ (Somakit-TATE) and are pleased by the initial demand and patient support we have received. In the meantime, we are quite encouraged by the Priority Review designation for Lutathera and that patients are starting to receive treatment under the U.S. Expanded Access Program. These developments and the establishment of our first U.S. facility further support our preparations for launch in both the U.S. and Europe." Buono added, "We look forward to continuing our momentum in the second half of 2016, with the December 28 PDUFA date for Lutathera, and our plans to begin advancing the NeoBOMB1 and PSMA assets into clinical development."

#### **Second Quarter 2016 Financial Results**

Total sales for the second quarter of 2016 were €27.64 million (USD<sup>(1)</sup> 30.49 million), a 24.4% year-on-year increase compared to €22.21 million (USD<sup>(1)</sup> 24.50 million) in the prior year period.

Operating loss for the second quarter of 2016 was €0.96 million (USD<sup>(1)</sup> 1.06 million), compared to a loss of €1.97 million (USD<sup>(1)</sup> 2.17 million) for the prior year period.

For the second quarter of 2016, the Company reported a net loss of €1.43 million (USD<sup>(1)</sup> 1.58 million), compared to €2.56 million (USD<sup>(1)</sup> 2.82 million) for the prior year period.



For the second quarter of 2016, adjusted EBITDA (see corresponding reconciliation exhibit below) was €2.26 million (USD<sup>(1)</sup> 2.50 million), a 179% year-on-year increase compared to €0.81 million (USD<sup>(1)</sup> 0.89 million) for the prior year period.

*(1) Translated solely for convenience into USD at the noon buying rate of €1.00=1.1032 at June 30, 2016.*

## **Operational Updates**

In May, AAA Germany signed an asset purchase agreement to acquire, out of an insolvency procedure, assets and rights to operate two F-18 production sites in Munich and Erlangen, Germany.

In June, the FDA approved NETSPOT™ (Somakit-TATE) for the localization of somatostatin receptor positive neuroendocrine tumors (“NETs”) in adult and pediatric patients using Positron Emission Tomography. Shortly thereafter, AAA announced three additional radiopharmacy partners for the distribution of NETSPOT™ across the United States.

On June 27, AAA announced that the FDA had accepted the company’s New Drug Application and granted Priority Review for Lutathera, with a PDUFA target action date of December 28, 2016.

Subsequent to the end of the quarter, AAA announced the completion of its first U.S. manufacturing and distribution facility in Millburn, NJ, which is undergoing validation for production of Lutathera. In addition to future production of Lutathera, this site also serves as a distribution center for NETSPOT™ and Oxygen-18 enriched water, an important precursor for the production of fluorodeoxyglucose used in PET.

In early July, the first patient was treated with Lutathera under the U.S. Expanded Access Program.

In late July, AAA announced a clinical trial agreement with the National Cancer Institute (NCI), part of the National Institutes of Health, whereby NCI will sponsor and conduct a study of Lutathera in patients with inoperable pheochromocytoma and paraganglioma.

During the quarter AAA also announced the expansion of its theragnostic pipeline with NeoBOMB1, a unique new generation antagonist bombesin analogue, which binds selectively and with high affinity to the GRP receptors expressed by several types of tumors, including prostate, breast and gastrointestinal stromal tumors. Clinical studies in all three indications are currently being planned.

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## **About Lutathera**

Lutathera (or lutetium Lu 177 dotatate) is a Lu-177-labeled somatostatin analogue peptide currently in development for the treatment of gastro entero pancreatic neuroendocrine tumors (GEP-NETs), including foregut, midgut, and hindgut neuroendocrine tumors in adults. Lutathera belongs to an emerging form of treatments called Peptide Receptor Radionuclide Therapy (PRRT), which involves targeting carcinoid tumors with radiolabeled somatostatin analogue peptides. This novel compound has received orphan drug designation from the European Medicines Agency (EMA) and the US Food and Drug Administration (FDA). Lutathera was also granted fast-track designation by the FDA in April



2015 for the treatment of inoperable, progressive midgut NETs. Currently, Lutathera is also 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. In an analysis of the Phase 3 trial's primary endpoint of PFS assessment completed by the Company in September 2015, the number of disease progressions or deaths was 23 events in the Lutathera arm and 68 in the Octreotide LAR 60 mg arm. The NETTER-1 study met its primary endpoint by demonstrating that treatment with Lutathera was associated with a statistically significant and clinically meaningful risk reduction of 79% of disease progression or death versus Octreotide LAR 60 mg (hazard ratio 0.21, 95% CI: 0.13-0.33;  $p < 0.0001$ ). NDA and MAA submissions to the FDA and EMA are currently under review and have been granted Priority Review and Accelerated Assessment.

### **About Advanced Accelerator Applications**

Advanced Accelerator Applications (AAA) is an innovative radiopharmaceutical company that develops, produces and commercializes Molecular Nuclear Medicine (MNM) products. AAA's lead therapeutic product candidate, Lutathera, is a novel MNM compound that AAA is currently developing for the treatment of Neuro Endocrine Tumors, a significant unmet medical need. Founded in 2002, AAA has its headquarters in Saint-Genis-Pouilly, France. AAA currently has 22 production and R&D facilities able to manufacture both diagnostics and therapeutic MNM products, and has over 450 employees in 13 countries (France, Italy, UK, Germany, Switzerland, Spain, Poland, Portugal, The Netherlands, Belgium, Israel, U.S. and Canada). AAA reported sales of €88.6 million in 2015 (+26.8% vs. 2014). AAA is listed on the Nasdaq Global Select Market under the ticker "AAAP". For more information, please visit: [www.adacap.com](http://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. Molecular Nuclear Diagnostics employs a variety of imaging devices and radiopharmaceuticals. PET (Positron Emission Tomography) and SPECT (Single Photon Emission 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.



## Reconciliation of adjusted EBITDA to net loss for the year from continuing operations for the three and six months ended June 30, 2016 and 2015

	Three months		Three months		Six months	
	June 30, 2016	June 30, 2016	June 30, 2015	June 30, 2016	June 30, 2015	
	in USD thousands <sup>(1)</sup>	In € thousands		In € thousands		
<b>Net loss for the period from continuing operations</b>	<b>(1,580)</b>	<b>(1,432)</b>	<b>(2,560)</b>	<b>(4,408)</b>	<b>(8,463)</b>	
<b>Adjustments</b>						
Finance income (including changes in fair value of contingent consideration)	(1,142)	(1,035)	(129)	(445)	(85)	
Finance costs (including changes in fair value of contingent consideration)	1,797	1,629	568	3,217	4,311	
Income taxes	(138)	(125)	154	(447)	689	
Depreciation and amortization	3,562	3,228	2,778	6,427	5,460	
<b>Adjusted EBITDA</b>	<b>2,499</b>	<b>2,265</b>	<b>811</b>	<b>4,344</b>	<b>1,912</b>	
<b>Sales</b>	<b>30,492</b>	<b>27,640</b>	<b>22,210</b>	<b>54,559</b>	<b>42,974</b>	
<b>Adjusted EBITDA margin</b>	<b>8.19%</b>	<b>8.19%</b>	<b>3.65%</b>	<b>7.96%</b>	<b>4.45%</b>	

(1) Translated solely for convenience into dollars at the noon buying rate of EUR 1.00=USD 1.1032 at June 30, 2016.

### Cautionary Statement Regarding Forward-Looking Statements

This press release may contain 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, including statements relating to PDUFA target action date, reflect the Company's current expectation regarding future events. 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 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 Lutathera and our other products or product candidates; our estimates regarding the market opportunity for 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 U.S.; 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; and



general economic, political, demographic and business conditions in Europe, the U.S. 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.

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## CONDENSED CONSOLIDATED STATEMENTS OF INCOME

THREE MONTHS AND SIX MONTHS ENDED JUNE 30, 2016 AND 2015

In € thousands	Three months		Six months	
	June 30, 2016	June 30, 2015	June 30, 2016	June 30, 2015
Sales	27,640	22,210	54,559	42,974
Raw materials and consumables used	(5,572)	(4,839)	(11,196)	(9,091)
Personnel costs	(9,248)	(6,812)	(18,927)	(12,970)
Other operating expenses	(11,980)	(11,065)	(22,827)	(21,678)
Other operating income	1,425	1,317	2,735	2,677
Depreciation and amortization	(3,228)	(2,778)	(6,427)	(5,460)
<b>Operating loss</b>	<b>(963)</b>	<b>(1,967)</b>	<b>(2,083)</b>	<b>(3,548)</b>
Finance income (including changes in fair value of contingent consideration)	1,035	129	445	85
Finance costs (including changes in fair value of contingent consideration)	(1,629)	(568)	(3,217)	(4,311)
<b>Net finance loss</b>	<b>(594)</b>	<b>(439)</b>	<b>(2,772)</b>	<b>(4,226)</b>
<b>Loss before income taxes</b>	<b>(1,557)</b>	<b>(2,406)</b>	<b>(4,855)</b>	<b>(7,774)</b>
Income taxes	125	(154)	447	(689)
<b>Loss for the period</b>	<b>(1,432)</b>	<b>(2,560)</b>	<b>(4,408)</b>	<b>(8,463)</b>
<b>Attributable to:</b>				
Owners of the company	(1,432)	(2,560)	(4,408)	(8,463)
<b>Loss per share</b>				
Basic (€ per share)	(0.02)	(0.04)	(0.06)	(0.13)
Diluted (€ per share)	(0.02)	(0.04)	(0.06)	(0.13)



## CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME

THREE MONTHS AND SIX MONTHS ENDED JUNE 30, 2016 AND 2015

In € thousands	Three months		Six months	
	June 30, 2016	June 30, 2015	June 30, 2016	June 30, 2015
<b>Loss for the period</b>	<b>(1,432)</b>	<b>(2,560)</b>	<b>(4,408)</b>	<b>(8,463)</b>
<b>Other comprehensive income / (expense):</b>				
<b>Items that may be reclassified subsequently to profit or loss</b>				
Exchange differences on translating foreign operations	362	27	(399)	3,887
<b>Items that will never be reclassified subsequently to profit or loss</b>				
Remeasurement of defined benefit liability	(6)	56	(43)	37
<b>Other comprehensive income / (expense) net of tax <sup>(1)</sup></b>	<b>356</b>	<b>83</b>	<b>(442)</b>	<b>3,924</b>
<b>Total comprehensive loss for the year</b>	<b>(1,076)</b>	<b>(2,477)</b>	<b>(4,850)</b>	<b>(4,539)</b>
<b>Total comprehensive loss attributable to:</b>				
Owner of the company	(1,076)	(2,477)	(4,850)	(4,539)

(1) Positive tax effect of €3 thousand at Q2 2016 and negative tax effect of €28 thousand at Q2 2015  
 Positive tax effect of €22 thousand at first half 2016 and negative tax effect of €18 thousand at first half 2015



## CONDENSED CONSOLIDATED STATEMENTS OF FINANCIAL POSITION

AT JUNE 30, 2016

<b>ASSETS (in € thousands)</b>	<b>June 30, 2016</b>	<b>December 31, 2015</b>
<b>Non-current assets</b>	<b>151,096</b>	<b>116,872</b>
Goodwill	33,369	22,662
Other intangible assets	46,371	31,884
Property, plant and equipment	63,369	56,332
Financial assets	1,338	1,512
Other non-current assets	6,021	4,185
Deferred Tax assets	628	297
<b>Current assets</b>	<b>122,285</b>	<b>157,231</b>
Inventories	5,988	4,105
Trade and other receivables	29,556	23,625
Other current assets	11,002	10,615
Cash and cash equivalents	75,739	118,886
<b>TOTAL ASSETS</b>	<b>273,381</b>	<b>274,103</b>
<b>EQUITY AND LIABILITIES (in € thousands)</b>	<b>June 30, 2016</b>	<b>Dec 31, 2015</b>
<b>Equity attributable to owners of the Company</b>	<b>167,449</b>	<b>169,754</b>
Share capital	7,856	7,856
Share premium	213,982	213,982
Reserves and retained earnings	(49,981)	(35,083)
Net loss for the period/year	(4,408)	(17,001)
<b>Total equity</b>	<b>167,449</b>	<b>169,754</b>
<b>Non-current liabilities</b>	<b>70,913</b>	<b>68,341</b>
Non-current provisions	10,950	9,968
Non-current financial liabilities	14,319	16,205
Deferred tax liabilities	5,319	2,804
Other non-current liabilities	40,325	39,364
<b>Current liabilities</b>	<b>35,019</b>	<b>36,008</b>
Current provisions	250	-
Current financial liabilities	4,221	5,560
Trade and other payables	15,770	14,710
Other current liabilities	14,778	15,738
<b>Total liabilities</b>	<b>105,932</b>	<b>104,349</b>
<b>TOTAL EQUITY AND LIABILITIES</b>	<b>273,381</b>	<b>274,103</b>





## CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

SIX MONTHS ENDED JUNE 30, 2016 AND 2015

In € thousands	Six months ended	
	June 30, 2016	June 30, 2015
<b>Cash flows from operating activities</b>		
Net loss for the period	(4,408)	(8,463)
<u>Adjustments:</u>		
Depreciation, amortization and impairment of non-current assets	6,427	5,460
Share based payment expense	2,545	835
Loss / (Gain) on disposal of property, plant and equipment	85	7
Financial result	2,772	4,226
Income tax expense	(447)	689
Negative goodwill	(127)	-
<b>Subtotal</b>	<b>6,847</b>	<b>2,754</b>
(Increase)/decrease in inventories	(1,242)	(609)
(Increase)/decrease in trade receivables	(5,026)	(5,253)
Increase/(decrease) in trade payables	1,307	516
Change in other receivables and payables	(7,469)	(1,059)
Increase / (decrease) in provisions	415	176
<b>Change in working capital</b>	<b>(12,015)</b>	<b>(6,229)</b>
Income tax paid	(1,266)	(538)
<b>Net cash used in operating activities</b>	<b>(6,433)</b>	<b>(4,013)</b>
<b>Cash flows from investing activities</b>		
Acquisition of property, plant and equipment	(7,950)	(3,119)
Acquisition of intangible assets	(984)	(591)
Acquisition of financial assets	(18)	(45)
Reimbursement of financial assets	821	-
Interests received	287	176
Proceeds from disposal of property, plant and equipment	7	31
Acquisition of subsidiaries, net of cash acquired	(22,453)	-
<b>Net cash used in investing activities</b>	<b>(30,290)</b>	<b>(3,548)</b>
<b>Net cash from financing activities</b>		
Payment of deferred and contingent liabilities to former owners of acquired subsidiaries	(2,870)	-
Issuance of share capital	-	23,117
Repayment of borrowings	(3,156)	(2,464)
Interests paid	(177)	(388)
<b>Net cash (used) / generated in financing activities</b>	<b>(6,203)</b>	<b>20,265</b>
<b>Net (decrease) / increase in cash and cash equivalents</b>	<b>(42,927)</b>	<b>12,704</b>
Cash and cash equivalents at the beginning of the period	118,886	45,096
Effect of exchange rate changes on cash and cash equivalents	(220)	661
<b>Cash and cash equivalents at the end of the period*</b>	<b>75,739</b>	<b>58,461</b>

\* Netted of bank overdrafts presented in financial statements