



Interim Report January – June 2011

Report on the six months ending June 30, 2011 and Interim Consolidated Financial Statements

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Interim Results for the First Six Months 2011

In the first half year 2011 Santhera achieved net sales of CHF 1.6 million with Catena®. Net cash burn was reduced to CHF 12.3 million and the net result amounted to CHF –15.0 million. As of June 30, 2011, Santhera had cash and cash equivalents of CHF 31.4 million.

The main achievement in 2011 so far was the submission of the Marketing Authorization Application (MAA) for Catena® in Leber's Hereditary Optic Neuropathy (LHON) to the European Medicines Agency (EMA). Santhera's filing has been accepted and is currently under review by the EMA.

Cash reserves of CHF 31.4 million and CHF 1.6 million revenue from Catena® sales

As of June 30, 2011, Santhera had cash and cash equivalents of CHF 31.4 million (end of 2010: CHF 43.7 million). Net change in cash in the first half year of 2011 was CHF –12.3 million compared to CHF –13.8 million in the same period in 2010. Total equity at mid-year 2011 amounted to CHF 54.5 million (2010: CHF 67.1 million).

In the first six months of 2011, Catena® generated net sales of CHF 1.6 million (first half of 2010: CHF 1.7 million). Operating expenses amounted to CHF 15.6 million (first half of 2010: CHF 15.7 million) in line with management expectation. As a consequence, the operating result (CHF –13.9 million) was on the same level as in the same period in the previous year (first half of 2010: CHF –13.7 million). The expenses for research and development were CHF 9.1 million, while expenses for marketing and sales accounted to CHF 1.3 million and CHF 5.1 million for general and administrative. For the first half of 2011, Santhera reports a net result of CHF –15.0 million (first half of 2010: CHF –14.2 million).

During the six month period ending June 30, 2011, Santhera employed 46 full-time equivalents on average (first half of 2010: 50).

Outlook

Upon publication of this report, Santhera announced plans for restructuring the Company and to further focus its activities on the Catena® franchise. Following the legally required consultation period with the Swiss employees, decisions on the final restructuring can be taken and will be announced accordingly.

Interim Consolidated Balance Sheet

	In CHF thousands	Notes	June 30, 2011 (unaudited)	December 31, 2010 (audited)
Assets				
Tangible assets			1,242	1,283
Intangible assets		5	28,062	29,120
Financial assets long-term			360	360
Deferred tax assets			179	394
Noncurrent assets		10	29,843	31,157
Prepaid expenses and accrued income			214	173
Inventories		6	3,020	3,082
Trade and other receivables			884	672
Cash and cash equivalents		7	31,399	43,682
Current assets			35,517	47,609
Total assets			65,360	78,766
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	In CHF thousands	Notes	June 30, 2011 (unaudited)	December 31, 2010 (audited)
Equity and liabilities				
Share capital		8	3,660	3,660
Capital reserves and share premium			273,035	272,315
Retained earnings			-215,282	-200,267
Treasury shares		8	-177	-177
Other components of equity			-6,717	-5,904
Total equity			54,519	69,627
Long-term finance lease liabilities		9	2,224	2,241
Pension liabilities			1,618	1,542
Long-term provisions			0	99
Total noncurrent liabilities			3,842	3,882
Trade and other payables			2,535	996
Short-term financial lease liabilities		9	33	32
Accrued expenses			4,136	3,749
Short-term provisions			295	480
Total current liabilities			6,999	5,257
Total liabilities			10,841	9,139
Total equity and liabilities			65,360	78,766

Interim Consolidated Income Statement (Unaudited)

For the half year ended June 30, in CHF thousands	Notes	2011	2010
Net sales	10	1,626	1,711
Cost of goods sold		-180	-229
Gross profit		1,446	1,482
Other operating income	11	258	552
Research and development	12,13	-9,129	-7,947
Marketing and sales	12,13	-1,329	-2,151
General and administrative	12,13	-5,094	-5,553
Other operating expenses	12,13	-77	-52
Operating expenses	12,13	-15,629	-15,703
Operating result		-13,925	-13,669
Financial income		1,355	2,458
Financial expenses		-2,188	-2,870
Result before taxes		-14,758	-14,081
Income taxes		-257	-82
Net loss		-15,015	-14,163
Basic and diluted loss per share (in CHF)		-4,10	-3,87

Interim Consolidated Statement of Comprehensive Income (Unaudited)

For the half year ended June 30, in CHF thousands	Notes	2011	2010
Net loss		-15,015	-14,163
Currency translation differences		-813	-2,970
Other comprehensive result		-813	-2,970
Total comprehensive result		-15,828	-17,133

Interim Consolidated Statement of Cash Flows (Unaudited)

For the half year ended June 30, in CHF thousands	Notes	2011	2010
Result before taxes		-14,758	-14,081
Depreciation of tangible assets		125	198
Reversal of depreciation of tangible assets		0	-151
Amortisation of intangible assets		219	225
Expenses for share options	12,13	720	941
Change in pension liabilities		76	26
Change in long-term provisions		-98	0
Change in short-term provisions		-185	561
Change in deferred tax assets		215	27
Tax expenses		-257	-82
Change in net working capital		1,859	-1,890
Total financial result		833	413
Interest received		61	52
Interest paid		-34	-66
Cash flow from operating activities		-11,224	-13,827
Investments in tangible assets		-87	-52
Disposal of tangible assets	5	2	151
Cash flow from investing activities		-85	99
Capital increases	8	0	6
Amortization of tangible assets		-17	-16
Cash flow from financing activities		-17	-10
Effects of exchange rate changes on cash and cash equivalents		-957	-105
Net increase/(decrease) in cash and cash equivalents		-12,283	-13,843
Cash and cash equivalents at January 1		43,682	53,320
Cash and cash equivalents at June 30		31,399	39,477

Interim Consolidated Statement of Changes in Equity (Unaudited)

	In CHF thousands	Notes	Share capital	Capital reserves and share premium	Retained earnings	Treasury shares	Translation differences	Total
Balance at January 1, 2010			3,654	270,467	-189,011	0	-1,598	83,512
Net loss			0	0	-14,163	0	0	-14,163
Currency translation differences			0	0	0	0	-2,970	-2,970
Total comprehensive result for the period			0	0	-14,163	0	-2,970	-17,133
Share-based payment transactions		12,13	0	941	0	0	0	941
Capital increase from options exercise		8	6	0	0	0	0	6
Transferred treasury shares ¹			0	0	0	-177	0	-177
Balance at June 30, 2010			3,660	271,408	-203,174	-177	-4,568	67,149
¹ In February 2010, Santhera received the equivalent of CHF 176,616 in treasury shares from former Juvantia shareholders as pledge to cover possible financial claims from Finnish tax authorities.								
Balance at January 1, 2011			3,660	272,315	-200,267	-177	-5,904	69,627
Net loss			0	0	-15,015	0	0	-15,015
Currency translation differences			0	0	0	0	-813	-813
Total comprehensive result for the period			0	0	-15,015	0	-813	-15,828
Share-based payment transactions		12,13	0	720	0	0	0	720
Balance at June 30, 2011			3,660	273,035	-215,282	-177	-6,717	54,519

Notes to the Unaudited Consolidated Financial Statements

1 General Information

Santhera Pharmaceuticals Holding AG (the **Company** together with its subsidiaries **Santhera** or **Group**) is a specialty pharmaceutical company focused on the development and commercialization of specialty niche products for the treatment of neurodegenerative and neuromuscular diseases, areas of high unmet medical need and orphan indications with no current therapy. Santhera's vision is to become a global market leader in the treatment of such diseases, which frequently qualify for orphan drug status.

The Company, having its primary listing of its registered shares (**Shares**) on the SIX Swiss Exchange is a Swiss stock corporation and the parent company of the Group. Its purpose is to acquire, dispose and manage investments. The Company has its registered offices at Hammerstrasse 49 in CH-4410 Liestal, Switzerland.

The consolidated interim financial statements were approved for publication by the Board of Directors (**Board**) on August 29, 2011.

2 Summary of Significant Accounting Policies

The accounting policies used in the preparation of the interim financial statements are consistent with those used in the preparation of the Group's annual financial statements for the year ended December 31, 2010, except for the adoption of new standards and interpretations as of January 1, 2011, as noted below.

Basis of preparation

These consolidated interim financial statements were prepared in accordance with IAS 34 Interim Financial Reporting and should be read in conjunction with the annual financial statements for the year ended December 31, 2010.

The presentation currency is Swiss Francs (**CHF**). All figures included in these financial statements and notes to the financial statements are rounded to the nearest CHF 1,000 except where otherwise indicated.

Changes in accounting policies

Various standards and interpretations of the International Financial Reporting Standards (**IFRS**) have been revised or were introduced with effective date January 1, 2011. The following standards did have an effect on accounting policies but not on reported amounts or disclosures in these financial statements:

- IAS 1 Presentation of Financial Statements: revised. Effective for annual periods beginning on or after January 1, 2010. The amendment clarifies that an option to present an analysis of each component of other comprehensive income may be included either in the statement of changes in equity or in the notes to the financial statements.

- IAS 34 Interim Financial Reporting: revised. Effective for annual periods beginning on or after January 1, 2011. The improvement emphasizes the principle that the disclosure about significant events and transactions in interim periods should update the relevant information presented in the most recent annual financial report.

The adoption of the following standards and interpretations did neither have an effect on the disclosure in these financial statements nor on currently relevant accounting policies:

- IFRS 7 Financial Instruments: Disclosures. Effective for annual periods beginning on or after January 1, 2011
- IAS 24 Related Party Disclosures. Effective for annual periods beginning on or after January 1, 2011
- IAS 32 Financial Instruments: Presentation. Effective for annual periods beginning on or after February 1, 2010
- IFRIC 13 Customer Loyalty Programmes. Effective for annual periods beginning on or after January 1, 2011
- IFRIC 14 IAS 19 The Limit on a Defined Benefit Asset, Minimum Funding Requirements and their Interaction. Effective for annual periods beginning on or after January 1, 2011
- IFRIC 19 Extinguishing Financial Liabilities with Equity Instruments. Effective for annual periods beginning on or after July 1, 2010

3 Seasonality

The operating result is not subject to significant seasonal variations during the financial year.

4 Exchange Rates of Principal Currencies

	Income statements		Balance sheet in CHF	
	in CHF (average rates)		(rates as of period end)	
	Six months ended June 30, 2011	Six months ended June 30, 2010	June 30, 2011	December 31, 2010
1 euro (EUR)	1.2699	1.4379	1.1985	1.2468
1 US dollar (USD)	0.9061	1.0829	0.8329	0.9408
1 Canadian dollar (CAD)	0.9270	1.0473	0.8527	0.9409

5 Intangible Assets

The decrease of CHF 1.1 million in intangible assets (CHF 28.1 million as per June 30, 2011) primarily results from exchange rate differences on the major intangible asset Catena®/Sovrima® (INN: idebenone) in various indications, an asset which, from the merger in 2004, is to a large extent denominated in EUR. Catena® is currently being investigated in five indications and is approved in Canada under conditions for the treatment of Friedreich's Ataxia (FA). Recently the European Medicines Agency accepted Santhera's filing of a Marketing Authorization Application in the indication Leber's Hereditary Optic Neuropathy (LHON). Catena®/Sovrima® is furthermore currently being developed in a Phase III international pivotal study for the treatment of Duchenne Muscular Dystrophy (DMD) as well as in proof-of-concept studies in the indications MELAS syndrome and Primary-Progressive Multiple Sclerosis.

Impairment testing of intangible assets

Intangible assets are tested for impairment annually (in the ordinary course of business as per December 31), as well as when circumstances could indicate and raise reasons to believe that the carrying value might be impaired. Santhera's impairment test for intangible assets is based on value in use calculations using a risk-adjusted Net-Present-Value model which is a customary model used in the pharmaceutical industry for the valuation of intangible assets.

IFRS requires the consideration of the relationship between market capitalization and book values, among other factors, when reviewing for indicators of impairment. On June 30, 2011, the market capitalization of Santhera was below the book value of its equity as it was the case on December 31, 2010. As of June 30, 2011, the underlying key assumptions for the impairment testing were unchanged and the Catena®/Sovrima® projects had progressed well in the first half year 2011 why there were no indicators showing that an impairment testing was required to be carried out. As long as Catena®/Sovrima® could further be developed while preserving the potential of regulatory approval in a major market for one of the above mentioned indications, no impairment is deemed necessary.

As of June 30, 2011 Santhera held CHF 3.4 million as intangible in relation to fipamezole. The analysis of additional data generated with fipamezole by Santhera and its partners and recent scientific debate on optimal clinical endpoints for the measurement of dyskinesia in Parkinson's' disease, as well as feedback from the ongoing licensing process for North America revealed uncertainties about the further clinical development of fipamezole. This may require additional discussions on Phase III development with the regulatory authorities and delay the ongoing partnering process.

Based on the current situation, the company has not identified any triggers for impairment but a significant uncertainty remains as to whether a final and successful market registration could be achieved. Therefore, at the balance-sheet date, a respective risk of causing a future adjustment to the carrying amount of Santhera's intangible assets remains.

6 Inventories

This position consists mainly of the value of active pharmaceutical ingredient which is kept by Santhera as stock for market supply and development as well as general inventory risk management purposes (security stock) for Catena®/Sovrima®.

7 Cash and Cash Equivalents

	In CHF thousands	June 30, 2011	December 31, 2010
Cash at banks and on hand			
In CHF		15,422	19,375
In EUR		8,744	6,002
In USD		4,715	1,856
In CAD		2,518	2,076
Short-term money market deposits			
In EUR		0	8,728
In USD		0	5,642
Total at period end		31,399	43,682

In accordance with Santhera's treasury management policies, cash and cash equivalents in foreign currencies are to a large extent being kept in line with planned expenses over the relevant planning horizon.

8 Share Capital

Ordinary share capital

During the reporting period ending June 30, 2011, no Shares were issued out of conditional share capital upon the exercise of stock options. 6,023 Shares were issued in the same period for 2010.

Therefore, as of June 30, 2011, the issued nominal share capital was unchanged compared to December 31, 2011, and amounted to CHF 3,660,438, divided into 3,660,438 Shares.

Authorized share capital

The Board is authorized to increase the share capital at any time until April 26, 2012, through the issuance of up to 1,800,000 Shares with a nominal value of CHF 1 each.

Treasury shares

In connection with the liquidation of Juvantia, acquired in 2009, Santhera received a total of 8,028 Shares from former Juvantia shareholders in 2010. These treasury shares serve as pledge from the former owners of Juvantia for compensation of a potential tax claim related to pre-acquisition activities of Juvantia. Final tax assessment by the Finnish government is expected by end of 2011.

Conditional share capital

As of June 30, 2011, the Company had conditional share capital, pursuant to which the share capital may be increased by

- (i) a maximum amount of CHF 644,492 through the issuance of up to 644,492 Shares, through the exercise of option rights whereby the exercise price of each option shall – at the full discretion of the Board – either equal (a) the weighted average share price during the three months preceding the grant or (b) the closing price of the share at the grant date (for information on options outstanding see note 14 "Stock Option Plans").
- (ii) a maximum amount of CHF 600,000 by issuing up to 600,000 Shares through the exercise of warrants/options and/or notes granted in connection with bonds or similar debt instruments linked with option and/or conversion rights granted by the Company. The Board can therefore issue up to 600,000 additional Shares.

9 Long- and Short-term Finance Lease Liabilities

In September 2009, the Santhera organization in Switzerland moved to a new rental building. Some installations were built-in following Santhera's specifications and financed through a finance lease liability in accordance with IAS 17. The total financial lease liability amounted to CHF 2.3 million as at June 30, 2011, split into a long- and short-term portion (long-term CHF 2.22 million, short-term CHF 33,246). At December 31, 2010, the total financial lease liability amounted to CHF 2.3 million (long-term 2.24 million, short-term CHF 32,307).

10 Segment and Geographic Information

Segment information

Santhera operates in one business segment, namely development and commercialization of small-molecule pharmaceutical products for the treatment of severe neuromuscular diseases. The Board, the Executive Management and the Management Team, being the chief operating decision makers, assess the reporting data and allocate resources as one segment on an aggregated consolidated level according to operating expenses by function. Santhera generates revenue from sales of Catena® primarily for the treatment of FA in Canada, but also some revenues by prescriptions for DMD and LHON patients. Geographic revenue information is based on location of the customer.

Geographical information

	In CHF thousands	June 30, 2011	June 30, 2010
Net sales:			
North America		1,495	1,608
Europe		131	103
Total		1,626	1,711
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Noncurrent assets:			
EU		20,825	23,077
Switzerland		8,475	10,465
North America		4	15
Total		29,304	33,557

11 Other Operating Income

AFM (Association Française contre les Myopathies, Paris, France) reimbursed development expenses for a project with the compound omigapil in the indication Congenital Muscular Dystrophy in the amount CHF 0.21 million. The remaining amount of CHF 0.05 million was mainly received in connection with the sale of non-core assets.

12 Operating Expenses by Function

	In CHF thousands	Six months ended June 30, 2011	Six months ended June 30, 2010
Research (preclinical)		-865	-1,018
Development		-8,264	-6,929
Total research and development expenses		-9,129	-7,947
<i>Of which non-cash-relevant expenses for share-based payments</i>		-176	-262
Marketing and sales		-1,329	-2,151
<i>Of which non-cash-relevant expenses for share-based payments</i>		-110	-167
Business development and licensing		-513	-763
Finance and administration		-4,581	-4,790
Total general and administrative expenses		-5,094	-5,553
<i>Of which non-cash-relevant expenses for share-based payments</i>		-434	-512
Other operating expenses		-77	-52
Total operating expenses		-15,629	-15,703

13 Operating Expenses by Nature

	In CHF thousands	Six months ended June 30, 2011	Six months ended June 30, 2010
External research and development expenses		-6,315	-4,994
Patent and license expenses		-211	-372
Marketing expenses		-418	-532
Employee expenses		-6,512	-7,683
<i>Of which non-cash-relevant expenses for share-based payments</i>		-720	-941
General and administrative expenses		-1,785	-1,835
Depreciation and amortization		-311	-235
Other operating expenses		-77	-52
Total operating expenses		-15,629	-15,703

14 Stock Option Plans

Santhera has established employee stock option plans (**ESOP**), the ESOP 2004, the ESOP 2008, the ESOP 2010, the 2006 Executive Incentive Plan (EIP) and the 2011 Board stock option plan (**BSOP**), to align the long-term interests of the Board, the Executive Management, employees and consultants, including members of the Scientific Advisory Board. Options granted under these stock option plans are equity settled. New grants are only possible currently under the ESOP 2010 and BSOP 2011.

In the reporting period ended June 30, 2011, a total of 16,500 options with exercise prices between CHF 7.36 and CHF 9.40 were granted. This compares to 19,400 options granted in the period ending June 30, 2010, at exercise prices between CHF 24.45 and CHF 27.85.

The fair value of stock options is determined at each grant date by using the Hull-White option pricing model. For the calculation of the fair value of stock options granted during the reporting period in 2011, the same range of valuation parameters as disclosed in the financial statements as of December 31, 2010, was applied. The non-cash relevant expenses for all unvested stock options in the reporting period 2011 amounts to CHF 0.7 million compared to CHF 0.9 million in the same period in 2010.

Options outstanding

	Number of options	Six months ended June 30, 2011	Six months ended June 30, 2010
At January 1		521,843	416,663
Granted ¹		16,500	19,400
Forfeited		-3,217	-20,125
Exercised		0	-6,023
At June 30²		535,126	409,915

¹ The weighted average fair value of the stock options granted during the reporting period in 2011 was CHF 3.90 (CHF 13.51 in the reporting period 2010)

² Based on the closing price of CHF 9.10 of the Santhera shares on June 30, 2011, a total of 90,385 stock options were in the money, whereof 75,935 were vested.

For information about conditional capital for the stock option plans, see note 8 "Share Capital".

15 Contingent Liabilities

Contracts for clinical development

Santhera has entered into contracts for clinical development with e.g. clinical research organizations and clinics. Santhera compensates these service providers for their services usually on a monthly basis. It has the right to terminate such agreements at any time at its sole discretion. In case of early termination, Santhera has to pay for all cost which is incurred by the respective counterparty. The expected payments for these contracts are as follows:

	In CHF thousands	June 30, 2011	June 30, 2010
Within 1 year		4,334	3,348
1 year through 5 years		1,632	1,639
After 5 years		0	0
Total at period end		5,966	4,987

16 Related Party Transactions

During the reporting period 2011 a total of 4,500 options were granted to members of the Board. In the same period in 2010 a total of 12,000 options were granted to members of the Executive Management and the Board (see note 14 "Stock Option Plans").

17 Subsequent Events

On July 1, 2011, Santhera Pharmaceuticals (Switzerland) AG signed an addendum to its existing lease contract for its premises in Liestal according to which the annual lease could be reduced by 13%, starting with April 1, 2012. As per July 1, 2011, the commitment for operating lease of buildings of Santhera and its facilities in Liestal (Switzerland), Charlestown (US), and Montréal (Canada) is as follows:

	In CHF thousands	2011	2010
Within 1 year		744	771
1 year through 5 years		474	542
After 5 years		0	0
Total at period end		1,218	1,313

At its meeting on August 29, 2011, the Board has decided to further focus its activities on the Catena® franchise and to implement a plan for restructuring the organization. The legally required consultation period with the employees in Switzerland will start on August 30, 2011 and end on September 13, 2011. As part of such restructuring, the Board intends to implement a social plan for the affected employees whereby all unvested stock options will have an accelerated vesting and could be exercised until the end of 2012 where normally unvested stock options would forfeit and under the stock option plans 2008, 2010 and the Board stock option plan, stock options would have to be exercised within six months following termination of employment.

Only following such consultation period, the Board could take final decisions on such restructuring and assess its financial impact.

Report on Review of Interim Condensed Consolidated Financial Statements

To the Board of Directors of Santhera Pharmaceuticals Holding AG

Introduction

We have reviewed the interim condensed consolidated financial statements of Santhera Pharmaceuticals Holding AG, Liestal and its subsidiaries (the Group) as of June 30, 2011, comprising of the interim consolidated balance sheet as of June 30, 2011 and the related interim consolidated income statement, interim consolidated statement of comprehensive income, interim consolidated statement of cash flows and interim consolidated statement of changes in equity for the six-month period then ended and explanatory notes (pages 4 to 15). The Board of Directors is responsible for the preparation and presentation of these interim condensed consolidated financial statements in accordance with International Financial Reporting Standard IAS 34 "Interim Financial Reporting". Our responsibility is to express a conclusion on these interim condensed consolidated financial statements based on our review.

Scope of Review

We conducted our review in accordance with International Standard on Review Engagements 2410, "Review of Interim Financial Information Performed by the Independent Auditor of the Entity". A review of interim financial information consists of making inquiries, primarily of persons responsible for financial and accounting matters, and applying analytical and other review procedures. A review is substantially less in scope than an audit conducted in accordance with International Standards on Auditing and consequently does not enable us to obtain assurance that we would become aware of all significant matters that might be identified in an audit. Accordingly, we do not express an audit opinion.

Conclusion

Based on our review, nothing has come to our attention that causes us to believe that the interim condensed consolidated financial statements are not prepared, in all material respects, in accordance with International Financial Reporting Standard IAS 34 "Interim Financial Reporting".

Emphasis of matter

We draw attention to note 5 to the interim condensed financial statements, which describes a material uncertainty regarding the valuation of the related intangible assets. Our conclusion is not qualified in respect of this matter.

Basel, August 29, 2011
Ernst & Young AG

Jürg Zürcher
Licensed audit expert
(Auditor in charge)

David Haldimann
Licensed audit expert

Forward-Looking Statements

This Interim Report expressly or implicitly contains certain forward-looking statements concerning Santhera Pharmaceuticals Holding AG and its business. Such statements involve certain known and unknown risks, uncertainties and other factors, which could cause the actual results, financial condition, performance or achievements of Santhera Pharmaceuticals Holding AG to be materially different from any future results, performance or achievements expressed or implied by such forward-looking statements. There can be no guarantee that any of the development projects described will succeed or that any new products or indications will be brought to market. Similarly, there can be no guarantee that Santhera Pharmaceuticals Holding AG or any future product or indication will achieve any particular level of revenue. In particular, management's expectations could be affected by, among other things, uncertainties involved in the development of new pharmaceutical products, including unexpected clinical trial results; unexpected regulatory actions or delays or government regulation generally; the Company's ability to obtain or maintain patent or other proprietary intellectual property protection; competition in general; government, industry, and general public pricing and other political pressures. Santhera Pharmaceuticals Holding AG is providing the information in this Interim Report as of the date of the publication, and does not undertake any obligation to update any forward-looking statements contained herein as a result of new information, future events or otherwise.

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