

BIOTIE THERAPIES CORP. FINANCIAL STATEMENT R

FINANCIAL STATEMENT RELEASE 28 February, 2013 at 9.00 a.m.

#### Biotie financial statement report 1 January – 31 December 2012

# Positive pipeline newsflow in 2012 supports future growth strategy

# Company Highlights October - December 2012

- Biotie's partner H.Lundbeck A/S received a positive opinion from the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) recommending marketing authorization of Selincro(<sup>TM</sup>).
- Biotie reported top-line data from a Phase 2b study with tozadenant (SYN115) in Parkinson's
  disease (PD) patients experiencing levodopa related end of dose wearing off. The study met its
  primary endpoint of a statistically highly significant decrease in 'off' time vs. placebo, as well as
  demonstrating efficacy across multiple secondary endpoints.
- Biotie reported top-line data from an investigator-initiated and US Department of Defense funded study with nepicastat (SYN117) in post-traumatic stress disorder. Treatment with nepicastat was not effective in relieving PTSD-associated symptoms when compared to placebo. Nepicastat was generally well tolerated and will continue to be developed for cocaine dependence.
- Due to a lack of success in partnering efforts Biotie has fully impaired the carrying value of ronomilast on December 31, 2012. This resulted in a non-cash impairment charge of EUR 3.4 million in Q4/2012.
- Biotie ended 2012 with cash, cash equivalents and short term investments of EUR 33.8 million (EUR 33.9 million, 31 December 2011).

# **Key figures**

EUR thousand Continuing operations	10-12/ 2012 3 months	10-12/ 2011 3 months	1-12/ 2012 12 months	1-12/ 2011 12 months
Revenues	592	30	4,831	1,007
Research and development costs	-7,227	-5,614	-24,229	-35,315
Financial result (net loss):	-8,772*	-3,221	-25,607*	-31,727**
Earnings per share (EUR)	-0.02	-0.01	-0.06	-0.09
Cash flow from operating activities	-7,695	-4,437	-27,108	-18,765

<sup>\*</sup>Financial result for 2012 was impacted by a non-cash impairment charge of EUR 3.4 million for ronomilast.

<sup>\*\*</sup>Financial result for 2011 was impacted by a non-cash impairment charge of EUR 11.7 million for SYN118.



EUR thousand	Dec 31, 2012	Dec 31, 2011
Liquid assets	33,847	33,938
Equity	75,032	73,337
Equity ratio (%)	66.7	62.0

Timo Veromaa, Biotie's President and CEO commented, "2012 was an exciting year for Biotie. We reported positive outcomes for two of our late stage pipeline products and further strengthened our financial position thanks to the support of our strategic partners and new and existing investors. We enter 2013 in a strong position with an alcohol dependence drug that once approved could potentially change the treatment landscape of alcohol dependence and an exciting novel product with robust Phase 2 data in Parkinson's disease where there has been a lack of innovation. We look forward to further significant milestones in the coming year including a decision from the European Commission on final approval of Selincro and launch of Selincro by our partner Lundbeck."

# Drug development projects:

**Selincro (nalmefene)** is a small molecule opioid receptor antagonist that inhibits the reward pathway in the brain that reinforces the desire and craving for alcohol. As a result, Selincro removes a person's desire to drink.

On December 14, 2012 Biotie announced that its partner H.Lundbeck A/S received a positive opinion from the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) recommending marketing authorization of Selincro(<sup>TM</sup>) for the reduction of alcohol consumption in adult patients with alcohol dependence who have a high level of alcohol consumption. Once approved, Lundbeck will provide Selincro as part of a new treatment concept that includes continuous psychosocial support focused on the reduction of alcohol consumption and treatment adherence.

The European Commission usually delivers its final decision on approval within 2-3 months of the CHMP recommendation. The decision will be applicable to all 27 European Union member states plus Iceland and Norway.

Biotie has licensed global rights to nalmefene to Lundbeck. Under the terms of the agreement, Biotie is eligible for up to EUR 89 million in upfront and milestone payments plus royalties on sales of nalmefene. Biotie has previously received EUR 12 million of such milestone payments from Lundbeck. Further milestone payments are expected on potential commercial launch of Selincro and on the product potentially reaching certain predetermined sales. Lundbeck is responsible for the registration, manufacturing and marketing of the product.

**Tozadenant (SYN115)** is an oral, potent and selective adenosine A2a receptor antagonist, which enters the brain and modulates regions associated with motor and non-motor function. Biotie holds a license from Roche for development and commercialization of tozadenant in all indications.

On December 11, 2012 Biotie reported top-line data from a Phase 2b study evaluating tozadenant in Parkinson's disease (PD) patients experiencing levodopa related end of dose wearing off. The study met its primary endpoint of a statistically highly significant decrease in 'off' time vs. placebo, as well as demonstrating efficacy across multiple secondary endpoints.



In the 420 patient study, tozadenant displayed clinically relevant and statistically highly significant effects on PD across multiple pre-specified evaluation metrics including: a decrease vs. placebo in 'off' time, an increase in 'on' time, an improved score on UPDRS part III and UPDRS parts I-III combined, as well as improvements on clinician- and patient-assessed global impression scores. Additionally, the study identified the minimally efficacious and maximum feasible dose levels, as well as clinically useful target doses for Phase 3. Tozadenant was generally well tolerated in the study. Full data from the study will be disclosed at upcoming medical conferences and in scientific publications.

Biotie has granted UCB Pharma S.A. a license for exclusive, worldwide rights to tozadenant. Biotie is eligible for up to \$360 million in upfront and milestone payments plus royalties on sales. After the reporting period, February 26, 2013 Biotie announced that UCB has licensed worldwide exclusive rights to Biotie's tozadenant (SYN115), As a result, Biotie will receive a one-time fee payment of USD 20 million from UCB. In addition, the parties have amended their original licence agreement, such that Biotie will now conduct phase 3 development of tozadenant in return for additional payments from UCB relating to defined development, regulatory and commercialization milestones.

**SYN120** is an oral, potent and selective antagonist of the 5-HT<sub>6</sub> receptor. The 5-HT<sub>6</sub> receptors are exclusively located in the brain and antagonism of these receptors modulates the release of acetylcholine and glutamate, two neurotransmitters known to be involved with memory function. Cognitive deficits are an important component of many CNS diseases, especially Alzheimer's and schizophrenia. SYN120 has completed single and multiple ascending dose Phase 1 clinical studies and a Phase 1 PET ("positron emission tomography") imaging study to determine therapeutic dose for subsequent Phase 2 studies.

Topline data from the PET study were announced on March 1, 2012. The study was conducted at the Johns Hopkins University School of Medicine in the United States and evaluated occupancy of the 5-HT<sub>6</sub> receptor in the brain in nine healthy volunteers who were administered different doses of SYN120. The results demonstrated that target levels of receptor occupancy expected for efficacy can be achieved with SYN120 doses that are an order of magnitude lower than those that have previously been shown to be safe and well tolerated for up to two weeks in healthy older volunteers. In addition, with somewhat higher but equally safe and well tolerated doses of SYN120 block the 5-HT2a receptor which has recently been validated by others as a target in psychosis in PD.

In June 2012 Biotie announced that it will retain global development and commercialization rights to SYN120, following Roche's decision not to exercise its opt-in right due to strategic portfolio reasons. Biotie will seek a partnership for late stage clinical trials and has received interest from several parties for SYN120.

**BTT-1023 (VAP-1 antibody)** VAP-1, in addition to its clinically demonstrated role in inflammatory diseases, has an important role in fibrotic diseases. These data, generated in part in collaboration with National Institute for Health Research Liver Biomedical Research Unit at the University of Birmingham, UK, reveal significant potential for BTT-1023 in certain niche liver inflammatory fibrotic diseases. These data represent potentially new and exciting development opportunities for BTT-1023 in a range of conditions. The company has successfully completed the scale-up of the manufacturing process for BTT-1023 for further clinical studies. Biotie has previously demonstrated encouraging efficacy and safety for BTT-1023 in early clinical studies in rheumatoid arthritis and psoriasis patients and in a range of preclinical models of inflammatory diseases, including COPD and certain neurological conditions.

In April 2012 Biotie announced that it agreed with its partner Seikagaku Corporation to terminate their License Agreement on Biotie's VAP-1 antibody program. The license, under which Biotie had granted Seikagaku exclusive rights for development and commercialization of BTT-1023 in Japan, Taiwan, Singapore, New Zealand and Australia, was executed in April 2003 and was built around Seikagaku's expertise in locomotive diseases. Biotie has re-profiled BTT-1023 to focus on fibrotic diseases, and this is



not a focus in Seikagaku's development strategy. The agreement also included an option for Biotie's VAP-1 SSAO small molecule inhibitors, which has been terminated.

Biotie has concluded that the best way to maximize value of BTT-1023 is with a partnership and partnering efforts are being prioritized. Biotie does not plan to enter into Phase 2 clinical studies without a partner.

**Nepicastat (SYN117)** is an orally administered, potent and selective inhibitor of the enzyme dopamine beta hydroxylase (DBH), the enzyme responsible for the conversion of dopamine into norepinephrine. The compound, licensed from Roche in 2007, has demonstrated potential as a treatment for cocaine dependence and PTSD.

On December 27, 2012 Biotie reported top-line data from a Phase 2 study evaluating nepicastat in combat veterans suffering from post-traumatic stress disorder (PTSD). The study was funded by the U.S. Department of Defense and conducted as an Investigator-initiated study in the United States using clinical trial material supplied by Biotie.

Treatment with nepicastat was not effective in relieving PTSD-associated symptoms when compared to placebo, though the product was generally well tolerated and safe.

Independent from PTSD, Biotie has signed a Collaborative Research and Development Agreement with the National Institute on Drug Abuse (NIDA) at the US National Institutes of Health to investigate the safety and efficacy of nepicastat (SYN117) in the treatment of cocaine dependence. NIDA will fund the conduct of a randomized, double-blind placebo-controlled trial, lasting 11 weeks, in 180 treatment-seeking cocaine-dependent subjects using nepicastat supplied by Biotie. The study will be conducted at approximately 12 US clinics specializing in the treatment of drug dependence.

Biotie and NIDA have previously collaborated on preclinical and clinical studies evaluating potential pharmacokinetic and pharmacodynamic interactions between nepicastat and drugs of abuse. Biotie retains rights to nepicastat and will be able to use data from studies conducted with NIDA to support future potential regulatory submissions.

Ronomilast is a once-daily, potentially best-in-class oral phosphodiesterase-4 (PDE4) inhibitor with therapeutic potential in chronic inflammatory disorders, including chronic obstructive pulmonary disease (COPD), a serious respiratory disorder with major unmet medical need. In three clinical studies with a total of 126 subjects ronomilast was safe and well tolerated at all tested doses up to 100mg once daily. Robust and statistically highly significant biomarker responses confirmed the pharmacological activity of well tolerated doses of ronomilast in man. Due to the complexity and size of studies required for the development of medicines for the treatment of COPD, Biotie has been seeking a corporate partnership to optimize the development path for ronomilast. Due to a lack of success in partnering efforts Biotie has fully impaired the carrying value of ronomilast on December 31, 2012. This resulted in a non-cash impairment charge of EUR 3.4 million in Q4/2012.

# Financial review for reporting period January – December 2012

Figures in brackets, unless otherwise stated, refer to the same period the previous year (EUR million).

**Revenues:** Revenues amounted to EUR 4.8 million (1.0). Revenues consisted of pre-agreed development funding from UCB which was recognized in H2 2012 and periodization of previously received up-front payments from licensing agreements.

Research and development costs amounted to EUR 24.2 million (35.3). The majority of the R&D investments were assigned to the development of tozadenant SYN 115 and VAP-1 antibody.



Total comprehensive income including the currency translation differences amounted to EUR -26.8 million (-26.3).

**Financial result:** Net loss for continuing operations for the reporting period was EUR 25.6 million (31.7). Due to a lack of success in partnering efforts Biotie has fully impaired the carrying value of ronomilast on December 31, 2012. This resulted in a non-cash impairment charge of EUR 3.4 million in Q4/2012. Financial result for 2011 was impacted by a non-cash impairment charge of EUR 11.7 million for SYN118.

**Financing:** Cash, cash equivalents and short term investments totaled EUR 33.8 million on 31 December 2012 (EUR 41.7 million at 30 September 2012). The group's financial position was strengthened by EUR 30 million equity raise in September 2012.

Biotie announced on 7 September execution of a directed share issue to institutional and strategic investors of 46,511,630 newly issued shares at a subscription price of EUR 0.43 per share. As a result of the Offering, the share capital of Biotie increased by EUR 20,000,000.90.

Biotie announced on 7 September that H. Lundbeck A/S subscribed for 18,604,651 shares in Biotie at a subscription price of EUR 0.5375 per share amounting to an investment of EUR 10 million. In connection with this transaction, the worldwide license agreement regarding Selincro (nalmefene) was amended whereby the royalties on the sales on markets outside the European Union, the European Free Trade Area and the United States were decreased in order to support the possible launch of the product in these markets. Biotie may also receive an additional sales milestone payment in the amount of EUR 5 million in Japan.

Biotie has a standby equity distribution agreement (SEDA) in place with US fund Yorkville. Yorkville is under certain pre-agreed terms and conditions obliged to subscribe and pay for Biotie shares in multiple tranches up to a total value of EUR 20 million during the period until November 2015 at Biotie's discretion (Biotie option). The purpose of this arrangement is to have an option to secure the financing of Biotie's working capital in the short and medium term. Biotie has made use of this arrangement in H2 2010 and raised a total amount of EUR 1.1 million. In 2011/2012 Biotie did not convey any shares under this agreement.

**Shareholder's equity:** The shareholders' equity of the group amounted to EUR 75.0 million (IFRS) on 31 December 2012. Biotie's equity ratio was 66.7% on 31 December 2012 (62.0 % on December 2011).

**Investments and cash flow:** Cash flow from operating activities in January – December 2012 amounted to EUR -27.1 million for continuing operations (-18.8) and EUR 0.0 million for discontinued operations (-2.4). Negative cash flow from operating activities for continuing operations was higher than in the same period in 2011 mainly due to the acquisition of Synosia.

The group's investments in tangible and intangible assets during the reporting period amounted to EUR 113 thousand (EUR 65 thousand).

# **Change in the Board of Directors**

On 2 August 2012 the Board of Directors appointed Ismail Kola as a member of the Nomination and Remuneration Committee. The composition of the Nomination and Remuneration Committee after the nomination is Peter Fellner as Chairman and William M. Burns and Ismail Kola as members.

#### Change in the management team

After the reporting period on January 2, 2013 David Cook was appointed Chief Financial Officer (CFO) and a member of the Group's management team, effective February 25, 2013. David Cook reports to Timo



Veromaa, President and Chief Executive Officer. In addition to his CFO role David Cook will also be responsible for Biotie's business development activities. Chris Piggott, Company's Chief Business Officer, retires but will continue as an advisor.

Kristian Rantala, interim CFO, resumes his prior duties as Vice President, Finance and Administration, Finland.

## **Personnel**

During the reporting period January – December 2012, the average number of employees amounted to 38(39) and at the end of the reporting period, Biotie employed 37 people (39 people).

### **Option rights**

Biotie has issued option rights to certain of its employees and managers pursuant to option programs in 2009. Each option right granted based on these two option programs entitles the holder to subscribe one share in the company.

The Swiss company Synosia Therapeutics Holding AG (currently Biotie Therapies Holding AG) acquired by Biotie in February 2011 also has a stock option plan based on which stock options have been granted to employees, directors and consultants. In connection with the completion of the acquisition of Synosia, the option plan was amended so that instead of shares in Synosia an aggregate maximum of 14,912,155 shares in Biotie may be subscribed based on the plan.

The conveyed shares previously held by the Company's subsidiary have not carried any voting rights. As a result of the conveyances, the total number of votes attached to Biotie's shares increased (5/2011 – 12/2012 by 6,300,378 votes to 444,098,961 votes. The conveyance does not affect the number of registered shares (total of 452,710,738 shares) but the number of the Company's shares held by the Biotie Therapies group is reduced to 8,611,777 shares. The parent company Biotie does not own any treasury shares.

In December 2011, The Board of Directors of Biotie approved two new share-based incentive plans for the Group employees; a stock option plan for mainly its European employees and an equity incentive plan for mainly its US employees.

# Stock Option Plan 2011

The maximum total number of stock options issued is 7,401,000, and they entitle their owners to subscribe for a maximum total of 7,401,000 new shares in the company or existing shares held by the company. The number of shares subscribed by exercising stock options now issued corresponds to a maximum total of 1.87 per cent of the shares and votes in the company, if new shares are issued in the share subscription.

# Equity Incentive Plan

The maximum number of share units to be granted and the number of corresponding shares to be delivered on the basis of the plan will be a total of 4,599,000 shares, which corresponds to 1.17 per cent of the shares and votes in the company, should new shares be delivered.

The Board of Directors approved in its meeting on 23 February 2012 that a total of 1,558,600 share unit awards are granted for 2011 under the company's equity incentive plan. Each granted share unit award entitles the holder to one share in the company, subject to a vesting period of approximately two (2) years pursuant to the terms and conditions of the equity incentive plan.

The Board of Directors approved in its meeting on 19 December 2012 that a total of 1,614,000 share unit awards are granted for 2012 under the company's equity incentive plan. Each granted share unit award



entitles the holder to one share in the company, subject to a vesting period of approximately two (2) years pursuant to the terms and conditions of the equity incentive plan. For 2013, a maximum of 2,020,000 share unit awards may be granted under the equity incentive plan, subject to the maximum of 4,599,000 shares.

# Shares and options held by management

At the end of financial year 2012 the amount of company's shares held by the Board of Directors and the company's management and their controlled companies amounted to 2,994,569 shares, 1,215,000 share units and 8,747,843 option rights of which 750,000 options are conditional achieving certain set targets.

# Share capital and shares

Biotie shares are all of the same class and have equal rights. Each share entitles the holder to one vote at the general meeting of shareholders. All shares are quoted on NASDAQ OMX Helsinki Ltd (Small cap).

On December 19, 2012 NASDAQ OMX reported the annual review of its market capitalization segments. The revision is based on the average market cap value in November 2012. Following to this Biotie's market cap segment changed to Mid Cap segment from 2 January, 2013.

As described in more detail in Biotie's stock exchange releases announced on 7 September 2012, a total of 65,116,281 new shares were offered in Biotie's directed issues of shares to H. Lundbeck A/S as well as to institutional and strategic investors. The related share capital increase of EUR 30,000,000.90 was registered with the Finnish Trade Register on 17 September 2012.

On 31 December 2012 the registered number of shares in Biotie Therapies Corp. was 452,710,738. Of these shares 8,611,777 were held by the company or its group companies. The registered share capital of Biotie was EUR 195,919,182.85.

## Market capitalization and trading

At the end of the reporting period the share price was EUR 0.41 the highest price during the reporting period January – December was EUR 0.55, the lowest was EUR 0.32, and the average price was EUR 0.45 Biotie's market capitalization at the end of the reporting period was EUR 185.6 million.

The trading volume on NASDAQ OMX Helsinki during the reporting period January – December was 83,333,092 shares, corresponding to a turnover of EUR 37,315,054.

# Changes in ownership

During the reporting period, January – December 2012, Biotie made one announcement according to Chapter 2, Section 10 of the Finnish Securities Market Act.

Information on notices of changes in ownership and a monthly updated list of Biotie's major shareholders is available on the company's website at <a href="https://www.biotie.com/investors">www.biotie.com/investors</a>.

# Ten largest shareholders of Biotie registered in the shareholders' register maintained by Euroclear Finland Ltd on December 31, 2012

Ilmarinen Mutual Pension Insurance Company	16,732,271	3.70%
The Finnish National Fund for Research and		
Development Sitra	11,985,350	2.65%



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Veritas Pension Insurance Compar	ny Ltd. 8,678,519	1.92%
Juha Jouhki and his controlled com - Thominvest Oy (2,937,900) - Dreadnought Finance (2,098,416) - Juha Jouhki (1,501,356)		1.44%
Sijoitusrahasto Alfred Berg Finland		1.12%
The Local Government Pensions In		0.80%
FIM Fenno Sijoitusrahasto	3,271,810	0.72%
Harri Markkula and his controlled co -Harri Markkula (2,468,868)	·	0.040/
-Tilator Oy (429,775)	2,898,643	0.64%
Nordea Fennia Fund	2,000,000	0.44%
Alfred Berg Small Cap Finland Fund	d 1,687,500	0.37%
	62,477,148	13.80%
Nominee registered shares total	278,136,998	61.44%
Others	112,096,592	24.76%
Number of shares, total	452,710,738	100.00%

A subsidiary of Biotie Therapies Corp. owns 8,611,777 shares of the Company which do not carry any voting rights.

The parent company Biotie does not own any treasury shares.

# **Decisions of the Annual General Meeting**

The stock exchange release regarding the resolutions of The Annual General Meeting of Biotie Therapies Corp. was published on 29 March, 2012.

# Short-term risks and uncertainties

Biotie's strategic risks are predominantly related to the technical success of the drug development programs, regulatory issues, strategic decisions of its partners and, ability to obtain and maintain intellectual property rights for its products. Once products reach the market, the development of their sales may be significantly impacted by decisions of pricing and reimbursement authorities, acceptance by prescribers and patients, as well as changes in the competitive environment, such as the launch of competitive products. The development and success of Biotie's products depends to a large extent on third parties. Any adverse circumstance in relation to any of its programs might impair the value of the asset and thus, represent a severe risk to the company. Such adverse events could happen on a short term notice and are not possible to foresee.

The key operational risks of Biotie's activities include the dependency on key personnel, assets (especially in relation to intellectual property rights) and dependency on its license partners' decisions.



The group can influence to some extent the amount of capital used in its operations by adapting its cost base according to the financing available.

Furthermore, significant financial resources are required to advance the drug development programs into commercialized pharmaceutical products. To fund the operations, Biotie relies on financing from two major sources: income (royalty and milestone payments) from its license partners and raising equity financing in the capital markets. Additionally, financing may be applied from debt providers.

The company relies on capital markets to raise equity financing from time to time. There can be no assurance that sufficient funds can be secured in order to permit the company to carry out its planned activities. Current capital market conditions are very volatile. While in September 2012 the company was able to raise a significant amount of capital from a share issue to fund its operations in the medium term, there can be no assurance that the company can secure equity financing in the future if and when it needs it.

Although Biotie has currently active license agreements in place, the termination of any such agreement would have a negative effect on the short to medium term access to liquidity for the company. While income generated from commercial agreements with third parties relating to its clinical programs might significantly improve Biotie's financial position, a forecast on possible income from future licensing arrangements cannot be provided reliably. Therefore, it is possible that Biotie will need to secure additional financing from share issues in the future.

#### The Board of Directors proposal for handling of the loss

The Board of Directors proposes that no dividend from the financial year 2012 will be paid, and that the loss of the parent company for the financial year EUR 12.9 million (FAS) will be carried forward to shareholders' equity.

# **Annual General Meeting**

Biotie's Annual General Meeting will be held at the auditorium of Mauno Koivisto Centre in Turku on Thursday, April 4, 2013 at 10.00 a.m.

# Outlook for 2013 and key upcoming milestones

**Selincro (nalmefene)**: On December 14, 2012 Biotie´s partner Lundbeck received a positive opinion from the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) recommending marketing authorization of Selincro(<sup>TM</sup>) (nalmefene; an opioid system modulator) for the reduction of alcohol consumption in adult patients with alcohol dependence who have a high level of alcohol consumption.

The European Commission usually delivers its final decision on approval within 2-3 months of the CHMP recommendation. Subject to the Commission's final approval and completion of pricing and reimbursement discussions, Lundbeck expects to launch Selincro in a number of European markets by mid-2013.

Pending approval, the next milestone payments to Biotie are expected on commercial launch of Selincro and on the product reaching certain predetermined sales.

**Tozadenant (SYN115):** Biotie has granted UCB Pharma S.A. a license for exclusive, worldwide rights to tozadenant. After the reporting period, February 26, 2013 Biotie announced that UCB has licensed worldwide exclusive rights to Biotie's tozadenant (SYN115), As a result, Biotie will receive a one-time fee payment of USD 20 million from UCB. In addition, the parties have amended their original licence



agreement, such that Biotie will now conduct phase 3 development of tozadenant in return for additional payments from UCB relating to defined development, regulatory and commercialization milestones.

**SYN120:** An oral, potent and selective antagonist of the 5-HT<sub>6</sub> receptor with dual receptor modulation potential against 5-HT2a SYN120 has an extensive clinical and preclinical data package and is ready to enter Phase 2. Biotie is seeking a partner for further development and commercialization of this product.

**Nepicastat (SYN117):** Biotie, in partnership with the U.S. National Institute of Drug Abuse (NIDA), will jointly investigate the safety and efficacy of nepicastat in the treatment of cocaine dependence. A Phase 2 trial is expected to start in Q1 2013.

On 27 December 2012 Biotie reported that an investigator-initiated study with nepicastat in post-traumatic stress disorder (PTSD) did not meet its primary efficacy endpoint. Biotie will work with the study investigators to analyze and understand the data in more detail before deciding on next steps with nepicastat in PTSD.

**BTT-1023 (VAP-1 antibody):** A first-in-class, fully human monoclonal antibody for inflammatory and fibrotic diseases. As BTT-1023 is a biologic the company has concluded that the best way to maximize the value of this program is with a partnership and partnering efforts are being prioritized. Biotie does not plan to enter into Phase 2 clinical studies without a partner.

Following on the positive CHMP opinion for Selincro and positive top-line date for tozadenant, Biotie is undertaking a portfolio review to ensure appropriate prioritization of projects that have the best development potential and provide the best opportunities of enhancing shareholder value. The review will comprise both Biotie's internal development pipeline as well as certain potential new strategic opportunities. The company expects to report on the results of this review during Q2/2013.

# Financial calendar 2013:

Financial statements 2012 March 7, 2013

Corporate Governance Statement 2012 March 7, 2013.

The statement will be published separately from the Board of Directors' report

Biotie's Annual General Meeting is planned be held on April 4, 2013

Interim report January - March May 3, 2013
Interim report for January - June August 2, 2013
Interim report for January - September November 1, 2013

# Key events after the reporting period

After the reporting period on January 2, 2013 David Cook was appointed Chief Financial Officer (CFO) and a member of the Group's management team, effective February 25, 2013. David Cook reports to Timo Veromaa, President and Chief Executive Officer. In addition to his CFO role David Cook will also be responsible for Biotie's business development activities. Chris Piggott, Company's Chief Business Officer, retires but will continue as an advisor.

After the reporting period, February 26, 2013 Biotie announced that UCB has licensed worldwide exclusive rights to Biotie's tozadenant (SYN115), As a result, Biotie will receive a one-time fee payment of USD 20 million from UCB. In addition, the parties have amended their original licence agreement, such that Biotie will now conduct phase 3 development of tozadenant in return for additional payments from UCB relating to defined development, regulatory and commercialization milestones.



#### **About Biotie**

Biotie is a specialized drug development company focused on the development of drugs for neurodegenerative and psychiatric disorders (e.g. Parkinson's disease, Alzheimer's disease and other cognitive disorders, alcohol and drug dependence (addiction) and post-traumatic stress disorder), and inflammatory and fibrotic liver disease. The company has a strong and balanced development portfolio with several innovative small molecule and biological drug candidates at different stages of clinical development. Biotie's products address diseases with high unmet medical need and significant market potential.

Biotie's most advanced product, Selincro<sup>TM</sup> (nalmefene), licensed to Lundbeck A/S, has on 14 December 2012 received a positive opinion from the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) recommending marketing authorization of Selincro(TM) for the reduction of alcohol consumption in adult patients with alcohol dependence who have a high level of alcohol consumption. In addition, Biotie has a strategic collaboration with UCB Pharma S.A. covering tozadenant which has successfully completed a Phase 2b study in 420 patients with advanced Parkinson's disease. Biotie shares are listed on NASDAQ OMX Helsinki Ltd.

**Group structure:** The parent company of the group is Biotie Therapies Corp. The domicile of the Company is Turku, Finland. The company has an operative subsidiary Biotie Therapies Inc, located in San Francisco, United States of America and an operative subsidiary, Biotie Therapies AG, located in Basel, Switzerland.

The Group also has two non-operational subsidiaries named Biotie Therapies GmbH, located in Radebeul, Germany and Biotie Therapies International Ltd in Finland.

# IFRS and accounting principles

The 2012 financial statements have been prepared in accordance with IFRS recognition and measurement principles, and applying the same accounting policies as for the 2011 financial statements, with the exception of new and amended standards and interpretations effective as of 1 January 2012. The financial statement release has not been prepared in accordance with IAS 34, Interim Financial Reporting.

In addition, as a result of the acquisition of Synosia Therapeutics, Biotie has applied the following principle beginning with the Q1 2011 financial statements:

The results and financial position of all the group entities that have a currency different from the presentation currency are translated into the presentation currency as follows:

- Assets and liabilities for each balance sheet presented are translated at the closing rate at the date of that balance sheet.
- b) Income and expenses for each income statement are translated at average exchange rates.
- c) All resulting exchange differences are recognised in other comprehensive income.

On consolidation, exchange differences arising from the translation of the net investment in foreign operations, and of inter-company borrowings that are considered of being part of the net investment, are taken to other comprehensive income. When a foreign operation is disposed of or sold (either partially or as a whole), exchange differences that were recorded in equity are recognised in the income statement.

Goodwill and fair value adjustments arising on the acquisition of a foreign entity are treated as assets and liabilities of the foreign entity and translated at the closing rate.

This financial statement report is unaudited.



BIOTIE THERAPIES CORP.

FINANCIAL STATEMENT RELEASE 28 February, 2013 at 9.00 a.m.

Turku, 28 February 2013

Biotie Therapies Corp. Board of Directors



# CONSOLIDATED STATEMENT OF COMPREHENSIVE INCOME (IFRS)

	10-12/ 2012	10-12/ 2011	1-12/ 2012	1-12/ 2011
EUR 1,000	3 months	3 months	12 months	12 months
Revenue	592	30	4,831	1,007
Research and development expenses	-7,227	-5,614	-24,229	-35,315
General and administrative expenses	-2,622	-2,833	-7,533	-9,721
Other operating income	799	1,728	1,716	2,518
Operating profit/loss	-8,458	-6,688	-25,216	-41,510
Financial income	56	2,791	168	3,160
Financial expenses	-370	308	-972	-1,132
Profit/loss before taxes	-8,772	-3,589	-26,020	-39,482
Taxes	0	368	414	7,755
Net income/loss, continuing operations	-8,772	-3,221	-25,607	-31,727
Net income/loss, discontinued operations	-748	0	-748	0
Net income/loss	-9,520	-3,221	-26,355	-31,727
Other comprehensive income:				
Currency translation differences	-695	1,743	-420	5,449
Total comprehensive income of the period	-10,215	-1,478	-26,775	-26,278
Net income/loss attributable to				

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BIOTIE THERAPIES CORP.	FINANCIAL ST	ATEMENT RELE	ASE 28 Februa	ary, 2013 at 9.0	0 a.m.
Parent company shareholders	-9,520	-3,221	-26,355	-31,727	
Total comprehensive income attributable to:					
Parent company shareholders	-10,215	-1,478	-26,775	-26,278	
Earnings per share (EPS) basic & diluted, EUR, continuing operations	-0.02	-0.01	-0.06	-0.09	
Earnings per share (EPS) basic & diluted, EUR, discontinued operations	0.00	-	0.00	-	



# CONSOLIDATED STATEMENT OF FINANCIAL POSITION (IFRS) EUR 1,000

	Dec 31, 2012	Dec 31, 2011
Assets		
Non-current assets		
Intangible assets	71,084	75,206
Goodwill	5,497	5,549
Property, plant and equipment	256	305
Investment property	846	1,376
Other shares	10	10
	77,694	82,446
Current assets		
Investments held to maturity	0	16,000
Accounts receivables and other receivables	2,888	1,852
Financial assets at fair value through profit or loss	20,294	169
Cash and cash equivalents	13,553	17,769
	36,735	35,790
Total	114,429	118,236
Equity and liabilities		
Shareholders' equity		
Share capital	193,285	166,446
Reserve for invested unrestricted equity	4,882	4,657
Cumulative translation adjustment	5,029	5,449



BIOTIE THERAPIES CORP.	FINANCIAL STATEMENT RELEA	SE 28 Fe	ebruary, 2013 at 9.00 a.m.
Retained earnings	-101,808	-71,488	
Net income/loss	-26,355	-31,727	
Shareholders' equity total	75,032	73,337	-
Non-current liabilities			
Non-current financial liabilities	23,492	23,492	
Pension benefit obligation	558	435	
Other non-current liabilities	8,489	7,804	
Non-current deferred revenues	2,000	246	
Deferred tax liabilities	2,238	2,619	
	36,776	34,596	-
Current liabilities			
Provisions	0	566	
Pension benefit obligation	15	16	
Current financial liabilities	0	116	
Current deferred revenues	0	120	
Accounts payable and other currer liabilities	at 2,605	9,485	
	2,621	10,303	-
Liabilities total	39,397	44,899	
Total	114,429	118,236	



# BIOTIE THERAPIES CORP.

FINANCIAL STATEMENT RELEASE 28 February, 2013 at 9.00 a.m.

# CONSOLIDATED STATEMENT OF CHANGES IN SHAREHOLDERS' EQUITY

Attributable to equity holders of the parent company

EUR 1,000	Shares (1000 pcs)	Share Capital	Share issue	Reserve for invested un- restricted equity	Own Shares	Retained Earnings	Share- holders' equity total
BALANCE AT 1.1.2011	176,004	43,378	500	1,180	-15	-74,509	-29,466
Total comprehensive income for the period						-26,278	-26,278
Options granted				2,662		3,037	5,699
Options exercised				815			815
Directed issue of treasury shares		500	-500				0
Directed issues of new shares	211,590	115,892					115,892
Directed offer of new shares		7,964					7,964
Cost of share issue		-1,289					-1,289
	211,590	123,068	-500	3,477	0	-23,242	102,803
BALANCE AT 31.12.2011	387,594	166,446	0	4,657	-15	-97,751	73,337
Total comprehensive income for the period						-26,775	-26,775
Options granted						1,606	1,606
Options exercised				224			224
SEDA costs						-200	-200
Directed issues of new shares	65,116	28,000					28,000
Cost of share issue		-1,160					-1,160
	65,116	26,840	0	224	0	-25,369	1,695
BALANCE AT 31.12.2012	452,711	193,285	0	4,882	-15	-123,119	75,032



1-12/

1-12/

# CONSOLIDATED STATEMENT OF CASH FLOWS

	2012	2011
EUR 1,000	12 months	12 months
Cash flow from operating activities		
Continuing operations		
Net income/loss	-25,607	-31,727
Adjustments:		
Non-cash transactions	6,827	20,663
Interest and other financial expenses	972	1,132
Interest income	-168	-3,160
Foreign exchange losses/gains on operating activities	115	-124
Taxes	-399	-7,786
Change in working capital:		
Change in accounts receivables and other receivables	-4,447	1,164
Change in accounts payable and other liabilities	-4,361	1,131
Change in mandatory provisions	0	-23
Interests paid	-40	-42
Interests received	0	0
Taxes paid	0	6
Net cash from operating activities, continuing operations	-27,108	-18,765
Net cash from operating activities, discontinued operations	0	-2,400
Net cash from operating activities	-27,108	-21,165
Cash flow from investing activities		
Continuing operations		
Acquisition of subsidiary, net of cash acquired	0	16,339



Change in financial assets at fair value through profit or loss

Additions	-20,141	0
	·	
Disposals	0	6,653
Change in investments held to maturity		
Additions	0	-26,000
Disposals	16,000	10,000
Interests from investments held to maturity	344	78
Investments to tangible assets	-111	-63
Investments to intangible assets	-2	-2
Net cash used in investing activities, continuing operations	-3,910	7,005
Net cash used in investing activities, discontinued operations	0	0
Net cash used in investing activities	-3,910	7,005
Cash flow from financing activities		
Continuing operations		
Payments from share issue	28,224	27,803
Share issue costs	-1,160	-1,190
SEDA costs	-200	0
Proceeds from borrowings	0	226
Repayment of loans	0	-40
Repayment of lease commitments	-145	0
Net cash from financing activities, continuing operations	26,719	26,799
Net cash from financing activities, discontinued operations	0	0



#### BIOTIE THERAPIES CORP. FINANCIAL STATEMENT RELEASE 28 February, 2013 at 9.00 a.m. Net increase (+) or decrease (-) -4,299 12,639 in cash and cash equivalents Effect on changes in exchange rates on cash and cash 84 1,071 equivalents Cash and cash equivalents at the beginning of the period 17,769 4,059 Cash and cash equivalents at the end of the period 17,769 13,553



BIOTIE THERAPIES CORP.

FINANCIAL STATEMENT RELEASE 28 February, 2013 at 9.00 a.m.

#### SYNOSIA OPTION PLAN

As a result of the combination agreement signed with Synosia Therapeutics Holding AG Biotie Therapies Corp. has issued 14,912,155 shares as a bonus issue to its subsidiary Biotie Therapies Holding AG to be held in treasury and to be used to satisfy exercise of Biotie Therapies Holding AG (formerly Synosia Therapeutics Holding AG) options in accordance with the existing Biotie Therapies Holding AG option plans.

The option plan has been described more in detail in Q1 2011 interim report released May 13, 2011.

The following table provides information on the number and pricing of options at December 31, 2012

	Amount	Weighted average exercise price
Options exercised	6,300,378	0.17
Options outstanding	8,256,813	0.24
Options exercisable	6,953,516	0.21
CONTINGENT LIABILITIES  EUR 1,000	Dec 31, 2012	Dec 31, 2011
Operating lease commitments	231	156
Due within a year	122	101
Due later	109	55
Rent commitments	194	377
Due within a year	194	247
Due later	0	130
Total	425	533

The Group leases motor vehicles, machines and equipment with leases of 3 to 5 years. Rent commitments include subleased Pharmacity premises until 30 November 2011.

# Commitments

On 31 December 2012 Biotie had purchase commitments, primarily for contract research work services, totaling EUR 2.4 million.



# TRANSACTIONS WITH RELATED PARTIES

There have not been major changes within the related party transactions in 2012.





# **KEY FIGURES**

BIOTIE THERAPIES CORP.

The formulas for the calculation of the key figures are presented in the notes of the consolidated financial statements 2012

Including both continuing and discontinued operations	1-12/ 2012	1-12/ 2011	1-12/ 2010
EUR 1,000	12 months	12 months	12 months
Business development			
Revenues	4,831	1,007	2,928
Personnel on average	38	39	70
Personnel at the end of period	37	39	23
Research and development costs	24,229	35,315	12,229
Capital expenditure	113	65	270
Profitability			
Operating profit/loss	-25,216	-41,510	-20,720
as percentage of revenues, %	-521.98	-4,122.14	-707.65
Profit/loss before taxes	-26,020	-39,482	-21,573
as percentage of revenues, %	-538.63	-3,920.75	-736.78
Balance sheet			
Liquid assets	33,847	33,938	4,059
Shareholders' equity	75,032	73,337	-29,466
Balance sheet total	114,429	118,236	11,205
Financial ratios			
Return on equity, %	-	-	-
Return on capital employed, %	-26.1	-82.8	-341.5



BIOTIE THERAPIES CORP.	FINANCIAL STATEMENT RELEASE	28 February,	2013 at 9.00 a.m.
Equity ratio, %	66.7	62.0	-263.0
Gearing, %	-13.8	-14.1	-73.7
Per share data			
Earnings per share (EPS) basic, El	JR -0.06	-0.09	-0.15
Earnings per share (EPS) diluted, E	-0.06	-0.09	-0.15
Shareholders' equity per share,€	0.19	0.19	0.17
Dividend per share, EUR	-	-	-
Pay-out ratio, %	-	-	-
Effective dividend yield, %	-	-	-
P/E-ratio	-	-	-
Share price			
Lowest share price, EUR	0.32	0.34	0.30
Highest share price, EUR	0.55	0.82	0.65
Average share price, EUR	0.45	0.58	0.48
End of period share price, EUR	0.41	0.50	0.50
Market capitalization	185.6	193.8	88.0
at the end of period MEUR			
Trading of shares			
Number of shares traded	83,333,092	243,335,806	90,049,678
As percentage of all	18.4	62.8	51.2
Adjusted weighted average number of shares during the period	408,166,908	365,219,028	161,919,250
Adjusted number of shares at the end of the period	452,710,738	387,594,457	176,003,931



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