



**3,761,418 American Depositary Shares
Representing 300,913,440 Shares
BIOTIE THERAPIES CORP.**
(incorporated in the Republic of Finland)

We are offering 3,761,418 ADSs, at a public offering price of \$14.888 per ADS. The last reported sales price of our shares on the NASDAQ OMX Helsinki Ltd. on June 10, 2015 was €0.169 per share.

This is the initial public offering of American Depositary Shares, or ADSs, representing shares of Biotie Therapies Corp., a Finnish company. Each ADS represents 80 shares. Our shares have no nominal value.

We have also granted the underwriters an option to purchase up to 44,629 ADSs, and UCB S.A., who we refer to as the selling shareholder, has granted the underwriters an option to purchase up to 519,583 ADSs, within 30 days of this offering. We will not receive any proceeds from ADSs sold by the selling shareholder pursuant to the underwriters' option to purchase additional ADSs.

The ADSs have been approved for listing on the NASDAQ Global Select Market, or the NASDAQ, under the symbol "BITL." Our shares are listed on the NASDAQ OMX Helsinki Ltd., or the Finnish Stock Exchange, under the symbol "BTH1V."

We are an "emerging growth company" under the U.S. federal securities laws and will be subject to reduced public company reporting requirements.

Investing in the ADSs involves risks. See "Risk Factors" beginning on page 15 of this prospectus.

	<u>Per ADS</u>	<u>Total</u>
Public offering price	\$14.888	\$55,999,991
Underwriting discounts and commissions ¹	\$ 1.042	\$ 3,919,999
Proceeds, before expenses, to us	\$13.846	\$52,079,992

¹ We have agreed to reimburse the underwriters for certain FINRA-related expenses. See "Underwriting," page 209.

Certain of our existing investors and members of our board of directors have indicated an interest in purchasing up to an aggregate of \$17 million of the ADSs in this offering at the public offering price. However, because indications of interest are not binding agreements or commitments to purchase, these entities and persons may determine to not purchase any ADSs in this offering. It is also possible that these entities and persons and additional existing investors could indicate an interest in purchasing more of the ADSs. In addition, the underwriters could determine to sell fewer ADSs to any of these entities or persons than such entities or persons indicate an interest in purchasing or to not sell any ADSs to these entities and persons.

The ADSs are expected to be ready for delivery on or about June 16, 2015.

Neither the U.S. Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

RBC CAPITAL MARKETS

STIFEL

JMP SECURITIES

ROTH CAPITAL PARTNERS

The date of this prospectus is June 10, 2015

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Unless otherwise indicated or the context otherwise requires, all references in this prospectus to “Biotie,” “Biotie Therapies Corp.,” “Biotie Therapies Oyj,” the “Company,” “we,” “our,” “ours,” “us” or similar terms refer to Biotie Therapies Oyj (translated as Biotie Therapies Corp. in English), together with its subsidiaries.

In this offering, the underwriters will subscribe for our shares which will be deposited with the depositary in exchange for ADSs, and investors will purchase ADSs. In this prospectus, for the sake of convenience, we refer to this offering as an offering of ADSs.

Our consolidated financial statements are presented in euros. Unless otherwise indicated in this prospectus, all references in this prospectus to “\$,” “dollars” and “USD” mean U.S. dollars, all references to “€” and “euros” mean euros, and are to the currency introduced at the start of the third stage of European Economic and Monetary Union pursuant to the Treaty establishing the European Community and all references to “CHF” mean Swiss Franc. Unless otherwise indicated, throughout this prospectus and solely for convenience, conversions from one currency to another:

- relating to payments made or received on or before March 31, 2015 were made at the rate used in preparation of the relevant financial statements; and
- relating to future payments were made at the euro to dollars rate of €1.00=\$1.1279, the official rate quoted by the European Central Bank on June 10, 2015.

These conversions should not be considered representations that any such amounts have been, could have been or could be converted into such other currency at that or any other exchange rate as at that or any other date.

We have not authorized anyone to provide any information other than that contained in this prospectus or in any free writing prospectus prepared by or on behalf of us or to which we may have referred you. We take no responsibility for, and can provide no assurance as to the reliability of, any other information that others may give you. We and the underwriters have not authorized any other person to provide you with different or additional information. Neither we nor the underwriters are making an offer to sell the ADSs in any jurisdiction where the offer or sale is not permitted. You should assume that the information appearing in this prospectus is accurate only as of the date on the front cover of this prospectus, regardless of the time of delivery of this prospectus or any sale of the ADSs. Our business, financial condition, results of operations and prospects may have changed since the date on the front cover of this prospectus.

For investors outside the United States: Neither we nor the underwriters have done anything that would permit this offering or possession or distribution of this prospectus in any jurisdiction, other than the United States, where action for that purpose is required. Persons outside the United States who come into possession of this prospectus must inform themselves about, and observe any restrictions relating to, the offering of the ADSs and the distribution of this prospectus outside the United States.

Through and including July 5, 2015 (the 25th day after the date of this prospectus), all dealers effecting transactions in these securities, whether or not participating in this offering, may be required to deliver a prospectus. This is in addition to the dealers' obligation to deliver a prospectus when acting as underwriters and with respect to their unsold allotments or subscriptions.

SUMMARY

This summary highlights information contained elsewhere in this prospectus. This summary may not contain all the information that may be important to you, and we urge you to read this entire prospectus carefully, including the “Risk Factors,” “Business” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations” sections and our consolidated financial statements and notes to those statements, included elsewhere in this prospectus, before deciding to invest in the American Depositary Shares, or ADSs representing our shares.

Our Business

We are a biopharmaceutical company primarily focused on developing therapeutics for central nervous system disorders. Our pipeline includes product candidates designed to address unmet medical needs in Parkinson’s disease and related dementia, other neurodegenerative indications and primary sclerosing cholangitis, an orphan fibrotic liver disease. In addition, we have successfully developed a product for alcohol dependence that is being commercialized by Lundbeck and is a source of further potential milestone payments and ongoing royalties.

We are preparing to commence a pivotal Phase 3 clinical trial of our lead product candidate, tozadenant, that we believe could form the basis for its approval in the United States as an adjunctive treatment to levodopa in Parkinson’s. Levodopa, the most widely prescribed treatment for Parkinson’s, loses effectiveness in most patients over time. Parkinson’s patients often experience a reemergence of debilitating symptoms on a daily basis as their levodopa doses wear off. Tozadenant is an oral, selective adenosine A_{2a} receptor antagonist that aims to address this wearing off effect. In a 420-patient Phase 2b trial, tozadenant displayed clinically important and statistically significant effects across prespecified primary and multiple secondary endpoints at a number of doses. In addition, tozadenant has been found to be generally safe and well tolerated in our ten clinical trials conducted to date.

We also have two additional development-stage product candidates: SYN120 for Parkinson’s disease dementia and Alzheimer’s disease; and BTT1023 for primary sclerosing cholangitis, an orphan fibrotic liver disease. In addition, under our license and commercialization agreement with H. Lundbeck A/S, or Lundbeck, for Selincro, our product for alcohol dependence, we have received €22.0 million in upfront and milestone payments to date and are eligible to receive additional regulatory and commercial milestone payments and ongoing royalties.

Our Market Opportunity

Parkinson’s disease is the second most common neurodegenerative disorder worldwide, affecting an estimated 6.3 million sufferers, including at least one million people in the United States. Its prevalence increases with age; globally, approximately 1% of those aged 60 years or older and 4% or more of those aged 80 years or older are affected. As a result, prevalence will increase as the global population ages. The Parkinson therapeutics market size in the United States, five major EU markets, Brazil and Japan is currently estimated at approximately \$3.6 billion and is projected to rise to \$5.3 billion by 2022, and the United States is projected to have the largest Parkinson’s therapeutics market share at 44% by 2022. Within four to six years of commencing treatment with levodopa, an estimated 40% of Parkinson’s patients will experience wearing off episodes, increasing by an additional 10% per year after that.

While motor symptoms are the hallmark of Parkinson’s, non-motor symptoms are common and include sleep disturbance, autonomic dysfunction, mood disturbance, including anxiety and depression, and

cognitive disorders, including memory difficulties and dementia. Alzheimer's, the most prevalent neurodegenerative disease, is also an irreversible brain disease that causes progressive deterioration of memory and cognitive skills. Currently, it is estimated that there are approximately 34 million Alzheimer's patients worldwide, of which 5.3 million are in the United States. The average per-person Medicare spending for those with Alzheimer's and other dementias is three times higher than for those without these conditions. Nearly one in every five dollars spent by Medicare is on patients with Alzheimer's or another form of dementia. Globally, the Alzheimer's disease market is expected to grow to \$10.1 billion by 2020.

Primary sclerosing cholangitis, or PSC, is a fibrotic liver disease. Epidemiological studies in Northern Europe and North America have shown prevalence rates of PSC ranging from approximately 4 to 16 per 100,000 inhabitants which meets the criteria for orphan disease designation. BTT1023 has received orphan drug designation for the treatment of PSC in Europe. We intend to pursue orphan drug designation for BTT1023 in the United States.

According to a 2014 study, over 47 million people in the five major EU markets, 42 million people in the United States and 19 million people in Japan engaged in heavy episodic drinking (defined as consumption of more than 60 grams of pure alcohol, or more than six standard drinks) within the last 30 days. A recently published modelling study showed that increasing the drug-based treatment of alcohol dependency in Europe by 40% would reduce alcohol-attributable mortality by 9% for women and 13% for men, potentially saving 11,700 lives annually. Up until 2025, alcohol per capita consumption is expected to continue to increase in the United States and South-East Asia, and Europe is expected to remain the region with the highest per capita consumption in the world.

Our Strategy

Our goal is to be a leading global specialty central nervous system company focused on diseases with unmet medical needs. Key elements of our strategy are to:

- Advance development of tozadenant through regulatory approval.
- Leverage our expertise in drug development and advance the product candidates in our pipeline.
- Selectively establish partnerships and collaborations to derive near-term value from our existing assets.
- Continue to take advantage of non-dilutive sources of funding to fund future trial costs.

We have a commercial and development stage portfolio, as summarized below:

Portfolio	Indication	Phase 1	Phase 2	Phase 3	Marketed	Status
<u>Development Product Candidates</u>						
Tozadenant	Parkinson's Disease					• Enrollment for pivotal Phase 3 trial expected to begin mid-2015
SYN120	Parkinson's Disease					• Currently enrolling patients for Phase 2a trial with top-line data expected by YE 2016
	Dementia					• Phase 2 trial ready (funding dependent)
BTT1023	Primary Sclerosing Cholangitis					• Currently enrolling patients for Phase 2 proof of concept trial in with interim data expected YE 2016
<u>Commercial Product</u>						
Selincro	Alcohol Dependence					• Launched in 29 European countries by our partner Lundbeck

Tozadenant

Tozadenant is an orally administered, potent and selective inhibitor of the adenosine A_{2a} receptor that we are developing for the treatment of Parkinson's. Tozadenant has been evaluated in Parkinson's patients in two published clinical trials. Most recently, in a 420-patient Phase 2b clinical trial of tozadenant, in the 120 mg arm, the duration of end-of-dose wearing off episodes, or OFF-time, was improved in levodopa-treated Parkinson's patients from a mean OFF-time at baseline of 6.1 hours per day to 4.2 hours per day which was an improvement of 1.9 hours over baseline, and a 1.1 hour placebo-adjusted improvement. There was a corresponding improvement in awake time not spent in OFF episodes, or ON-time, which increased by 1.2 hours compared with placebo. Notably, clinically important improvements were not associated with increases in troublesome dyskinesia. Dyskinesia, or involuntary muscle movements, is generally distinguished by patients as troublesome or not depending on whether the movements adversely affect motor function. Parkinson's patients treated with levodopa often, over time, experience dyskinesia during ON-time and current adjunctive treatments to levodopa frequently further increase dyskinesia. Tozadenant has also been evaluated in healthy subjects in eight clinical trials in which safety, tolerability, pharmacokinetics and pharmacodynamics were examined. In these ten clinical trials, tozadenant has been found to be generally safe and well tolerated.

Based on our discussions with the U.S. Food and Drug Administration, or the FDA, at our End of Phase 2 meeting, we believe our planned Phase 3 clinical program, together with existing data, could form the basis for approval of tozadenant as an adjunctive treatment to levodopa in Parkinson's patients experiencing end-of-dose wearing off episodes. Since the End of Phase 2 meeting, we have progressed preparations for our planned pivotal Phase 3 clinical trial, including chemistry manufacturing and control work, non-clinical work and Phase 3 enabling pharmacological trials, and expect to begin recruiting for the Phase 3 clinical trial by the middle of 2015. The FDA has agreed to a Special Protocol Assessment with respect to the design of our Phase 3 trial of tozadenant. We have also requested scientific advice from the European Medicines Agency, or the EMA, with respect to the design of our Phase 3 trial. Based on their response, we expect EMA approval of tozadenant to be contingent on conducting studies in addition to the currently planned Phase 3 program. We plan to engage in further discussions with the EMA with respect to their requirements for the approval of tozadenant.

Our Phase 3 program for tozadenant will consist of a double-blind trial followed by an open-label extension, and, if this trial demonstrates safety and efficacy, a separate open-label trial to generate further information on safety. The double blind portion will be a six-month trial comparing 60 mg and 120 mg twice/day doses of tozadenant to placebo as an adjunctive therapy in 450 levodopa-treated patients with Parkinson's who are experiencing end-of-dose wearing off episodes. Following the double-blind treatment period, patients will be eligible to enroll in a one-year open label treatment period, which will evaluate the safety of tozadenant during long-term administration. If the double-blind portion of the first trial meets its primary efficacy endpoint, we will initiate another open-label trial in 450 of a separate population of Parkinson's patients to establish the requisite number of unique patient exposures required for approval.

Assuming that the pivotal Phase 3 clinical trial yields positive data, and long-term safety is demonstrated in open-label treatment, we intend to file for registration, initially in the United States. At this time, we plan to determine the most appropriate commercial strategy, which may involve establishing our own infrastructure, partnering with another commercial company, or a combination of both.

Our Additional Product Candidates

SYN120 is our oral product candidate to treat both cognitive deficits and psychosis, which frequently coincide in neurodegenerative diseases such as Parkinson's and Alzheimer's. We have completed single and multiple ascending dose Phase 1 trials of SYN120, an oral dual antagonist of the 5HT₆ and 5HT_{2a} receptors, in healthy volunteers. In these trials, doses well above the anticipated therapeutic dose were well tolerated. An 80-patient Phase 2a randomized, double-blind, placebo-controlled trial of SYN120 in Parkinson's dementia, largely funded by the Michael J. Fox Foundation for Parkinson's Research, is being conducted by the Parkinson Study Group, which began recruiting patients at the end of 2014. Top-line data is expected by the end of 2016.

BTT1023 is our product candidate for the orphan disease PSC, a chronic and progressive fibrotic liver disease for which there is no FDA-approved treatment. We have partnered with the U.K. National Institute of Health Research to fund a Phase 2 proof of concept trial of BTT1023 in PSC, which is being conducted in collaboration with the University of Birmingham. Interim data is expected by the end of 2016. BTT1023 has received orphan drug designation for the treatment of PSC in Europe. We intend to pursue orphan drug designation for BTT1023 in the United States.

Our Marketed Product

Our marketed product, Selincro, an orally administered opioid receptor ligand used in alcohol dependence therapy, received European marketing authorization in 2013 and has been introduced across Europe in 29 countries by our partner, Lundbeck, a Danish pharmaceutical company specializing in central nervous system products.

Corporate Information

Our full name is Biotie Therapies Oyj, translated as Biotie Therapies Corp. in English. We are domiciled in Turku, Finland, and our address is Joukahaisenkatu 6, FI-20520 Turku, Finland. Our telephone number is +358 2 274 8900. We are a Finnish public limited liability company and must comply with Finnish legislation. We were incorporated in Finland in 1998. We listed our shares on the Finnish Stock Exchange on October 31, 2002, and our shares currently trade under the symbol "BTHIV." In February 2011, we acquired Synosia Therapeutics Holding AG, or Synosia, a company that had been formed by certain former executives of F. Hoffmann-La Roche Ltd., or Roche, that had licensed a number of central nervous system focused assets that

had previously been under development by Roche, including tozadenant and SYN120. Our primary operating subsidiary, Biotie Therapies, Inc., is located in South San Francisco, California.

Investors should contact us for any inquiries through the address and telephone number of our principal executive office. Our principal website is *www.biotie.com*. The information contained on our website is not a part of this prospectus.

Risks Associated with Our Business

Our business is subject to numerous risks, as more fully described in the section entitled “Risk Factors.” You should read these risks before you invest in the ADSs. We may be unable, for many reasons, including those that are beyond our control, to implement our business strategy. In particular, risks associated with our business include the following:

- We have incurred net losses since our inception and anticipate that we will continue to incur substantial operating losses for the foreseeable future. As of March 31, 2015, our retained earnings were an accumulated deficit of €160.8 million. We may never achieve or sustain profitability.
- The adequacy of our capital resources is particularly dependent on cash generation from milestones and royalties in connection with sales of Selincro and other sources of non-dilutive funding. We cannot assure you of the adequacy of our capital resources to successfully complete the development and commercialization of our product candidates, and a failure to obtain additional capital, if needed, could force us to delay, limit, reduce or terminate our product development or commercialization efforts.
- Raising additional capital may cause dilution to our existing shareholders, restrict our operations or require us to relinquish, or license on unfavorable terms, our rights to our product candidates and may impact any future potential revenue streams.
- We depend significantly on the success of tozadenant and our other product candidates. Tozadenant and our other product candidates are still in clinical development. If our clinical trials are not successful, we do not obtain regulatory approval or we are unable, or unable to find a partner, to commercialize tozadenant or our other product candidates, or we experience significant delays in doing so, our business, financial condition and results of operations will be materially adversely affected.
- We have substantial value allocated to our intangible assets and goodwill resulting from business combinations, which could be substantially impaired upon indications of impairment. Such non-cash impairments could have an adverse effect on our financial condition and the value of our assets.
- Clinical drug development involves a lengthy and expensive process with uncertain timelines and uncertain outcomes. The results of previous clinical trials may not be predictive of future results and clinical trials of product candidates may not be successful.
- If clinical trials of our product candidates are prolonged or delayed, we may be unable to obtain required regulatory approvals, and therefore be unable to commercialize our product candidates on a timely basis or at all.
- Clinical development, regulatory review and approval by the FDA, the EMA and comparable foreign regulatory authorities are lengthy, time consuming, expensive and inherently unpredictable activities. If we are ultimately unable to obtain regulatory approval for our product candidates, our business will be substantially harmed.

- We are likely to face significant competition and if our competitors develop and market products that are more effective, safer or less expensive than our product candidates, our commercial opportunities will be negatively impacted.
- We depend on licenses for development and commercialization rights to our products, product candidates and technologies. Termination of these rights or the failure to comply with obligations under these or other agreements under which we obtain such rights could materially harm our business and prevent us from developing or commercializing our products and product candidates.
- The success of our strategic partnerships and collaborations depends, to a significant degree, on the performance of our partners, over which we have little or no control.
- We rely on third parties to conduct our nonclinical and clinical trials and perform other tasks for us. If these third parties do not successfully carry out their contractual duties, meet expected deadlines, or comply with regulatory requirements, we may not be able to obtain regulatory approval for, or commercialize, our product candidates and our business could be substantially harmed.
- We currently rely on third-party suppliers and other third parties for production of our product candidates and our dependence on these third parties may impair the advancement of our research and development programs and the development of our product candidates.
- If we are unable to obtain and maintain sufficient intellectual property protection for our product or product candidates, or if the scope of our intellectual property protection is not sufficiently broad, our ability to commercialize our product and product candidates successfully and to compete effectively may be adversely affected.
- If we fail to attract and keep senior management and key scientific personnel, we may be unable to successfully develop our products, conduct our clinical trials and commercialize our product candidates.

Implications of Being an Emerging Growth Company

As a company with less than \$1.0 billion in revenue during our last fiscal year, we qualify as an “emerging growth company,” as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act. An emerging growth company may take advantage of specified reduced reporting and other burdens that are otherwise applicable generally to public companies. These provisions include:

- the ability to include only two years of audited financial statements and only two years of related Management’s Discussion and Analysis of Financial Condition and Results of Operations disclosure;
- an exemption from the auditor attestation requirement in the assessment of our internal control over financial reporting pursuant to the Sarbanes-Oxley Act of 2002, as amended, or the Sarbanes-Oxley Act; and
- to the extent that we no longer qualify as a foreign private issuer (1) reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements; and (2) exemptions from the requirements of holding a nonbinding advisory vote on executive compensation, including golden parachute compensation.

We may take advantage of these provisions for up to five years or such earlier time that we are no longer an emerging growth company. We would cease to be an emerging growth company if we have more than \$1.0 billion in annual revenue, have more than \$700 million in market value of our shares held by

non-affiliates, or issue more than \$1.0 billion of nonconvertible debt over a three-year period. We may choose to take advantage of some but not all of these reduced burdens. For example, Section 107 of the JOBS Act provides that an emerging growth company can use the extended transition period provided in Section 7(a)(2)(B) of the Securities Act of 1933, as amended, or the Securities Act, for complying with new or revised accounting standards. Given that we currently report and expect to continue to report under International Financial Reporting Standards, or IFRS, as issued by the International Accounting Standards Board, or IASB, we have irrevocably elected not to avail ourselves of this extended transition period and, as a result, we will adopt new or revised accounting standards on the relevant dates on which adoption of such standards is required by the IASB. We have taken advantage of reduced reporting requirements in this prospectus. Accordingly, the information contained herein may be different than the information you receive from other public companies in which you hold equity securities.

Implications of Being a Foreign Private Issuer

Upon consummation of this offering, we will report under the Securities Exchange Act of 1934, as amended, or the Exchange Act, as a non-U.S. company with foreign private issuer status. Even after we no longer qualify as an emerging growth company, as long as we qualify as a foreign private issuer under the Exchange Act, we will be exempt from certain provisions of the Exchange Act that are applicable to U.S. domestic public companies, including:

- the sections of the Exchange Act regulating the solicitation of proxies, consents or authorizations in respect of a security registered under the Exchange Act;
- the sections of the Exchange Act requiring insiders to file public reports of their stock ownership and trading activities and liability for insiders who profit from trades made in a short period of time; and
- the rules under the Exchange Act requiring the filing with the U.S. Securities and Exchange Commission, or SEC, of quarterly reports on Form 10-Q containing unaudited financial and other specified information, or current reports on Form 8-K, upon the occurrence of specified significant events.

Notwithstanding these exemptions, we will file with the SEC, within four months after the end of each fiscal year, or such applicable time as required by the SEC, an annual report on Form 20-F containing financial statements audited by an independent registered public accounting firm, and will submit to the SEC, on Form 6-K, unaudited quarterly financial information for the first three quarters of each fiscal year.

We may take advantage of these exemptions until such time as we are no longer a foreign private issuer. We would cease to be a foreign private issuer at such time as more than 50% of our outstanding voting securities are held by U.S. residents and any of the following three circumstances applies: the majority of our executive officers or directors are U.S. citizens or residents, more than 50% of our assets are located in the United States or our business is administered principally in the United States.

THE OFFERING

This summary highlights information contained elsewhere in this prospectus. This summary may not contain all the information that may be important to you, and we urge you to read this entire prospectus carefully, including the “Risk Factors,” “Business” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations” sections and our consolidated financial statements and notes to those statements, included elsewhere in this prospectus, before deciding to invest in the ADSs.

Issuer Biotie Therapies Corp.

ADSs offered by us 3,761,418 ADSs, representing 300,913,440 shares in the aggregate.

Offering price per ADS \$14.888.

Option to purchase additional ADSs . . . We have granted the underwriters an option to purchase up to an additional 44,629 ADSs from us, and UCB S.A., who we refer to as the selling shareholder, has granted the underwriters an option to purchase up to 519,583 ADS from it, within 30 days of the date of this prospectus in connection with the offering. We will not receive any proceeds from ADSs sold by the selling shareholder pursuant to the underwriters’ option to purchase additional ADSs.

American Depositary Shares Each ADS will represent 80 shares. As an ADS holder you will have the rights provided in the deposit agreement among us, the Depositary and holders and beneficial owners of ADSs from time to time. To better understand the terms of the ADSs, you should carefully read the section in this prospectus entitled “Description of American Depositary Shares.” We also encourage you to read the deposit agreement, which will be filed as an exhibit to the registration statement that includes this prospectus.

Depositary The Bank of New York Mellon.

Shares to be outstanding after this offering 977,281,615 shares, including the shares to be issued upon the automatic conversion of all outstanding convertible notes issued in connection with the Convertible Notes Financings and excluding the underwriters’ option to purchase additional ADSs.

Voting rights Each of our shares has one vote. Each ADS represents 80 shares.

NASDAQ listing	The ADS's have been approved for listing on the NASDAQ Global Select Market under the symbol "BITI."
Finnish Stock Exchange Listing	Our shares are listed on the NASDAQ OMX Helsinki Ltd. under the symbol "BTH1V."
Use of proceeds	We estimate that we will receive net proceeds of approximately \$49.1 million (€43.5 million), assuming the offering information described above, after deducting the underwriting discounts and commissions and estimated offering expenses payable by us (\$49.7 million (€44.1 million) if the underwriters exercise in full their option to purchase additional ADSs). We intend to use the net proceeds from this offering, together with a portion of our current liquid assets (which subsequent to March 31, 2015 includes \$33.5 million (€30.3 million) in net proceeds from the Convertible Notes Financings) to fund our Phase 3 double-blind clinical trial (and extension) of tozadenant in Parkinson's through completion, which we expect to require an investment of approximately €75 million, including all related studies that will be performed. We intend to fund the SYN120 Phase 2a clinical trial in Parkinson's dementia and the BTT1023 Phase 2 clinical trial in PSC, which we expect to cost approximately €5 million in total, and other working capital requirements, with our remaining liquid assets, milestone and royalty revenues from Lundbeck for Selincro, and already identified non-dilutive sources. We will not receive any proceeds from ADSs sold by the selling shareholder pursuant to the underwriters' option to purchase additional ADSs. See "Use of Proceeds."
Dividend policy	We have not declared or paid any cash dividends on our shares since our incorporation and do not currently intend to pay cash dividends on our shares, as we do not expect to have distributable reserves that would enable us to pay a dividend, in the foreseeable future. Currently, we have not adopted a dividend policy. We intend to retain all available funds and any future earnings to fund the development and expansion of our business. Even if our board of directors decides to propose dividends in the future, the form, frequency and amount of such dividends will depend upon our future operations and earnings, capital requirements and surplus, general financial condition, contractual restrictions and other factors our board of directors may deem relevant. The terms of our capital loans may restrict our ability to pay dividends in the future. We did not have distributable assets as of March 31, 2015.
Lock-up agreements	We have agreed with the underwriters, subject to certain exceptions, not to offer, sell, or dispose of any of our share capital or securities

convertible into or exchangeable or exercisable for any of our share capital during the 180-day period following the date of this prospectus. Members of our board of directors and our senior management, as well as certain of our shareholders, have agreed to substantially similar 180-day lock-up provisions, subject to certain exceptions. The selling shareholder has agreed to the same provisions for a 30-day period following the date of this prospectus.

Risk factors See “Risk Factors” and the other information included in this prospectus for a discussion of factors you should consider before deciding to invest in the ADSs.

Except as otherwise indicated herein, in this prospectus the number of our outstanding shares after this offering is based on 455,968,174 shares outstanding as of March 31, 2015, including 452,272,890 shares with voting rights and 3,695,284 treasury shares that are held by us and that we cannot vote, and includes 300,913,440 shares to be issued by us in this offering and 220,400,001 shares to be issued by us upon the automatic conversion of all outstanding convertible notes issued in connection with the Convertible Notes Financings upon the completion of this offering, as described below in “Management’s Discussion and Analysis of Financial Condition and Results of Operation — Subsequent Events — The Convertible Notes Financings” but excludes (as of March 31, 2015):

- a maximum of 2,824,772 shares issuable upon exercise of options outstanding pursuant to our Swiss option scheme, at a weighted-average exercise price of €0.24 per share, and which will be settled from the current treasury shares held by us;
- a maximum of 2,678,000 shares issuable upon the exercise of options outstanding pursuant to our stock option plan 2011, at an exercise price of €0.01 per share, and of which a maximum of 720,500 shares will be settled from the current treasury shares held by us;
- a maximum of 945,000 shares issuable upon the settlement of share units outstanding pursuant to our equity incentive plan 2011, at a subscription price of nil, a maximum of 150,000 shares of which will be settled from the current treasury shares held by us;
- a maximum of 7,412,000 shares issuable upon the exercise of options outstanding pursuant to our stock option plan 2014, at an exercise price of €0.01 per share, of which a maximum of 4,320,000 shares are subject to a market-related performance condition at the time of vesting;
- a maximum of 6,328,750 shares issuable upon the settlement of share units outstanding pursuant to our equity incentive plan 2014, at a subscription price of the euro equivalent of \$0.01 per share, of which 2,520,000 share units are subject to a market-related performance condition at the time of settlement;
- a maximum of 9,409,250 shares issuable upon the exercise of share options and settlement of share units that may be, but have not yet been, granted pursuant to our stock option plan 2014 and our equity incentive plan 2014, at a subscription price of €0.01 and the euro equivalent of \$0.01 respectively;
- the number of shares that would be issuable upon the exercise of our right to offer shares to be subscribed or purchased by YA Global Master SPV Ltd. pursuant to the Standby Equity Distribution Agreement, or the SEDA, which at March 31, 2015, could be for a maximum value of €20.0 million; for more information on the SEDA, see “Description of Share Capital and Articles of Association — Share Capital — Standby Equity Distribution Agreement”;

- 828,000 shares issuable upon conversion of the outstanding convertible capital loan as of March 31, 2015, at a conversion rate of €1.8688 per share for 540,000 of the shares and €2.3359 for 288,000 of the shares; and
- a maximum of 220,400,001 shares issuable upon the exercise of warrants outstanding as of May 28, 2015 at an exercise price of €0.17 per share.

Unless otherwise indicated, all information contained in this prospectus also reflects and assumes:

- the automatic conversion of all outstanding convertible notes issued in connection with the Convertible Notes Financings into 220,400,001 shares upon the closing of this offering;
- no exercise, settlement or vesting of options or share units after March 31, 2015;
- no conversion of the convertible capital loan;
- no exercise of our right to offer shares under the SEDA (described above) after March 31, 2015; for the time being, we do not intend to use this instrument;
- an initial public offering price of \$14.888 per ADS, a share to ADS ratio of 80 to 1 and an exchange rate of \$1.1279 per euro; and
- no exercise by the underwriters of their option to purchase up to an additional 44,629 ADSs from us and 519,583 ADSs from the selling shareholder within 30 days of the date of this prospectus in connection with the offering.

Certain of our existing investors and members of our board of directors have indicated an interest in purchasing up to an aggregate of \$17 million of the ADSs in this offering at the public offering price. However, because indications of interest are not binding agreements or commitments to purchase, these entities and persons may determine to not purchase any ADSs in this offering. It is also possible that these entities and persons and additional existing investors could indicate an interest in purchasing more of the ADSs. In addition, the underwriters could determine to sell fewer ADSs to any of these entities or persons than such entities or persons indicate an interest in purchasing or to not sell any ADSs to these entities and persons.

SUMMARY FINANCIAL AND OTHER INFORMATION

The consolidated statements of comprehensive income data (except for the unaudited pro forma loss per share, pro forma information and pro forma as adjusted information) for each of the years ended December 31, 2014 and 2013 have been derived from our audited consolidated financial statements included elsewhere in this prospectus. The consolidated statements of comprehensive income data (except for the unaudited pro forma loss per share, pro forma information and pro forma as adjusted information) for each of the three-month periods ended March 31, 2015 and 2014 and the summary consolidated statement of financial position data as of March 31, 2015 have been derived from our unaudited condensed consolidated financial statements included elsewhere in this prospectus. The unaudited condensed financial statements have been prepared on the same basis as the audited financial statements and, in the opinion of management, reflect all adjustments necessary to state fairly our results of operations for the three months ended March 31, 2015 and 2014 and our financial position as of March 31, 2015. The summary consolidated financial information below should be read in conjunction with our consolidated financial statements, including the notes thereto, included elsewhere in this prospectus as well as the “Presentation of Financial and Other Information” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations” sections of this prospectus.

Our audited consolidated financial statements for the years ended December 31, 2014 and 2013 and our unaudited condensed consolidated financial statements for the three-month periods ended March 31, 2015 and 2014 have been prepared in accordance with IFRS as issued by the IASB.

Our historical results are not necessarily indicative of our future results. The summary financial information below does not contain all the information included in our financial statements. In addition, our historical results for the three months ended March 31, 2015 are not necessarily indicative of results to be expected for a full year or any other interim period.

On April 23, 2015 and May 7, 2015, we and certain new and existing investors entered into agreements pursuant to which such investors subscribed for €27.5 million and €5.6 million, respectively, of our non-interest bearing, convertible promissory notes, respectively, and received warrants exercisable for our shares on May 28, 2015. The convertible notes may be converted by their holders into our shares at a conversion price of €0.15 per share at any time prior to the repayment of the convertible notes, which must occur on or after May 1, 2035. Furthermore, the convertible notes mandatorily convert into new shares upon the completion of this offering. If this offering is not completed by May 1, 2016, we may force the conversion of the outstanding convertible notes at any time thereafter until May 1, 2035. The warrants entitle the holder to subscribe for our shares from November 1, 2015 until November 1, 2020 at a fixed conversion price of €0.17 per share. We refer to these transactions herein as the Convertible Notes Financings. For further information, see “Management’s Discussion and Analysis of Financial Condition and Results of Operation—Subsequent Events—The Convertible Notes Financings.”

Consolidated Statements of Comprehensive Income Data

	Year Ended December 31,		Three Months Ended March 31,	
	2014	2013	2015	2014
(€ thousands, except per share data)			(unaudited)	
Revenue	14,901	27,712	871	5,096
Research and development expenses	(17,192)	(17,807)	(4,766)	(4,803)
Impairment of in-process research and development assets	(27,605)	—	—	—
General and administrative expenses	(7,326)	(8,971)	(1,730)	(1,950)
Other operating income	1,132	565	—	135
Operating (loss) income	(36,090)	1,499	(5,625)	(1,522)
Interest income	—	37	1	—
Interest expenses	(687)	(726)	(151)	(152)
Other net financial income (expenses)	1,612	2,841	(119)	(45)
(Loss) income before taxes	(35,165)	3,651	(5,894)	(1,719)
Income tax benefit	—	2,195	—	—
Net (loss) income	(35,165)	5,846	(5,894)	(1,719)
Other comprehensive income (loss)				
Remeasurements of post-employment benefit obligations	(81)	—	—	—
Currency translation differences	6,593	(2,629)	8,181	315
Total comprehensive (loss) income	(28,653)	3,217	2,287	(1,404)
Net (loss) income attributable to equity holders of the parent	(35,165)	5,846	(5,894)	(1,719)
Total comprehensive (loss) income attributable to equity holders of the parent	(28,653)	3,217	2,287	(1,404)
(Loss) earnings per share (EPS) basic & diluted(1)	(0.08)	0.01	(0.01)	(0.00)
Pro forma (loss) earnings per share (EPS) basic & diluted(1)(2)	(0.05)	0.01	(0.00)	(0.00)

- (1) Basic and diluted (loss) earnings per share are the same in all periods because outstanding options, share units and the convertible loan would have been anti-dilutive for the year ended December 31, 2014 and for the three months ended March 31, 2015 and 2014. Dilutive shares had no impact on EPS after rounding for the year ended December 31, 2013.
- (2) The unaudited pro forma (loss) earnings per share (EPS) basic & diluted data gives effect to the Convertible Notes Financings. The pro forma information is presented for informational purposes only and is not necessarily indicative of what our results would have been had the conversion of the convertible notes actually occurred at such date nor is it indicative of our future performance.

Consolidated Statement of Financial Position Data

The table below presents a summary of our actual balance sheet data and pro forma balance sheet data as of March 31, 2015:

	As at March 31, 2015		
	Actual	Pro Forma(1)	Pro Forma As Adjusted(2)
		(€ thousands)	
Cash and cash equivalents	6,315	36,662	80,177
Shareholders' equity			
Share capital(1)(2)	193,285	223,700	267,214
Reserve for invested unrestricted equity	5,389	5,389	5,389
Other reserves	17,210	17,210	17,210
Retained earnings	(160,789)	(160,789)	(160,789)
Total shareholders' equity	55,095	85,510	129,024

- (1) The unaudited pro forma balance sheet data gives effect to the Convertible Notes Financings and the automatic conversion of the convertible notes issued in the Convertible Notes Financings into shares. For pro forma purposes, we have preliminarily evaluated the accounting for the convertible notes and warrants and expect that the subscription price will be recorded in full in equity as share capital in accordance with the Finnish Companies Act, net of transaction costs, as the instruments will be settled in our shares based on a fixed conversion ratio. As a result, the net proceeds from the convertible notes will result in an increase of cash of approximately €30.3 million with a corresponding amount recorded in share capital at issuance.
- (2) The unaudited pro forma as adjusted balance sheet data gives effect to the following transactions: (i) the Convertible Notes Financings; (ii) the automatic conversion of the convertible notes issued in connection with the Convertible Notes Financings upon the completion of this offering into shares; and (iii) the issuance and sale of 3,761,418 ADSs in this offering at an initial public offering price of \$14.888 per ADS, a share to ADS ratio of 80 to 1 and an exchange rate of \$1.1279 per euro, after deducting estimated underwriting discounts and commissions and offering expenses payable by us, as set forth under "Use of Proceeds"; and excludes the underwriters' option to purchase additional ADSs.

The pro forma as adjusted information is presented for informational purposes only and is not necessarily indicative of what our financial position and results would have been had these transactions actually occurred at such date nor is it indicative of our future financial position or performance.

The pro forma as adjusted data does not reflect the effects of the conversion of the warrants, which are exercisable into 220,400,001 of our shares at an exercise price of €0.17 for proceeds of €37.5 million.

RISK FACTORS

You should carefully consider the risks and uncertainties described below and the other information in this prospectus before making an investment in the American Depositary Shares, or ADSs. Our business, financial condition or results of operations could be materially and adversely affected if any of these risks occurs, and as a result, the market price of the ADSs could decline and you could lose all or part of your investment. This prospectus also contains forward-looking statements that involve risks and uncertainties. See “Cautionary Statement Regarding Forward-Looking Statements.” Our actual results could differ materially and adversely from those anticipated in these forward-looking statements as a result of certain factors.

Risks Related to Our Financial Position

We have incurred net losses since our inception and anticipate that we will continue to incur substantial operating losses for the foreseeable future.

We are a developmental stage company with a history of operating losses. With the exception of the year ended December 31, 2013, we have never been profitable and have incurred losses in each year since our inception. Although we made a profit in 2013, this was primarily due to a nonrefundable development milestone payment received from UCB Pharma S.A., or UCB, for tozadenant, which cannot be expected to recur in the future. Our net results were a €35.2 million loss and a €5.8 million profit for the years ended December 31, 2014 and 2013, respectively. As of March 31, 2015, we had retained earnings, which were an accumulated deficit, of €160.8 million. Substantially all of our losses have resulted from funding our research and development programs and general and administrative costs associated with our operations. Our marketed product, Selincro, received European marketing authorization in 2013, but it is still in the early stages of commercialization and a reliable revenue stream will depend on the ability of our partner, H. Lundbeck A/S, or Lundbeck, to successfully grow sales of Selincro. The remainder of our pipeline products, including our lead product candidate, tozadenant, are still in the clinical development phase and we are preparing to commence a pivotal Phase 3 trial of tozadenant.

We have devoted most of our financial resources to research and development, including our clinical and preclinical development activities, and will continue to do so for the foreseeable future. To date, we have mainly funded our operations through private placements of equity securities, nonconvertible and convertible capital loans, long-term research and development loans, development milestone payments, milestone payments under our license and commercialization agreement with Lundbeck, or the Lundbeck License Agreement, and, most recently, royalties under the Lundbeck License Agreement, and a number of trials of product candidates have been partially or wholly funded through non-dilutive funding. The amount of our future net losses will depend, in part, on the rate of our future expenditures, our ability to obtain additional funding and the relative levels of milestone payments and royalties on sales of Selincro from Lundbeck. We expect to continue to incur significant expenses and net losses for at least the next several years. Our research and development expenses may vary from period to period based on the timing of our research and development activities, including due to timing of initiation of clinical trials and enrollment of patients in clinical trials. Product candidates in later stages of clinical development generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials. We expect our research and development expenses to increase for the foreseeable future as our product candidates progress in clinical trials. In particular, research and development expenses are expected to increase as we advance the clinical development of tozadenant. The successful development of our product candidates is highly uncertain. At this time we cannot reasonably estimate the nature, timing or costs of the efforts that will be necessary to complete the development of, or the period, if any, in which material net cash inflows may commence from, any of our product candidates.

Because of the numerous risks and uncertainties associated with pharmaceutical product development, we are unable to accurately predict the timing or amount of increased expenses or when, or if, we will be able to achieve profitability.

We may never achieve or sustain profitability.

Our ability to achieve net profits in the future will depend on, among other factors, whether or not we can successfully develop our product candidates into marketable drugs and obtain necessary regulatory approvals, and on the ability of our partner Lundbeck to successfully grow sales of Selincro. Even if one or more of the product candidates that we develop is approved for commercial sale, we anticipate incurring significant costs associated with commercializing any approved product candidate. Our operations and financial condition have been, and will likely continue to be, dependent on our ability to find suitable partners that have the capacity to participate in, or take over, any or all late stage clinical trials, manufacturing and marketing of our product candidates. Assuming the successful product development and regulatory approval of our product candidates by the relevant authorities, our ability to generate revenue depends on the acceptance of the products by physicians and patients. The market acceptance of any product depends on a number of factors, including the continued demonstration of efficacy and safety in commercial use, cost-effectiveness, convenience and ease of administration, ability to supply sufficient quantities of product to the market, competition, adverse or favorable publicity, governmental efforts to reduce health care costs or reform government health care programs and marketing and distribution support. Our future results may vary significantly due to the potential, or the absence of, forthcoming upfront and development and commercial milestone payments related to the commercialization of our development products.

We may not succeed in these activities, and we may never generate revenue from product sales that is significant enough to achieve profitability. Even if we achieve profitability in the future, we may not be able to sustain profitability in subsequent periods. Our failure to become or remain profitable could impair our ability to raise capital, expand our business, discover or develop other product candidates or otherwise adversely affect our business and operations. A decline in the value of our company could cause you to lose all or part of your investment.

We cannot assure you of the adequacy of our capital resources, including the proceeds from this offering, to successfully complete the development and commercialization of our product candidates, and a failure to obtain additional capital, if needed, could force us to delay, limit, reduce or terminate our product development or commercialization efforts.

As of March 31, 2015, we had liquid assets amounting to €27.8 million. We define “liquid assets” as cash and cash equivalents together with our financial assets at fair value through profit or loss, which consist of money market funds. We believe that we will continue to expend substantial resources for the foreseeable future developing tozadenant and our other product candidates. These expenditures will include costs associated with research and development, conducting preclinical studies and clinical trials, seeking regulatory approvals, as well as launching and commercializing products approved for sale, if any, and potentially acquiring new products. In addition, other unanticipated costs may arise. Because the outcome of our anticipated clinical trials is highly uncertain, we cannot reasonably estimate the actual amounts necessary to successfully complete the development and commercialization of our product candidates. Based on our current operating plan, we believe that the net proceeds of this offering, together with our current liquid assets and the milestone and royalty revenues that we expect to receive from Lundbeck for Selincro, will enable us to fund our Phase 3 double-blind clinical trial (and extension) of tozadenant in Parkinson’s through completion, as well as our portion of the costs of the SYN120 Phase 2a clinical trial in Parkinson’s dementia and the BTT1023 Phase 2 clinical trial in PSC. We intend to fund the remaining

portion of these trials from already identified non-dilutive sources. We have based this estimate on assumptions that may prove to be incorrect, and we could expend our capital resources sooner than we currently expect.

Our future funding requirements will depend on many factors, including but not limited to:

- the numerous risks and uncertainties associated with developing drugs;
- the level of Selincro sales achieved by Lundbeck and Lundbeck's ability to obtain regulatory approvals in additional countries, which will affect the amount of milestones and royalties that we receive;
- the number and characteristics of product candidates that we pursue;
- the rate of enrollment, progress, cost and outcomes of our clinical trials, which may or may not meet their primary end-points, and other related activities;
- the timing of, and cost involved in, conducting nonclinical studies that are regulatory prerequisites to conducting clinical trials of sufficient duration for successful product registration;
- the cost of manufacturing clinical supplies and establishing commercial supplies of our product candidates;
- the timing of, and the costs involved in, obtaining regulatory approvals for tozadenant and our other product candidates if clinical trials are successful;
- the timing of, and costs involved in, conducting post-approval studies that may be required by regulatory authorities;
- the cost of commercialization activities for tozadenant and our other product candidates, if any of our product candidates are approved for sale;
- the terms and timing of any collaborative, licensing, and other arrangements that we may establish, including any required milestone and royalty payments thereunder and any non-dilutive funding that we may receive;
- the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing patent claims, including litigation costs, if any, and the outcome of any such litigation; and
- the timing, receipt, and amount of sales of, or royalties on, our future products, if any.

In addition, our operating plan may change as a result of many factors currently unknown to us. As a result of these factors, we may need additional funds sooner than planned. We expect to finance future cash needs primarily through a combination of public or private equity offerings, debt financings, strategic collaborations and non-dilutive funding. If sufficient funds on acceptable terms are not available when needed, or at all, we could be forced to significantly reduce operating expenses and delay, scale back or eliminate one or more of our development programs.

The adequacy of our capital resources is particularly dependent on cash generation from milestones and royalties in connection with sales of Selincro and other sources of non-dilutive funding.

Under the terms of our November 2006 option agreement with Lundbeck and the Lundbeck License Agreement, to date we have received €22.0 million in upfront and milestone payments and are eligible to receive an additional potential €72.0 million in milestone payments upon achievement of specified regulatory and commercial milestones. In addition to milestone payments, we are eligible to receive

royalties on sales of Selincro. The payment of milestone payments and royalties under the Lundbeck License Agreement is dependent on a combination of factors, including the successful registration of Selincro for alcohol dependence in non-European countries, the successful registrations of Selincro in indications other than alcohol dependence and the level of sales of Selincro, which is partly dependent on the first two factors. We expect to use the milestone payments and royalty revenues that we receive from Selincro to partially fund our planned Phase 3 clinical program for tozadenant and clinical trials of our other product candidates. Lundbeck's commercialization of Selincro is entirely outside of our control and we cannot assure you that we will receive further milestone payments and/or royalties. If we do not receive the levels of milestone payments and royalties that we expect to receive, we cannot assure you that we will be able to fully fund our planned Phase 3 program for tozadenant or clinical activity of our other product candidates, and we may have to raise additional capital.

In July 2014, we announced that we received a grant of up to \$2.0 million (€1.7 million) from the Michael J. Fox Foundation for Parkinson's Research, or the Michael J. Fox Foundation, to investigate SYN120 in Parkinson's dementia. Under the terms of the Michael J. Fox Foundation grant, we are subject to a repayment obligation and must pay the Michael J. Fox Foundation royalties on sales of SYN120-related products after such products reach a specified threshold of net sales, until we reach the royalty cap of the amount of award payments actually received, adjusted for inflation at the time of payment. The Michael J. Fox Foundation will largely fund an 80-patient, Phase 2a, randomized, double-blind, placebo-controlled trial of 16 weeks duration in patients with Parkinson's dementia, which will be conducted by the Parkinson Study Group. We are working in collaboration with the University of Birmingham to conduct a Phase 2 proof of concept clinical trial with BTT1023 in PSC. The investigator-sponsored clinical trial has been awarded partial funding from the U.K. National Institute of Health Research. As such, we have gained access to non-dilutive sources of funding to support our two Phase 2 clinical programs. We intend to continue to pursue additional sources of non-dilutive funding through our relationships with government, not-for-profit organizations and other partners, but cannot assure you that we will be able to maintain this funding or obtain similar funding in future. Further, an inability to meet conditions required for receiving grants, possible obligations to pay back certain or entire amounts of such grants or the unavailability of grants in the future may have a material adverse effect on our business results or operations and financial condition.

Raising additional capital may cause dilution to our existing shareholders, restrict our operations or require us to relinquish, or license on unfavorable terms, our rights to our product candidates and may impact any future potential revenue streams.

If our current liquid assets and the proceeds of this offering are insufficient to meet our operating requirements, we may seek additional capital through a variety of means, including through private and public equity offerings and debt financings. Although Finnish law provides existing shareholders with preemptive rights to subscribe for shares offered in proportion to the amount of shares in their possession in connection with any new offering of shares, this right is subject to waiver resolved upon by a majority which represents at least two-thirds of the votes cast and two-thirds of the shares represented at a shareholders' meeting, provided that, from the company's perspective, there is a weighty financial reason for the waiver. In addition, certain non-Finnish shareholders may not be able to exercise their preemptive subscription rights in any future offerings due to the legislation and regulations of their home country, including U.S. shareholders. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest may be diluted, and the terms of such equity or convertible debt securities may include liquidation or other preferences that are senior to or otherwise adversely affect your rights as a shareholder. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take certain actions, such as incurring additional debt,

making capital expenditures, declaring dividends or encumbering our assets to secure future indebtedness. If we are unable to raise additional capital when required or on acceptable terms, we may be required to:

- significantly delay, scale back or discontinue the development, manufacturing scale-up or commercialization of our product candidates;
- seek corporate partners on terms that are less favorable than might otherwise be available; or
- relinquish or license on unfavorable terms our rights to our product candidates that we otherwise would seek to develop or commercialize ourselves.

Any such consequence may have a material adverse effect on our business, operating results and prospects and on our ability to develop our product candidates.

In connection with the Convertible Notes Financings we have indemnification obligations to certain investors pursuant to the subscription agreement with such investors. These obligations could subject us to substantial liabilities.

In connection with the Convertible Notes Financings, we entered into a subscription agreement with certain investors pursuant to which we are obligated to indemnify such investors against damages arising from, among other things, our breach or alleged breach of any of our representations or warranties contained in the subscription agreement and any of our obligations under the subscription agreement. If we are required to indemnify the investors under the circumstances set forth in the subscription agreement, we may be subject to substantial liabilities. The maximum potential amount of such liabilities is the aggregate consideration paid by the investors party to the subscription agreement, or €27.5 million.

Impairment charges or write-downs on our assets could have a significant adverse effect on our results of operations and financial results.

Substantial value is allocated to our intangible assets and goodwill resulting from business combinations, which could be substantially impaired upon indications of impairment. Indications of impairment may primarily arise when: the clinical program for an asset does not proceed as expected, a different clinical development pathway is pursued than initially intended, the asset is partnered or out-licensed utilizing a transaction structure that changes the timing or amount of our future economic rights to the asset, or some of the economic value from the asset is realized. As a result, impairment testing could lead to additional material impairment charges in the future that could have an adverse effect on our financial condition and the value of our assets.

We regularly review our long-lived intangible and tangible assets, including identifiable intangible assets and goodwill, for impairment. Goodwill, acquired research and development, and acquired development projects not yet ready for use are subject to impairment review at least annually. Impairment testing under International Financial Reporting Standards, or IFRS, may lead to impairment charges in the future. Any significant impairment charges could have a material adverse effect on our results of operations and financial condition. In 2014, for example, we recognized impairment charges totaling €27.6 million in relation to nepicastat, which was fully written down as a result of the receipt of top-line data that did not meet its primary efficacy endpoint in respect of the Phase 2a trial, and SYN120, which was written down to its recoverable amount, as a result of a revision to our plans to develop SYN120 for Parkinson's dementia, which has smaller commercial potential than Alzheimer's. For a detailed discussion of how we determine whether an impairment has occurred, what factors could result in an impairment and the increasing impact of impairment charges on our results of operations, see "Business — Critical Accounting Estimates and Judgments of Our Management — Critical Accounting Estimates and Judgments — Impairment of Intangible Assets and Goodwill" and note 2 to our consolidated financial statements included elsewhere in this prospectus.

We are exposed to risks related to currency exchange rates.

We conduct a significant portion of our operations outside Finland and other eurozone countries, principally in the United States. Because our financial statements are presented in euros, changes in currency exchange rates have had and could have a significant effect on our operating results. Exchange rate fluctuations between local currencies and the euro create risk in several ways, including the following: weakening of the euro may increase the euro cost of our research and development expenses, which are principally in United States dollars; strengthening of the euro may decrease the value of our revenues denominated in other currencies; and the exchange rates on non-euro transactions and cash deposits can distort our financial results. In addition, in the next few years we expect to receive the majority of revenues (royalties from sales of Selincro) in euros and that the majority of our expenditure (continuing research and development expenses) will be incurred United States dollars, which may cause an impact on our financial results to the extent those revenues are used to fund those expenses.

Risks Related to the Development and Clinical Testing of Our Product Candidates

We depend significantly on the success of tozadenant and our other product candidates. Tozadenant and our other product candidates are still in clinical development. If our clinical trials are not successful, we do not obtain regulatory approval or we are unable, or unable to find a partner, to commercialize tozadenant or our other product candidates, or we experience significant delays in doing so, our business, financial condition and results of operations will be materially adversely affected.

We have invested a significant portion of our efforts and financial resources in the development of tozadenant, SYN120 and BTT1023, all of which are still in clinical development. Our ability to generate revenues from these product candidates, which we do not expect will occur for at least the next several years, if ever, will depend heavily on successful clinical development, obtaining regulatory approval and eventual commercialization of them. We cannot assure you that we will be able to successfully develop or commercialize our product candidates or any future product candidates. The potential success of tozadenant, particularly in the United States, is initially dependent on the success of our pivotal Phase 3 clinical trial.

More generally, the success of tozadenant, SYN120 and BTT1023 will depend on several factors, including the following:

- completing clinical trials that demonstrate the efficacy and safety of our product candidates;
- receiving marketing approvals from applicable regulatory authorities;
- establishing relationships for commercial manufacturing capabilities;
- launching commercial sales, marketing and distribution operations;
- acceptance of our product candidates by patients, the medical community and third-party payors;
- a continued acceptable safety profile following approval;
- competing effectively with other therapies; and
- qualifying for, maintaining, enforcing and defending our intellectual property rights and claims.

If we do not achieve one or more of these factors in a timely manner or at all, we could experience significant delays or an inability to obtain approval for and/or to successfully commercialize tozadenant, SYN120 or BTT1023, which would materially adversely affect our business, financial condition and results of operations.

Clinical drug development involves a lengthy and expensive process with uncertain timelines and uncertain outcomes.

To obtain the requisite regulatory approvals to market and sell any of our product candidates, we must demonstrate through extensive preclinical studies and clinical trials that our products are safe and effective in humans. To date, we have not completed all preclinical studies or clinical trials required for the approval of our product candidates (other than our approved product Selincro). We are preparing to commence a pivotal Phase 3 trial of tozadenant. We would not expect to have data for our Phase 3 double-blind clinical trial (and extension) of tozadenant until the second half of 2017 and would not be able to submit a new drug application, or NDA, until adequate safety data has been obtained from the open-label trial of the Phase 3 program. In addition to tozadenant, together with the Parkinson Study Group, we are currently conducting a Phase 2a trial of SYN120 in Parkinson's dementia and expect to announce top-line data by the end of 2016. A potential Phase 2 clinical trial of SYN120 in Alzheimer's is dependent on obtaining additional funding. Enrollment for the Phase 2 clinical trial of BTT1023 in PSC opened at the end of the first quarter of 2015, and interim data is expected by the end of 2016.

Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. This is due to numerous risks and uncertainties associated with developing drugs, including the uncertainty of:

- the rate of enrollment, progress, cost and outcomes of our clinical trials, which may or may not meet their primary end-points, and other related activities;
- the number and characteristics of product candidates that we pursue;
- the cost of manufacturing clinical supplies, and establishing commercial supplies, of our product candidates and any products that we may develop;
- the timing of, and cost involved in, conducting nonclinical studies that are regulatory prerequisites to conducting clinical trials of sufficient duration for successful product registration;
- the timing of, and the costs involved in, obtaining regulatory approvals for tozadenant and our other product candidates if clinical trials are successful;
- the cost of commercialization activities for tozadenant and our other product candidates, if any of our product candidates are approved for sale;
- the terms and timing of any collaborative, licensing, and other arrangements that we may establish, including any required milestone and royalty payments thereunder;
- the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing patent claims, including litigation costs and the outcome of such litigation; and
- the timing, receipt, and amount of sales of, or royalties on, our future products, if any.

A change in the outcome of any of these variables with respect to the development of tozadenant or our other product candidates could mean a significant change in the costs and timing associated with the development of such product candidate. Failure can occur at any time during the clinical trial process. Clinical trials must be conducted in accordance with U.S. Food and Drug Administration, or the FDA, European Medicines Agency, or the EMA and comparable foreign regulatory authorities' legal requirements, regulations or guidelines, and are subject to oversight by these governmental agencies and Institutional Review Boards, or IRBs, at the medical institutions where the clinical trials are conducted. In addition, clinical trials must be conducted with supplies of our product candidates produced under current good manufacturing practices, or cGMP, and other requirements. We depend on medical institutions and

clinical research organizations, or CROs, as well as on investigators and sponsors with which we collaborate on investigator-sponsored trials, such as the investigators and sponsors conducting the Phase 2a clinical trial of SYN120 in Parkinson's dementia and the Phase 2 clinical trial of BTT1023 in PSC, to conduct our clinical trials in compliance with current good clinical practice, or cGCP, standards. To the extent these medical institutions or CROs fail to enroll participants for our clinical trials or conduct the trial to cGCP standards or are delayed for a significant time in the execution of trials, including achieving full enrollment, we may be affected by increased costs, program delays or both, which may harm our business.

The results of previous clinical trials may not be predictive of future results and clinical trials of product candidates may not be successful.

Clinical failure can occur at any stage of clinical development. Clinical trials may produce negative or inconclusive results, and we or any of our current and future collaborators may decide, or regulators may require us, to conduct additional clinical or preclinical testing. We will be required to demonstrate with substantial evidence through well-controlled clinical trials that our product candidates are safe and effective for use in the intended treatment population before we can seek regulatory approvals for their commercial sale. The results of preclinical studies and early clinical trials of our product candidates may not be predictive of the results of later-stage clinical trials and future preclinical studies and the positive results generated to date in clinical trials for our product candidates do not ensure that later clinical trials will demonstrate similar results. For example, our prior product candidate under development for cocaine development, nepicastat, showed positive results in preclinical studies and an earlier clinical trial, but failed to distinguish from placebo in a Phase 2a clinical trial where it did not meet the primary efficacy endpoint of an increased proportion of subjects remaining abstinent from cocaine during the last two weeks of the treatment period. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through preclinical studies and initial clinical trials. For example, preladenant, another adenosine A_{2a} antagonist developed by Merck & Co., or Merck, demonstrated efficacy in a Phase 2b trial in Parkinson's patients experiencing OFF episodes on levodopa. However, in May 2013, Merck announced that it was discontinuing preladenant development due to a lack of efficacy demonstrated in three different Phase 3 trials, including two in Parkinson's patients with motor fluctuations. Product candidates that have shown promising results in early clinical trials may still suffer significant setbacks in subsequent clinical trials. A number of companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier trials. Further, progress in trials of one product candidate does not indicate that we will make similar progress in additional trials for that product candidate or in trials for our other product candidates. Furthermore, our Phase 2b trial evaluated the efficacy of tozadenant during a 12 week trial while our planned Phase 3 trial will evaluate efficacy over a 24 week period. In addition, patients will be taking tozadenant for nearly 18 months, considerably longer than in our previous trials. We cannot assure you that the efficacy and safety seen in previous trials will continue to be observed in trials of longer duration or with other trial design differences. Our future clinical trials may not be successful.

The success of tozadenant and our other product candidates initially depends on our ability to complete clinical trials that demonstrate the efficacy and safety of our product candidates. We cannot assure you that any Phase 2, Phase 3 or other clinical trials that we may conduct will demonstrate consistent or adequate efficacy and safety to obtain regulatory approval to market our product candidates.

If we are unable to successfully complete clinical trials of our product candidates or other testing, if the results of these trials or tests are unfavorable or are only modestly favorable or if there are safety concerns associated with tozadenant, BTT1023, SYN120 or any other product candidates we may decide to develop in the future, or if we are required to conduct additional clinical trials or other testing of tozadenant, SYN120, BTT1023 or any other product candidate that we may develop in future beyond the trials and testing that we contemplate, we may:

- be delayed in obtaining marketing approval for our product candidates;
- not obtain marketing approval at all;
- obtain approval for indications or patient populations that are not as broad as intended or desired;
- obtain approval with labeling that includes significant use or distribution restrictions or significant safety warnings, including boxed warnings;
- be subject to additional post-marketing testing or other requirements; or
- remove the product from the market after obtaining marketing approval.

The design and conduct of a clinical trial can determine whether its results will support approval of a product and flaws in the design of a clinical trial may not become apparent until the clinical trial is well advanced or completed.

In some instances, there can be significant variability in safety and/or efficacy results between different trials of the same product candidate due to numerous factors, including changes in trial procedures set forth in protocols, differences in the size and type of the patient populations, patient adherence to the dosing regimen and other trial protocols and the rate of dropout among clinical trial participants. In the case of any Phase 3 trials we conduct, results may differ from earlier trials due to the larger number of clinical trial sites and additional countries and languages involved in such trials. For example, in the recent Merck trials of praladenant in a similar Parkinson's population to that which we will evaluate in our Phase 3 trial of tozadenant, rasagiline, an approved drug that has consistently demonstrated efficacy in a number of trials in this population, was used as a positive control and also failed to demonstrate efficacy, suggesting the trials were flawed. A published post-hoc analysis identified a number of factors that potentially contributed to the trial failure. Based on our review of those factors we decided to limit trial conduct for tozadenant to North America and selected European countries, limit the number of trial sites, institute measures to monitor how patients will be identified and selected for enrollment and how both the investigators and patients are trained. While we believe these factors are critical in ensuring good trial design and conduct, we cannot assure you that our planned Phase 3 trial design or conduct will yield results that demonstrate the efficacy or safety of tozadenant or that any such results will be sufficient to support approval.

In addition, in the case of tozadenant, our Phase 2b clinical trial included, and our Phase 3 clinical trial will include, certain endpoints based on patient reported outcomes, some of which are captured daily from trial participants with diaries. Low compliance by patients in maintaining an accurate diary may impact the trials' validity or statistical power.

The FDA has agreed to a Special Protocol Assessment, or SPA, with respect to the design of our Phase 3 trial of tozadenant. We have also requested scientific advice from the EMA with respect to the design of our Phase 3 trial. Based on their response, we expect EMA approval of tozadenant to be contingent on conducting studies in addition to the currently planned Phase 3 program. We plan to engage in further discussions with the EMA with respect to their requirements for the approval of tozadenant.

If clinical trials of our product candidates are prolonged or delayed, we may be unable to obtain required regulatory approvals, and therefore be unable to commercialize our product candidates on a timely basis or at all.

We cannot assure you that our clinical trials will begin as planned or be completed on schedule, if at all, or that we will not need to restructure our trials after they have begun. Significant clinical trial delays could also shorten any periods during which we may have the exclusive right to commercialize our product candidates or allow our competitors to bring products to market before we do or shorten any periods during which we have the exclusive right to commercialize our product candidates, which may harm our business and results of operations. In addition, some of the factors that cause, or lead to, clinical trial delays may ultimately lead to the denial of regulatory approval of tozadenant, SYN120, BTT1023 or any other product candidate we may decide to develop in future. The completion of clinical trials for our clinical product candidates may be delayed, suspended or terminated as a result of many factors, including but not limited to:

- the delay or refusal of regulators or IRBs to authorize us to commence a clinical trial at a prospective trial site;
- changes in regulatory requirements, policies and guidelines;
- delays or failure to reach agreement on acceptable terms with prospective CROs and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- delays in patient enrollment and variability in the number and types of patients available for clinical trials;
- the inability to enroll a sufficient number of patients in trials to ensure adequate statistical power to detect statistically significant treatment effects;
- negative or inconclusive results, which may require us to conduct additional preclinical or clinical trials or to abandon projects that we expect to be promising;
- safety or tolerability concerns could cause us to suspend or terminate a trial if we find that the participants are being exposed to unacceptable health risks;
- regulators or IRBs requiring that we or our investigators suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements or safety concerns, among others;
- lower than anticipated retention rates of patients and volunteers in clinical trials;
- our CROs or clinical trial sites failing to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all, deviating from the protocol or dropping out of a trial;
- delays relating to adding new clinical trial sites;
- difficulty in maintaining contact with patients after treatment, resulting in incomplete data;
- delays in establishing the appropriate dosage levels;
- the quality or stability of the product candidate falling below acceptable standards;
- the inability to produce or obtain sufficient quantities of the product candidate to complete clinical trials; and
- exceeding budgeted costs due to difficulty in accurately predicting costs associated with clinical trials.

If serious adverse, undesirable or unacceptable side effects or preclinical findings are identified during the development of our product candidates or following approval, we may need to abandon our development of such product candidates, the commercial profile of any approved label may be limited, or we may be subject to other significant negative consequences following marketing approval.

If our product candidates are associated with serious adverse, undesirable or unacceptable side effects or preclinical findings, we may need to abandon their development or limit development to certain uses or sub-populations in which such side effects are less prevalent, less severe or more acceptable from a risk-benefit perspective. Many compounds that initially showed promise in preclinical or early stage testing have later been found to cause side effects that restricted their use and prevented further development of the compound for larger indications.

In our Phase 2b clinical trial of tozadenant, the majority of patients in each treatment group experienced at least one treatment emergent adverse event, or TEAE, during the trial. The most frequently reported TEAEs (occurring in more than 5% of patients in any treatment group, with incidence greater than placebo) were dyskinesia, nausea, dizziness, constipation, insomnia and fall. The majority of TEAEs were mild or moderate in maximum intensity. As expected with most central nervous system drugs, there was a dose-related increase in the reporting of adverse events and in the proportion of patients who discontinued early due to TEAEs, with a higher proportion (approximately 20%) of patients in the 240 mg twice/day tozadenant group discontinuing early due to TEAEs compared to the lower dose groups (approximately 8% to 12%). A total of 24 severe adverse events, or SAEs, were reported in 13 patients. The incidence of SAEs was 1.2%, 3.7%, 2.4%, and 4.8% in the 60 mg, 120 mg, 180 mg, and 240 mg groups, and 3.6% in the placebo group. Of the 24 SAEs reported, 11 occurred in two of the 13 patients. Nonfatal SAEs were reported for seven patients. All nonfatal SAEs resolved except for an event of atrial fibrillation in a placebo-group patient who also had an ischemic stroke. One nonfatal SAE of acute psychosis with paranoia was assessed by the investigator as being probably related to tozadenant; and we do not intend to take any further actions based on this isolated report. Fatal SAEs were reported for six patients, all of whom received tozadenant. An independent blinded data monitoring committee reviewed all TEAEs and SAEs during the trial and an independent expert panel reviewed these data after the trial was complete and unblinded. Both panels concluded that there was no relationship between tozadenant treatment and the fatal SAEs. Nevertheless, a data safety monitoring board will oversee the safety of the planned Phase 3 clinical trial. Occurrence of serious procedure- or treatment-related side effects could lead the safety monitoring board to recommend discontinuation of the trial or modification of the protocol, and could impede clinical trial enrollment and receipt of marketing approval from the FDA, the EMA and comparable foreign regulatory authorities. They could also adversely affect physician or patient acceptance of our product candidates.

Additionally if one or more of our product candidates receives regulatory approval, and we or others later identify undesirable side effects caused by such products, a number of potentially significant negative consequences could result, including:

- regulatory authorities may withdraw approvals of such product;
- regulatory authorities may require additional warnings on the label;
- regulatory authorities may limit or otherwise control the distribution of such products;
- we may be required to create a medication guide outlining the risks of such side effects for distribution to patients;
- we could be sued and held liable for harm caused to patients; and
- our reputation and physician or patient acceptance of our products may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of the particular product candidate, if approved, and could significantly harm our business, results of operations and prospects.

We depend on enrollment of patients in our clinical trials for our product candidates. If we are unable to enroll patients in our clinical trials, our research and development efforts could be materially adversely affected.

Successful and timely completion of clinical trials will require that we enroll a sufficient number of patient candidates. Trials may be subject to delays as a result of patient enrollment taking longer than anticipated or patient withdrawal and/or drop outs. Patient enrollment depends on many factors, including the size and nature of the patient population, eligibility criteria for the trial, the proximity of patients to clinical sites, the design of the clinical protocol, the availability of competing clinical trials, the availability of drugs approved for the indication the clinical trial is investigating, and clinicians' and patients' perceptions as to the potential advantages of the drug being studied in relation to other available therapies.

The specific target population of patients specified in a trial protocol may make it difficult for us to enroll enough patients to complete our clinical trials in a timely and cost-effective manner. In our Phase 3 clinical trial of tozadenant, we will seek to enroll Parkinson's patients receiving treatment with levodopa and who experience OFF episodes and meet other inclusion criteria, and are not otherwise excluded by meeting any of the exclusion criteria, defined in the trial protocol. We seek to identify, recruit, enroll and dose patients meeting these entry criteria. We opened enrollment to patients in a Phase 2 clinical trial of BTT1023 in PSC in the first quarter of 2015. PSC is an orphan indication, which means that the potential pool of appropriate patients for the trial is more limited than the potential pool of patients for trials in non-orphan indications. Delays in the completion of any clinical trial of our product candidates will increase our costs, slow down our product candidate development and approval process, delay or potentially jeopardize our ability to commence product sales and generate revenue and materially affect the competitive environment in which we may commercialize our product candidates. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates.

Due to our limited resources and access to capital, we must and have in the past decided to prioritize development of certain product candidates; these decisions may prove to have been wrong and may adversely affect our revenues.

Because we have limited resources and access to capital to fund our operations, we must decide which product candidates to pursue and the amount of resources to allocate to each. We are currently primarily focused on the development of tozadenant as an adjunctive treatment to levodopa in Parkinson's. Our decisions concerning the allocation of research, collaboration, management and financial resources toward particular compounds, product candidates or therapeutic areas may not lead to the development of viable commercial products and may divert resources away from better opportunities. Similarly, our potential decisions to delay, terminate or collaborate with third parties in respect of certain product development programs may also prove not to be optimal and could cause us to miss valuable opportunities. If we make incorrect determinations regarding the market potential of our product candidates or misread trends in the biopharmaceutical industry, our business, financial condition and results of operations could be materially adversely affected.

Risks Related to Regulatory Approval of Our Product Candidates

Clinical development, regulatory review and approval by the FDA, the EMA and comparable foreign regulatory authorities are lengthy, time consuming, expensive and inherently unpredictable activities. If we are ultimately unable to obtain regulatory approval for our product candidates, our business will be substantially harmed.

The process of obtaining regulatory approvals from the FDA, the EMA and comparable foreign regulatory authorities requires the expenditure of substantial time and financial resources and is inherently unpredictable. Approval policies, regulations, and the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions, which may cause delays in the approval or the decision not to approve an application, or cause a change to the decision to seek approval in some jurisdictions. It is possible that none of our existing product candidates or any product candidates we may seek to develop in the future will ever obtain regulatory approval. In addition, we may gain regulatory approval for tozadenant or other product candidates in some but not all of the territories available or some but not all of the target indications, resulting in limited commercial opportunity for the approved products.

Events that may prevent successful or timely commencement, enrollment, completion or regulatory authority acceptance of clinical development plans include:

- the FDA, the EMA or comparable foreign regulatory authorities may disagree with the design or implementation of our clinical trials;
- the population studied in the clinical program may not be sufficiently broad or representative to assure safety in the full population for which we seek approval;
- the FDA, the EMA or comparable foreign regulatory authorities may disagree with our interpretation of data from nonclinical studies or clinical trials;
- the data collected from clinical trials of our product candidates may not be sufficient to support the submission of a NDA or biologics license application or other submission or to obtain regulatory approval in the United States or elsewhere;
- the FDA, the EMA or comparable foreign regulatory authorities may require us to conduct additional clinical trials depending on the safety data from our planned future clinical trials;
- we may be unable to demonstrate to the FDA, the EMA or comparable foreign regulatory authorities that a product candidate's risk-benefit ratio for its proposed indication is acceptable;
- the FDA, the EMA or comparable foreign regulatory authorities may fail to approve the manufacturing processes, test procedures and specifications, or facilities of third-party manufacturers with which we contract for clinical and commercial supplies;
- we or any third-party service providers may be unable to demonstrate compliance with cGMP to the satisfaction of the FDA, the EMA or comparable foreign regulatory authorities which could result in delays in regulatory approval or require us to withdraw or recall products and interrupt commercial supply of our products; and
- the approval policies or regulations of the FDA, the EMA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

This lengthy approval process, as well as the unpredictability of the results of clinical trials, may result in our failing to obtain regulatory approval to market any of our product candidates, which would

significantly harm our business, results of operations, and prospects. Even if we believe the data collected from clinical trials of our product candidates are promising, such data may not be sufficient to support approval by the FDA, the EMA or comparable foreign regulatory authorities.

The FDA's agreement to our SPA for our Phase 3 trial of tozadenant does not guarantee any particular outcome from regulatory review, including ultimate approval and may not lead to a faster development or regulatory review or approval process.

We consulted with the FDA regarding the design and adequacy of our proposed Phase 3 clinical program to support marketing approval of tozadenant through a SPA. The FDA has agreed to our SPA with respect to the design of our Phase 3 trial of tozadenant.

The FDA's SPA process is designed to facilitate the FDA's review and approval of drugs by allowing the FDA to evaluate the proposed design and size of Phase 3 clinical trials that are intended to form the primary basis for determining a drug product's efficacy and safety. Upon specific request by a clinical trial sponsor, the FDA will evaluate the protocol and respond to a sponsor's questions regarding, among other things, primary efficacy endpoints, trial conduct and data analysis, within 45 days of receipt of the request. The FDA ultimately assesses whether the protocol design and planned analysis of the trial are acceptable to support regulatory approval of the product candidate with respect to the effectiveness in the indication studied. All agreements and disagreements between the FDA and the sponsor regarding a SPA must be clearly documented in a SPA letter or the minutes of a meeting between the sponsor and the FDA. However, even if an agreement regarding a SPA is reached, a SPA agreement does not guarantee approval of a product candidate, and even if the FDA agrees to the design, execution, and analysis proposed in protocols reviewed under the SPA process, the FDA may revoke or alter its agreement in certain circumstances. In particular, a SPA agreement is not binding on the FDA if public health concerns emerge that were unrecognized at the time of the SPA agreement, other new scientific concerns regarding product safety or efficacy arise, the sponsor company fails to comply with the agreed upon trial protocols, or the relevant data, assumptions or information provided by the sponsor in a request for the SPA change or are found to be false or omit relevant facts. In addition, even after a SPA agreement is finalized, the SPA agreement may be modified, and such modification will be deemed binding on the FDA review division, except under the circumstances described above, if the FDA and the sponsor agree in writing to modify the protocol and such modification is intended to improve the trial. The FDA retains significant latitude and discretion in interpreting the terms of the SPA agreement and the data and results from any trial that is the subject of the SPA agreement. We cannot assure you that our Phase 3 clinical trial of tozadenant will succeed, will be deemed binding by the FDA under our SPA, or will result in any FDA approval for tozadenant. We expect that the FDA will review our compliance with the protocol under our SPA agreement and that it will conduct inspections at some of the sites where the trial will be conducted. We cannot assure you that each of the clinical trial sites will pass such FDA inspections, and negative inspection results could significantly delay or prevent any potential approval for tozadenant. If the FDA revokes or alters its agreement under the SPA, or interprets the data collected from the clinical trial differently than we do, the FDA may not deem the data sufficient to support an application for regulatory approval, which could materially adversely affect our business, financial condition and results of operations. A revocation or alteration of our existing SPA could significantly delay or prevent approval of our application. Our SPA agreement with the FDA does not ensure that tozadenant will receive marketing approval or that the approval process will be faster than conventional regulatory procedures.

If we fail to obtain regulatory approval in any jurisdiction, we will not be able to market our products in that jurisdiction.

We intend to market our product candidates, including tozadenant, if approved, in international markets through partnerships. Such marketing will require separate regulatory approvals in each market and compliance with numerous and varying regulatory requirements. The approval procedures vary from country to country and may require additional testing. In addition, in many countries outside the United States, a product must undergo health economic assessments to agree on pricing and/or be approved for reimbursement before it can be approved for sale in that country, or before it becomes commercially viable. The FDA and the EMA may come to different conclusions regarding approval of a marketing application. Approval by the FDA or EMA does not ensure approval by regulatory authorities in other countries or jurisdictions, and approval by one foreign regulatory authority does not ensure approval by regulatory authorities in other foreign countries or by the FDA or EMA. We may not obtain regulatory approvals on a timely basis, if at all. We may not be able to file for regulatory approvals and may not receive necessary approvals to commercialize our products in any market. If we or any future partner are unable to obtain regulatory approval for tozadenant or our other product candidates in one or more significant jurisdictions, then the commercial opportunity for tozadenant or our other product candidates, and our financial condition, will be adversely affected.

We have also requested scientific advice from the EMA with respect to the design of our Phase 3 trial of tozadenant. Based on their response, we expect EMA approval of tozadenant to be contingent on conducting studies in addition to the currently planned Phase 3 program. We plan to engage in further discussions with the EMA with respect to their requirements for the approval of tozadenant.

Even if our product candidates obtain regulatory approval, we will be subject to ongoing regulatory review, which may result in significant additional expense. Additionally, our product candidates, if approved, could be subject to restrictions, and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our products.

If marketing authorization is obtained for any of our product candidates, the product will remain subject to continual regulatory review and therefore authorization could be subsequently withdrawn or restricted. Any regulatory approvals that we receive for our product candidates may also be subject to limitations on the approved indicated uses for which the product may be marketed or to conditions of approval, or contain requirements for potentially costly post-marketing testing, including Phase 4 clinical trials, and surveillance to monitor safety and efficacy. In addition, if the FDA, the EMA or a comparable foreign regulatory authority approves any of our product candidates, the manufacturing processes, labeling, packaging, distribution, adverse effect reporting, storage, advertising, promotion and recordkeeping, and, potentially, other post-marketing obligations, may result in significant expense and limit our ability to commercialize such products. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with cGMPs and cGCPs for any clinical trials that we conduct post-approval. Later discovery of previously unknown problems with an approved product, including adverse effects of unanticipated severity or frequency, or with manufacturing operations or processes, or failure to comply with regulatory requirements, may result in, among other things:

- restrictions on the marketing or manufacturing of the product, withdrawal of the product from the market, or voluntary or mandatory product recalls;
- fines, warning letters, or holds on clinical trials;
- refusal by the FDA, the EMA or comparable foreign regulatory authorities to approve pending applications or supplements to approved applications filed by us, or suspension or revocation of product license approvals;

- product seizure or detention, or refusal to permit the import or export of products; and
- injunctions or the imposition of civil or criminal penalties.

If any of these events occurs, our ability to sell such product may be impaired, and we may incur substantial additional expense to comply with regulatory requirements, which could materially adversely affect our business, financial condition and results of operations. The policies of the FDA, EMA or a comparable foreign regulatory authority may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained, which would adversely affect our business, prospects and ability to achieve or sustain profitability.

We may be unable to obtain orphan drug designation or exclusivity in the United States for BTT1023. If our competitors are able to obtain orphan drug exclusivity for their products in the same indication for which we are developing BTT1023, we may not be able to have our product candidate approved by the applicable regulatory authority for a significant period of time. Conversely, we may not be able to benefit from the associated marketing exclusivity from orphan drug exclusivity that we obtain.

Regulatory authorities in some jurisdictions, including the United States and Europe, may designate drugs for relatively small patient populations as orphan drugs. Under the Orphan Drug Act, the FDA may designate a product candidate as an orphan drug if it is a drug intended to treat a rare disease or condition, which is generally defined as a patient population of fewer than 200,000 individuals in the United States. In the European Union, the European Commission may designate a product candidate as an orphan medicinal product if it is a medicine for the diagnosis, prevention or treatment of life-threatening or very serious conditions that affects not more than five in 10,000 persons in the European Union, or it is unlikely that marketing of the medicine would generate sufficient returns to justify the investment needed for its development. BTT1023 has been granted orphan drug designation for PSC in Europe, and we intend to pursue orphan drug designation for BTT1023 in the United States. However, there is no assurance we will be able to receive orphan drug designation for BTT1023 in the United States, and even if we are successful in obtaining orphan drug designation for BTT1023 in the United States, orphan drug status may not ensure that we have market exclusivity in a particular market. Further, the granting of a request for orphan drug designation does not alter the standard regulatory requirements and process for obtaining marketing approval.

Generally, if a product candidate with an orphan drug designation receives the first marketing approval for the indication for which it has such designation, the product is entitled to a period of marketing exclusivity, which, subject to certain exceptions, precludes the FDA from approving the marketing application of another drug for the same indication for that time period or precludes the EMA, and other national drug regulators in the European Union, from accepting the marketing application for another medicinal product for the same indication. The applicable period is seven years in the United States and ten years in the European Union. The European Union period can be reduced to six years if a product no longer meets the criteria for orphan drug designation or if the product is sufficiently profitable so that market exclusivity is no longer justified. Orphan drug exclusivity may be lost in the United States if the FDA determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the product to meet the needs of patients with the rare disease or condition.

Even if we obtain orphan drug exclusivity for BTT1023 or another of our product candidates, that exclusivity may not effectively protect the product from competition because exclusivity can be suspended under certain circumstances. In the United States, even after an orphan drug is approved, the FDA can

subsequently approve another drug for the same condition if the FDA concludes that the later drug is clinically superior in that it is shown to be safer, more effective or makes a major contribution to patient care. In the European Union, orphan exclusivity will not prevent a marketing authorization being granted for a similar medicinal product in the same indication if the new product is safer, more effective or otherwise clinically superior to the first product or if the marketing authorization holder of the first product is unable to supply sufficient quantities of the product.

Risks Related to Commercialization of Our Product Candidates

We are likely to face significant competition and if our competitors develop and market products that are more effective, safer or less expensive than our product candidates, our commercial opportunities will be negatively impacted.

We are currently developing product candidates that are likely to compete with other drugs and therapies that currently exist or are being developed. Products we may develop in the future are also likely to face competition from other drugs and therapies, some of which we may not currently be aware. We have competitors both in the United States and internationally, including major multinational pharmaceutical companies, established biotechnology companies, specialty pharmaceutical companies, universities and other research institutions. Many of our competitors have significantly greater financial, manufacturing, marketing, drug development, technical and human resources than we do.

Large pharmaceutical companies, in particular, have extensive experience in clinical testing, obtaining regulatory approvals, recruiting patients and in manufacturing pharmaceutical products. These companies also have significantly greater research and marketing capabilities than we do and may also have products that have been approved or are in late stages of development, and collaborative arrangements in our target markets with leading companies and research institutions. Established pharmaceutical companies may also invest heavily to accelerate discovery and development of novel compounds or to in-license novel compounds that could make the product candidates that we develop obsolete. As a result of all of these factors, our competitors may succeed in obtaining patent protection and/or marketing approval or discovering, developing and commercializing products in our field before we do.

Smaller and other early stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These companies compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs. In addition, the biopharmaceutical industry is characterized by rapid technological change. If we fail to stay at the forefront of technological change, we may be unable to compete effectively. Technological advances or products developed by our competitors may render our product candidates obsolete, less competitive or not economical.

We are aware of a number of pharmaceutical and biotechnology companies that are actively engaged in the research and development of pharmaceutical products for the same, or similar, therapeutic indications as we are. A number of these companies are developing competing drugs or treatment methods to those that we are targeting. As competitors develop their product candidates, they may develop proprietary positions in certain areas that may have a material adverse effect on the competitiveness of our products on the market. We may not always be aware of development of competing products or technologies and, therefore, there may be significant competing products or treatment methods in development of which we have no knowledge.

Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe adverse effects, are more convenient or are less expensive than any products that we may develop. Our competitors may also obtain

FDA, EMA or comparable foreign regulatory approval for their products more rapidly than we may obtain approval for ours, which could delay approval of our products and/or result in our competitors establishing a strong market position before we are able to enter the market. Even if our product candidates achieve marketing approval, they may be priced at a significant premium over competitive products if any have been approved by then, resulting in reduced competitiveness.

There is a large number of companies developing or marketing treatments for central nervous system diseases and disorders, including many major pharmaceutical and biotechnology companies. These treatments consist of small molecule drug products in the case of Parkinson's, Alzheimer's and related neurodegenerative diseases and biologic therapeutics that work by using next-generation antibody technology platforms in the case of inflammation and fibrotic diseases.

Tozadenant

Current therapies, including levodopa, the most widely prescribed treatment for Parkinson's, lose effectiveness in most patients over time. The adenosine A_{2a} antagonists represent a novel mechanism of action for the treatment of Parkinson's, with the potential for treating both motor and nonmotor symptoms, and may have the potential for slowing disease progression. Currently approved adjunctive treatment for Parkinson's can be considered complementary rather than competitive to tozadenant as they may be used in combination. However, as most adjunctive treatments to levodopa will be generic by the time that we expect tozadenant to be approved for marketing, it is probable that they will be used prior to tozadenant.

Istradefylline (approved in Japan; Phase 3 elsewhere), also an adenosine A_{2a} antagonist, potentially addresses the same patient population as tozadenant. Istradefylline was refused FDA approval in 2008, but was approved for sale in Japan (as Nourias) in 2013. Kyowa Hakko Kirin recently announced a new 600-patient Phase 3 development program of istradefylline in the United States, which is expected to be completed by the end of 2015 or early 2016. If istradefylline is approved and commercially launched in the United States prior to tozadenant, it will result in direct competition with a molecule sharing the same mechanism of action.

SYN120

Currently, there are no therapies that cure Parkinson's or Alzheimer's. Existing therapies for both Parkinson's dementia and Alzheimer's are targeted at symptomatic improvement of cognitive function. Rivastigmine is the only product approved in the United States for the treatment of Parkinson's dementia. Five drugs have been approved by the FDA for symptomatic treatment of Alzheimer's.

There are several 5HT₆ antagonists currently in development. Pfizer's PF05212377 is in Phase 2, Lundbeck's LuAE58054 is in Phase 3 and GlaxoSmithKline reported results of a Phase 2 trial of SB742457 in mid-2011. SB742457 was acquired by Axovant Sciences, Inc. in December 2014 (referred to as RVT-101), which has announced plans to commence a Phase 3 program of RVT-101 for the treatment of mild-to-moderate Alzheimer's in the fourth quarter of 2015. When added on to Aricept, the current standard of care for Alzheimer's, both SB742457 and LuAE58054 demonstrated improvement in cognition in patients with Alzheimer's, validating the relevance of 5HT₆ receptors as a therapeutic target. These 5HT₆ antagonists are further advanced in development than SYN120 and may become treatment options prior to when SYN120 could reach the market. Differentiating SYN120 from these products will be necessary to effectively compete with them and we cannot assure you that this will be possible.

Other major development targets for symptomatic treatments of cognitive deficits are nicotinic acetylcholine receptor (nAChR) agonists or modulators and histamine H₃ receptor antagonists. Several nAChR compounds are in early-stage development. Pimavanserin, a 5HT_{2a} inverse agonist, has recently shown promise in improving neuropsychiatric symptoms in Parkinson's disease psychosis and therefore has validated the importance of the 5HT_{2a} receptor as a target in this condition. We expect that pimavanserin will be approved for treatment of Parkinson's disease psychosis prior to when SYN120 could be launched,

and pimavanserin could become the standard for treatment of the condition. Differentiation of SYN120 from pimavanserin will be necessary for it to compete effectively and we cannot assure you that this will be possible.

BTT1023

There are currently no FDA approved agents that can prevent, arrest or reverse fibrosis. We are aware of four competing clinical development programs in PSC all of which are in Phase 2. Gilead's simtuzumab (GS-6624) anti-lysyl oxidase-like 2 antibody targets an enzyme important for fibrogenesis and, if efficacious, is expected to improve liver pathology. The other three programs in development for PSC of which we are aware target bile acid transport in some way. Dr. Falk Pharma's norUrso is an ursodeoxycholic acid that may improve liver function. Lumena Pharmaceuticals (recently acquired by Shire plc) is developing LUM001, a bile acid transport inhibitor currently in a small, open label, pilot trial in PSC with safety and tolerability as primary endpoints and an estimated trial completion date of December 2015. Like norUrso it may improve liver function but is not expected to affect the underlying disease. Intercept's obeticholic acid is another semi-synthetic bile acid analogue which could improve liver function and which may have anti-fibrotic effects, and is currently in a trial with an estimated completion date in June 2019.

For more information on competition, see "Business — Competition."

The successful commercialization of our product candidates will depend in part on the extent to which governmental authorities and health insurers establish adequate reimbursement levels and pricing policies.

The successful commercialization of our product candidates will depend, in part, on the extent to which third-party coverage and reimbursement for our products will be available from government and health administration authorities, private health insurers and other third-party payors.

These bodies may deny or revoke the reimbursement status of a given drug product or establish prices for new or existing marketed products at levels that are too low to enable us to realize an appropriate return on our investment in product development. Obtaining and maintaining reimbursement status is time consuming and costly. Significant uncertainty exists as to the reimbursement status of newly approved medical products. Furthermore, rules and regulations regarding reimbursement change frequently, in some cases at short notice, and we believe that changes in these rules and regulations are likely. In addition, many governments and health insurers are increasingly attempting to manage health care costs by limiting both coverage and the level of reimbursement of new products. As a result, they may not cover or provide adequate payment for our future products.

The unavailability or inadequacy of third-party coverage and reimbursement could have a material adverse effect on the market acceptance of our product candidates and the future revenues we may expect to receive from those products. In addition, we are unable to predict what additional legislation or regulation relating to the health care industry or third-party coverage and reimbursement may be enacted in the future, or what effect such legislation or regulation would have on our business.

Even if approved, if any of our products or product candidates do not achieve broad market acceptance among physicians, patients, the medical community and third-party payors, our revenue generated from their sales will be limited.

Even when product development is successful and regulatory approval has been obtained, our ability to generate any significant revenue depends on the acceptance of the products by physicians and patients. The degree of market acceptance of our products will depend on a number of factors, including:

- limitations or warnings contained in the approved labeling for a product;
- changes in the standard of care for the targeted indications for any of our products;
- limitations in the approved clinical indications for our products;
- demonstrated clinical safety and efficacy compared to other products;
- lack of significant adverse side effects;
- sales, marketing and distribution support;
- availability and extent of reimbursement from managed care plans and other third-party payors;
- timing of market introduction and perceived effectiveness of competitive products;
- the degree of cost-effectiveness of our product candidates;
- availability of alternative therapies at similar or lower cost, including generic and over-the-counter products;
- the extent to which the product is approved for inclusion on formularies of hospitals and managed care organizations;
- whether the product is designated under physician treatment guidelines as a first-line therapy or as a second- or third-line therapy for particular diseases;
- adverse publicity about our product candidates or favorable publicity about competitive products;
- governmental efforts to reduce health care costs or reform government health care programs;
- convenience and ease of administration of our products; and
- potential product liability claims.

If any of our products or product candidates are approved, but do not achieve an adequate level of acceptance by physicians, patients and the medical community, we may not generate sufficient revenue from these products, and we may not become or remain profitable. In addition, efforts to educate the medical community and third-party payors on the benefits of our product candidates may require significant resources and may never be successful.

The market for tozadenant and our other product candidates may not be as large as we expect.

Our estimates of the potential market opportunity for tozadenant include several key assumptions based on our industry knowledge, industry publications, third-party research reports and other surveys. These assumptions include the size of the Parkinson's disease market, the number of patients who are treated and may become eligible for treatment with tozadenant and our penetration into that market. While we believe that our internal assumptions are reasonable, if any of these assumptions proves to be inaccurate, then the actual market for tozadenant could be smaller than our estimates of our potential market opportunity. If the actual market for tozadenant is smaller than we expect, our product revenue may be limited and it may be more difficult for us to achieve or maintain profitability. Similar estimates and assumptions apply to all of our product candidates.

We have never commercialized a product candidate before and may lack the necessary expertise, personnel and resources to successfully commercialize our products on our own or together with suitable partners.

We have relied, and will continue to rely, on Lundbeck for the commercialization of Selincro. We currently have no sales force, marketing or distribution capabilities and we have never commercialized a product candidate. For our product candidates for which we retain commercialization rights, we will have to develop our own sales, marketing and supply organization or outsource these activities to a third party.

Factors that may affect our ability to commercialize our product candidates on our own include recruiting and retaining adequate numbers of effective sales and marketing personnel, obtaining access to or persuading adequate numbers of physicians to prescribe our drug candidates and other unforeseen costs associated with creating an independent sales and marketing organization. Developing a sales and marketing organization will be expensive and time consuming and could delay the launch of our product candidates. We may not be able to build an effective sales and marketing organization. If we are unable to build our own distribution and marketing capabilities or to find suitable partners for the commercialization of our product candidates, we may not generate revenues from them or be able to reach or sustain profitability.

Risks Related to Our Reliance on Third Parties

Collaborations on products and product candidates are important to our business, and future collaborations may also be important to us. If we are unable to maintain any of these collaborations, if these collaborations are not successful, or if we fail to enter into new strategic relationships, our business could be adversely affected.

We have in the past entered into, and intend to continue to enter into, collaborations with other companies that we believe could provide us with valuable funding and other benefits. However, we cannot assure you that any such collaboration will continue or be successful. For example, in August 2010, Synosia Therapeutics AG, or Synosia, which we acquired in February 2011, entered into a license and collaboration agreement with UCB, or the UCB Collaboration Agreement, to develop and commercialize tozadenant. Pursuant to the UCB Collaboration Agreement, UCB was granted an option to receive an exclusive license to tozadenant. However, in March 2014, UCB terminated the UCB Collaboration Agreement and returned its rights to us following an assessment of its early and late stage clinical development pipeline as well as its other preclinical opportunities, which according to UCB, did not reflect any concerns regarding the safety or efficacy of tozadenant. The decision was made prior to the End of Phase 2 meeting with the FDA. In addition, we have entered into various other collaboration and license arrangements with third parties, including our development collaborations with the Parkinson Study Group, the National Institute of Health Research and the University of Birmingham, our license agreement with Roche Palo Alto LLC, Hoffman-La Roche Inc. and F. Hoffman-La Roche Ltd., collectively, the Roche Entities, and such agreement, the Roche License Agreement, and the Lundbeck License Agreement for the development and commercialization of Selincro. We cannot assure you that any such collaboration or license agreement will be successful.

In the future, we may enter into additional collaborations to fund our development programs or to gain access to sales, marketing or distribution capabilities. Our existing collaborations, and any future collaborations we enter into, may pose a number of risks, including the following:

- collaborators may have significant discretion in determining the efforts and resources that they will apply to these collaborations;
- collaborators may not perform their obligations as expected by us or by health authorities, such as the FDA, the EMA or comparable foreign regulatory authorities;

- collaborators may dissolve, merge, be bought, or may otherwise become unwilling to fulfill the initial terms of the collaboration with us;
- collaborators may not pursue development and commercialization of any product candidates that achieve regulatory approval or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in the collaborators' strategic focus or available funding, or external factors, such as an acquisition, that divert resources or create competing priorities;
- collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial or abandon a product candidate, repeat or conduct new clinical trials or may require a new formulation of a product candidate for clinical testing;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our products or product candidates if the collaborators believe that competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours;
- product candidates discovered in collaboration with us may be viewed by our collaborators as competitive with their own product candidates or products, which may cause collaborators to cease to devote resources to the commercialization of our product candidates;
- a collaborator with marketing and distribution rights to one or more of our product candidates that achieve regulatory approval may not commit sufficient resources to the marketing and distribution of such product or products;
- disagreements with collaborators or licensors, including disagreements over proprietary rights, contract interpretation, payment obligations or the preferred course of development, might cause delays or termination of the research, development or commercialization of products or product candidates, might lead to additional responsibilities, including financial obligations for us with respect to products or product candidates, or might result in litigation or arbitration, any of which would be time consuming and expensive;
- collaborators may not properly maintain or defend our intellectual property rights or may use our proprietary information in such a way that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential litigation;
- collaborators may infringe the intellectual property rights of third parties, which may expose us to litigation and potential liability; and
- collaborations may be terminated for the convenience of the collaborator and, if terminated, we could be required to raise additional capital to pursue further development or commercialization of the applicable product candidates.

If our collaborations on research and development candidates do not result in the successful development and commercialization of products or if one of our collaborators terminates its agreement with us, we may not receive any future research funding or milestone or royalty payments under the collaboration. If we do not receive the funding we expect under these agreements, our development of our product candidates could be delayed and we may need additional resources to develop our product candidates. All of the risks relating to product development, regulatory approval and commercialization described in this prospectus also apply to the activities of our program collaborators.

Additionally, subject to its contractual obligations to us, if one of our collaborators is involved in a business combination, the collaborator might deemphasize or terminate the development or commercialization of any product candidate licensed to it by us. If one of our collaborators terminates its agreement with us, we may find it more difficult to attract new collaborators in a timely manner.

We may in the future determine to collaborate with additional pharmaceutical and biotechnology companies for development and potential commercialization of our product candidates. We may face significant competition in seeking appropriate collaborators. Our ability to reach a definitive agreement for a collaboration will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of a number of factors. These factors may include the design or results of clinical trials, the likelihood of approval by the FDA, the EMA or comparable foreign regulatory authorities, the potential market for the subject product candidate, the costs and complexities of manufacturing and delivering such product candidate to patients, the potential of competing products, the existence of uncertainty with respect to our ownership of technology, which can exist if there is a challenge to such ownership without regard to the merits of the challenge and industry and market conditions generally. The collaborator may also consider alternative product candidates for similar indications that may be available to collaborate on and whether such collaboration could be more attractive than the one with us for our product candidate.

Collaborations are complex and time consuming to negotiate and document. In addition, there have been a significant number of recent business combinations among large pharmaceutical companies that have resulted in a reduced number of potential future collaborators. If we are unable to reach agreements with suitable collaborators on a timely basis, on acceptable terms, or at all, we may have to curtail the development of a product candidate, reduce or delay one or more of our other development programs, delay its potential commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to fund and undertake development or commercialization activities on our own, we may need to obtain additional expertise and additional capital, which may not be available to us on acceptable terms or at all. If we fail to enter into collaborations and do not have sufficient funds or expertise to undertake the necessary development and commercialization activities, we may not be able to further develop our product candidates or bring them to market and our business may be materially and adversely affected.

The success of our strategic partnerships and collaborations depends, to a significant degree, on the performance of our partners, over which we have little or no control.

In November 2006, we entered into an option agreement to negotiate the Lundbeck License Agreement, and subsequently entered into the Lundbeck License Agreement in May 2007. Pursuant to the Lundbeck License Agreement, we granted Lundbeck an exclusive, royalty-bearing, sublicensable worldwide license under certain patents and know-how related to Selincro owned by or exclusively licensed to us, to develop, manufacture and commercialize Selincro for any purpose. Under the terms of the Lundbeck License Agreement, we are eligible to receive royalties from Lundbeck on net sales of Selincro on a product-by-product and country-by-country basis until the later of either the date when there are no valid patent rights owned by us covering the licensed product or other statutory exclusivity rights covering the licensed product in force and May 23, 2017. We are also eligible to receive certain milestone payments under the Lundbeck License Agreement, upon the achievement of specified regulatory and commercial milestones. The timing of any milestone payments that we may receive is dependent on a combination of factors, including the successful registration of the product for alcohol dependence in non-European countries, the successful registrations in indications other than alcohol dependence and the level of sales of Selincro that Lundbeck achieves. In addition, the level of sales that Lundbeck achieves also determines the level of royalties that we will receive under the Lundbeck License Agreement. Lundbeck is solely responsible for all manufacturing costs and expenses, as well as commercialization activities relating to licensed products. Lundbeck is subject to certain obligations requiring it to use commercially reasonable efforts to develop and commercialize Selincro in various countries. If Lundbeck is required to perform additional studies in certain countries in order to obtain regulatory approval to market and sell Selincro products to treat alcohol dependence in such countries, Lundbeck may offset certain development costs related to such studies against any future

royalties or milestone payments payable to us. The ability of Lundbeck to continue to successfully commercialize Selincro is entirely outside of our control and we cannot assure you that we will receive or when we will receive further milestone payments and/or any royalties.

Lundbeck conducts, and we would expect any future partner we may have to conduct, its own regular strategic reviews of its research and development and/or commercialization programs and may elect to delay or terminate one or more of these strategic or collaborative partnerships, develop independently or in collaboration with a third party products that could compete with our product or product candidates, and could fail to commit sufficient resources to the development or commercialization of our product or product candidates which are subject to these partnerships or collaborations or otherwise fail to perform as we expect. If any of these risks materialize our revenues from up-front license payments, milestone payments and royalties generated from Selincro or, in the future, any of our product candidates that are subject to similar partnerships and collaborations may be substantially reduced, which would have a material adverse effect on our business, financial condition and results of operations.

We rely on third parties to conduct our nonclinical and clinical trials and perform other tasks for us. If these third parties do not successfully carry out their contractual duties, meet expected deadlines, or comply with regulatory requirements, we may not be able to obtain regulatory approval for, or commercialize, our product candidates and our business could be substantially harmed.

We have relied upon and plan to continue to rely upon third-party CROs to monitor and manage data for our ongoing nonclinical and clinical programs, including the clinical trials of tozadenant, SYN120 and BTT1023. In addition, we rely on investigators and sponsors with which we collaborate on investigator-sponsored trials, such as the investigators and sponsors conducting the Phase 2a clinical trial of SYN120 in Parkinson's dementia and the Phase 2 clinical trial of BTT1023 in PSC. We rely on these parties for execution of our nonclinical and clinical studies and control only certain aspects of their activities. Nevertheless, we are responsible for ensuring that each of our trials is conducted in accordance with the applicable protocol, legal, regulatory, and scientific standards and our reliance on the CROs does not relieve us of our regulatory responsibilities. We and our CROs, Contract Manufacturing Organizations, or CMOs and other vendors are required to comply with cGMP, cGCP, and Good Laboratory Practice, or GLP, which are regulations and guidelines enforced by the FDA, the EMA or comparable foreign regulatory authorities for all of our product candidates in nonclinical and clinical development. Regulatory authorities enforce these regulations through periodic inspections of trial sponsors, principal investigators, trial sites and other contractors. If we, or any of our CROs or vendors, fail to comply with applicable regulations, the data generated in our nonclinical and clinical trials may be deemed unreliable and the FDA, the EMA or comparable foreign regulatory authorities may require us to perform additional nonclinical and clinical trials before approving our marketing applications. We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that all of our clinical trials comply with cGCP regulations. In addition, our clinical trials must be conducted with product produced under cGMP regulations. Our failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process.

If any of our relationships with these third-party CROs terminates, we may not be able to enter into arrangements with alternative CROs or do so on commercially reasonable terms. In addition, our CROs are not our employees, and except for remedies available to us under our agreements with such CROs, we cannot control whether or not they devote sufficient time and resources to our ongoing nonclinical and clinical programs. If CROs do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the data they obtain is compromised due to the failure to adhere to our protocols, regulatory requirements, or for other reasons, our clinical trials may be extended, delayed, or terminated and we may not be able to obtain regulatory approval for or successfully commercialize our product candidates. During the course of development and conducting

our clinical trials, the projected costs of such studies may be increased by our CROs. As a result, our results of operations and the commercial prospects for our product candidates would be harmed, our costs could increase, and our ability to generate revenue could be delayed.

Switching or adding additional CROs involves additional cost and requires management time and focus. In addition, there is a natural transition period when a new CRO commences work. As a result, delays occur, which can materially impact our ability to meet our desired clinical development timelines. Though we carefully manage our relationships with our CROs, there can be no assurance that we will not encounter similar challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, financial condition, and prospects.

We currently rely on third-party suppliers and other third parties for production of our product candidates and our dependence on these third parties may impair the advancement of our research and development programs and the development of our product candidates.

We currently rely on and expect to continue to rely on third parties for the manufacturing and supply of drug products for the clinical trials of our product candidates, including tozadenant, SYN120 and BTT1023. For the foreseeable future, we expect to continue to rely on such third parties for the manufacture of any of our product candidates on a clinical or, if any of our product candidates receives regulatory approval, commercial scale. Reliance on third-party providers may expose us to different risks than if we were to manufacture product candidates ourselves. The facilities used by our contract manufacturers to manufacture our product candidates must be approved by the FDA, the EMA or comparable foreign regulatory authorities pursuant to inspections that will be conducted after we submit an NDA or comparable approval application to the FDA, the EMA or comparable foreign regulatory authorities. Although we have auditing rights with all our manufacturing counterparties, we do not have control over a supplier's or manufacturer's compliance with these laws, regulations and applicable cGMP standards and other laws and regulations, such as those related to environmental, health and safety matters. If our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA, the EMA or comparable foreign regulatory authorities, they will not be able to secure and/or maintain regulatory approval for their manufacturing facilities. In addition, we have no control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If the FDA, the EMA or comparable foreign regulatory authorities does not approve these facilities for the manufacture of our product candidates or if it withdraws any such approval in the future, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory approval for or market our product candidates, if approved. Any failure to achieve and maintain compliance with these laws, regulations and standards could subject us to the risk that we may have to suspend the manufacturing of our product candidates or that obtained approvals could be revoked, which would adversely affect our business and reputation.

Furthermore, third-party providers may breach agreements they have with us because of factors beyond our control. They may also terminate or refuse to renew their agreements because of their own financial difficulties or business priorities, potentially at a time that is costly or otherwise inconvenient for us. If they do not successfully carry out their contractual duties or obligations or meet expected deadlines, including due to scheduling conflicts, there might be a disruption in the clinical supply chain that would directly impact the continuity of our clinical trials. If we were unable to find adequate replacement or another acceptable solution in time, our clinical trials could be delayed or our commercial activities could be harmed.

In addition, the fact that we are dependent on our suppliers and other third parties for the manufacture, packaging and labeling, storage and distribution of our product candidates means that we are subject to the

risk that our product candidates and, if approved, commercial products may have manufacturing defects that we have limited ability to prevent or control. The sale of products containing such defects could result in recalls or regulatory enforcement action that could adversely affect our business, financial condition and results of operations.

Growth in the costs and expenses of components or raw materials may also adversely influence our business, financial condition and results of operations. Supply sources could be interrupted from time to time and, if interrupted, we cannot assure you that supplies could be resumed (whether in part or in whole) within a reasonable time frame and at an acceptable cost or at all.

Our current and anticipated future dependence upon others for the manufacturing of tozadenant, SYN120 and BTT1023 and any other product candidate that we develop may adversely affect our future profit margins and our ability to commercialize any products that receive marketing approval on a timely and competitive basis.

Certain of the drug substances and drug products for our product candidates are currently acquired from single-source suppliers. The loss of these suppliers, or their failure to supply us with the drug substance or drug product, could materially and adversely affect our business.

We do not currently, and do not expect in the future to, independently conduct manufacturing activities for our product candidates, including tozadenant, SYN120 and BTT1023. Our contract manufacturers may have a relationship with a preferred single supplier for certain materials for the manufacture of tozadenant, SYN120 and BTT1023. We are therefore reliant upon single-source third-party CMOs to manufacture and supply the drug substance and drug product and components thereof. We do not currently have any other reliable suppliers for the drug substance or drug product of our product candidates and, although we believe that there are alternate sources of supply that could satisfy our clinical and commercial requirements and have performed preliminary investigations to identify back-up manufacturers for our portfolio, we cannot assure you that identifying alternate sources and establishing relationships with such sources with the desired scale and capability would not result in significant delay and additional costs in the development of our product candidates. Additionally, we may not be able to enter into supply arrangements with alternative suppliers on commercially reasonable terms, or at all. A delay in the development of our product candidates or having to enter into a new agreement with a different third party on less favorable terms than we have with our current suppliers could have a material adverse impact upon our business.

Risks Related to Our Intellectual Property

If we are unable to obtain and maintain sufficient intellectual property protection for our product or product candidates, or if the scope of our intellectual property protection is not sufficiently broad, our ability to commercialize our product and product candidates successfully and to compete effectively may be adversely affected.

Our success depends in large part on our ability to obtain and maintain protection with respect to our intellectual property and proprietary technology. We rely upon a combination of patents, trade secret protection and confidentiality agreements to protect the intellectual property related to our products and product candidates, including Selincro and tozadenant. The patent position of pharmaceutical companies is generally uncertain because it involves complex legal and factual considerations. The standards applied by the United States Patent and Trademark Office, or USPTO, and foreign patent offices in granting patents are not always applied uniformly or predictably, and can change. For example, there is no uniform worldwide policy regarding patentable subject matter or the scope of claims allowable in pharmaceutical or biotechnology patents. The patent applications that we own or in-license may fail to result in issued patents, and if they do, such patents may not cover our products or product candidates in the United States or in

other countries. Accordingly, we cannot predict whether additional patents protecting our technology will issue in the United States or in non-U.S. jurisdictions, or whether any patents that do issue will have claims of adequate scope to provide us with a competitive advantage. Additionally, the laws of some foreign countries do not protect intellectual property rights to the same extent as the laws of the United States, and many companies have encountered significant problems in protecting and defending such rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents and other intellectual property rights, particularly those relating to biotechnology, which could make it difficult for us to stop the infringement of our licensed and owned patents, the reproduction of our manufacturing or other know-how or marketing of competing products in violation of our proprietary rights generally. Any of these outcomes could impair our ability to prevent competition from third parties, which may have an adverse impact on our business.

Competitors may use our technologies in jurisdictions where we have not obtained or are unable to adequately enforce patent protection to develop their own products and further, may export otherwise infringing products to territories where we have patent protection, but enforcement is not as strong as that in the United States and Europe. These products may compete with our products, and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing. Proceedings to enforce our patent rights in jurisdictions outside the United States, Europe and Japan, whether or not successful, could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

The patent prosecution process is expensive and time consuming, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is also possible that we may fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. In addition, we or our licensors, may only pursue, obtain or maintain patent protection in a limited number of countries. There is no assurance that all potentially relevant prior art relating to our patents and patent applications has been found. We may be unaware of prior art that could be used to invalidate an issued patent or prevent our pending patent applications from issuing as patents. Even if patents do successfully issue and even if such patents cover our products or product candidates, third parties (including our licensees) may challenge their validity, enforceability or scope, which may result in such patents being narrowed or invalidated. Further, the existence of issued patents does not guarantee our right to practice the patented technology or commercialize the patented product. Third parties may have or obtain rights to patents which they may use to prevent or attempt to prevent us from commercializing Selincro or any of our patented product candidates. If these other parties are successful in obtaining valid and enforceable patents, and establishing our infringement of those patents, we could be prevented from selling Selincro or any of our other products unless we were able to obtain a license under such third-party patents. In addition, third parties may seek approval to market their own products similar to or otherwise competitive with our products. In these circumstances, we may need to defend and/or assert our patents, including by filing lawsuits alleging patent infringement. In any of these types of proceedings, a court or agency of competent jurisdiction may find our patents invalid and/or unenforceable.

Furthermore, even if they are unchallenged, our patents and patent applications may not adequately protect our intellectual property, provide exclusivity for our products or product candidates, prevent others from designing around our claims or otherwise provide us with a competitive advantage. Additionally, our confidentiality agreements and other contractual protections may not be adequate to protect our intellectual

property from unauthorized disclosure, third-party infringement or misappropriation. We may not have adequate remedies in the case of a breach of any such agreements, and our trade secrets and other proprietary information could be disclosed to our competitors or others may independently develop substantially equivalent or superior proprietary information and techniques or otherwise gain access to our trade secrets or disclose such technologies. In addition, the research resulting in certain of our licensed patent rights and technology has been, and may in the future be, funded by the U.S. government. As a result, the government may have certain rights, including march-in rights, to such patent rights and technology.

If the patent applications we own or have in-licensed with respect to Selincro, tozadenant or our other product candidates fail to issue as patents, if their breadth or strength of protection is narrowed or threatened, or if they fail to provide meaningful exclusivity, it could dissuade companies from collaborating with us and adversely affect our competitive position. We cannot offer any assurances about which, if any, patents will issue, the breadth of any such patents or whether any issued patents will be found invalid or unenforceable or will be threatened by third parties. Any successful challenge to these patents or any other patents owned by or licensed to us could deprive us of rights necessary for the successful commercialization of any product or product candidate that we may develop and could impair or eliminate our ability to collect future revenues and royalties with respect to such products or product candidates. Since patent applications in the United States and most other countries are confidential for a period of time after filing, and some remain so until issued, we cannot be certain that we were the first to file any patent application related to a product or product candidate. If third parties have prepared and filed patent applications in the United States that also claim technology to which we have rights, we may have to participate in interference proceedings in the USPTO to determine priority of invention for patent applications filed before March 16, 2013, or in derivation proceedings to determine inventorship for patent applications filed after such date. In addition, patents have a limited lifespan. In the United States and most foreign jurisdictions, the natural expiration of a patent is generally 20 years after its effective filing date. Various extensions may be available; however, the life of a patent and the protection it affords is limited. If we encounter delays in obtaining regulatory approvals, the period of time during which we could market a product under patent protection could be reduced. Even if patents covering our product candidates are obtained, once such patents expire, we may be vulnerable to competition from similar or generic products. The launch of a generic version of one of our products in particular would be likely to result in an immediate and substantial reduction in the demand for our product, which could have a material adverse effect on our business.

Any loss of patent protection could have a material adverse impact on our business. We may be unable to prevent competitors from entering the market with a product that is similar to or the same as our products and product candidates.

Changes in patent law could diminish the value of patents in general, thereby impairing our ability to protect our product candidates.

As is the case with other biotechnology and pharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biopharmaceutical industry involves both technological and legal complexity, and obtaining and enforcing biopharmaceutical patents is costly, time consuming, and inherently uncertain. The U.S. Supreme Court has ruled on several patent cases in recent years, and these decisions have narrowed the scope of patent protection available in certain circumstances or weakened the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our and our licensors' ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents once obtained. Depending on future decisions by the U.S. Congress, the federal courts and the USPTO, as well as similar bodies in foreign jurisdictions, the laws and regulations governing patents could change in unpredictable ways that may weaken our and our licensors' ability to obtain new patents or to enforce existing patents and patents we and our licensors or collaborators may obtain in the future.

Recent patent reform legislation could increase the uncertainties and costs surrounding the prosecution of our and our licensors' patent applications and the enforcement or defense of our or our licensors' issued patents. On September 16, 2011, the Leahy-Smith America Invents Act, or the Leahy-Smith Act, was signed into law. The Leahy-Smith Act includes a number of significant changes to U.S. patent law. These include provisions that affect the way patent applications are prosecuted, redefine prior art, may affect patent litigation and switch the U.S. patent system from a "first to invent" system to a "first to file" system. The USPTO recently developed new regulations and procedures to govern administration of the Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act, and in particular, the first to file provisions, only became effective on March 16, 2013. Accordingly, it is not clear what, if any, impact the Leahy-Smith Act will have on the operation of our business. However, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our or our licensors' patent applications and the enforcement or defense of our or our licensors' issued patents, all of which could have a material adverse effect on our business and financial condition.

Our commercial success depends significantly on our ability to operate without infringing the patents and other proprietary rights of third parties.

Our success will depend in part on our ability to operate without infringing the proprietary rights of third parties. Other entities may have or obtain patents or proprietary rights that could limit our ability to make, use, sell, offer for sale or import our products and future approved products or impair our competitive position.

Patents could be issued to third parties that we may ultimately be found to infringe. Third parties may have or obtain valid and enforceable patents or proprietary rights that could block us from developing product candidates using our technology. Our failure to obtain or maintain a license to any technology that we require may materially harm our business, financial condition and results of operations. Furthermore, we would be exposed to a threat of litigation.

In the pharmaceutical industry, significant litigation and other proceedings regarding patents, patent applications, trademarks and other intellectual property rights have become commonplace. The types of situations in which we may become a party to such litigation or proceedings include:

- we or our collaborative partners may initiate litigation or other proceedings against third parties seeking to invalidate the patents held by those third parties or to obtain a judgment that our products or processes do not infringe those third parties' patents;
- if our competitors file patent applications that claim technology also claimed by us or our licensors, we or our licensors may be required to participate in interference, derivation, *inter partes* review or opposition proceedings to determine the priority of invention, inventorship or validity of the applicable patent rights which could jeopardize our patent rights and potentially provide a third party with a dominant patent position;
- if third parties initiate litigation claiming that our processes or products infringe their patent or other intellectual property rights, we and our collaborators will need to defend against such proceedings; and
- if a license to necessary technology is terminated, the licensor may initiate litigation claiming that our processes or products infringe or misappropriate their patent or other intellectual property rights and/or that we breached our obligations under the license agreement, and we and our collaborators would need to defend against such proceedings.

Any such lawsuit would be costly and could affect our results of operations and divert the attention of our management and scientific personnel. There is a risk that a court would decide that we or our collaborators are infringing the third-party's patents and would order us or our collaborators to stop the activities covered by the patents. In that event, we or our collaborators may not have a viable alternative to

the technology protected by the patent and may need to halt work on the affected product candidate or cease commercialization of an approved product. In addition, there is a risk that a court may order us or our collaborators to pay the other party damages. An adverse outcome in any litigation or other proceeding could subject us to significant liabilities to third parties and require us to cease using the technology that is at issue or to license the technology from third parties. We may not be able to obtain any required licenses on commercially acceptable terms or at all. Any of these outcomes could have a material adverse effect on our business.

The pharmaceutical and biotechnology industries have produced a significant number of patents, and it may not always be clear to industry participants, including us, which patents cover various types of products or methods of use. The coverage of patents is subject to interpretation by the courts, and the interpretation is not always uniform or predictable. If we are sued for patent infringement, we would need to demonstrate that our products or methods either do not infringe the patent claims of the relevant patent or that the patent claims are invalid or unenforceable, and we may not be able to do this. Proving invalidity is difficult. For example, in the United States, proving invalidity requires a showing of clear and convincing evidence to overcome the presumption of validity enjoyed by issued patents. Even if we are successful in these proceedings, we may incur substantial costs and divert management's time and attention in pursuing these proceedings, which could have a material adverse effect on us. If we are unable to avoid infringing the patent rights of others, we may be required to seek a license, defend an infringement action or challenge the validity or enforceability of the patents in court. We may not have sufficient resources to bring these actions to a successful conclusion and there is no assurance that such a license would be available or that a court would find in our favor. In addition, if we do not obtain a license, develop or obtain noninfringing technology, fail to defend an infringement action successfully or have infringed patents declared invalid or unenforceable, we may incur substantial monetary damages, encounter significant delays in bringing our product candidates to market and be precluded from manufacturing or selling our product candidates.

The cost of any patent litigation or other proceeding, even if resolved in our favor, could be substantial. Some of our competitors may be able to sustain the cost of such litigation and proceedings more effectively than we can because of their substantially greater resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace.

We are dependent on third parties for the prosecution, protection, and enforcement of intellectual property rights relating to some of our products and product candidates.

While we normally seek to obtain the right to control the prosecution, maintenance, enforcement and defense of intellectual property rights related to our products and product candidates, there may be times when our licensors or collaborators control, or have a first right to control, the filing, prosecution, enforcement and defense of such rights. For instance, pursuant to the Lundbeck License Agreement, Lundbeck has a first right to enforce our patent rights related to Selincro products against third party infringers worldwide. Similarly, under the terms of the Roche License Agreement, the Roche Entities have the first right to prosecute, maintain and enforce the licensed patent rights. We cannot be certain that our licensors or collaborators will prosecute, maintain, enforce and defend such intellectual property rights in a manner consistent with the best interests of our business, including by taking reasonable measures to protect the confidentiality of know-how and trade secrets, or the payment of all applicable prosecution and maintenance fees related to Selincro, tozadenant or any of our other product candidates. We also cannot be certain that the drafting or prosecution of the licensed patents by our licensors have been conducted in compliance with applicable laws and regulations, and will result in valid and enforceable patents and other intellectual property rights. If they fail to do so, we could lose our rights to the intellectual property, our ability to develop and commercialize those products or product candidates may be adversely affected and we may not be able to prevent competitors from making, using and selling competing products.

We depend on licenses for development and commercialization rights to our products, product candidates and technologies. Termination of these rights or the failure to comply with obligations under these or other agreements under which we obtain such rights could materially harm our business and prevent us from developing or commercializing our products and product candidates.

We are party to various agreements, including the Roche License Agreement and our license and commercialization agreement with Medarex, Inc., or the Medarex License Agreement, that we depend on for rights to use various technologies that are material to our business, including intellectual property rights relating to Selincro, tozadenant and other product candidates. In each of these cases, our rights to use the licensed intellectual property are subject to the continuation of and our compliance with the terms of these agreements.

These agreements impose, and we may enter into additional licensing arrangements or other agreements with third parties that may impose, diligence, development and commercialization timelines, milestone payments, royalty, insurance and other obligations on us. For example, pursuant to the Roche License Agreement, we are obligated to make certain milestone payments to the Roche Entities upon the achievement of specified regulatory and commercial milestones. We are also obligated to pay the Roche Entities royalties on net sales of licensed products. Pursuant to the Medarex License Agreement, we are also obligated to make certain milestone payments upon the achievement of specified regulatory and commercial milestones and to pay royalties on net sales of licensed products.

We also have diligence and development obligations under certain of our license agreements. For example, pursuant to the Roche License Agreement, we are required to use commercially reasonable efforts to develop and commercialize licensed products in the United States, Europe and other countries in which we deem it commercially reasonable to do so. Similarly, under the Medarex License Agreement, we must use commercially reasonable efforts to obtain regulatory approvals for BTT1023 worldwide and to pursue commercial sales in countries where such approvals are obtained. If we fail to comply with our obligations under current or future licensing agreements, these agreements may be terminated or the scope of our rights under them may be reduced and we might not have the rights or the financial resources to develop, manufacture or market any product that is covered by these agreements. Termination of these agreements or reduction or elimination of our rights under these agreements may result in our having to negotiate new or reinstated agreements with less favorable terms, seek alternative sources of financing or cause us to lose our rights under these agreements, including our rights to tozadenant, Selincro and other important intellectual property or technology. Any of the foregoing could prevent us from developing or commercializing Selincro, tozadenant or our other product candidates, which could have a material adverse effect on our operating results and overall financial condition.

If trademarks and trade names related to our products or product candidates are not adequately protected, then we may not be able to build name recognition in our markets of interest and our business may be adversely affected.

Our registered or unregistered trademarks or trade names, as well as the registered or unregistered trademarks or trade names used by our licensees or distributors in relation with our products or product candidates, may be challenged, infringed, circumvented or declared generic or determined to be infringing on other marks. We, or our licensees or distributors, may not be able to protect our rights to these trademarks and trade names, which we, our licensees or distributors, need to build name recognition by potential partners or customers in our markets of interest. Over the long term, if we, our licensees or distributors, are unable to establish name recognition based on our trademarks and trade names, then we, our licensees or distributors, may not be able to compete effectively and our business may be adversely affected.

If we are unable to protect the confidentiality of our proprietary information, the value of our technology and products could be adversely affected.

In addition to patent protection, we also rely on other proprietary rights, including protection of trade secrets, and other proprietary information. To maintain the confidentiality of trade secrets and proprietary information, we enter into confidentiality agreements with our employees, consultants, collaborators, CMOs, CROs and others upon the commencement of their relationships with us. These agreements require that all confidential information developed by the individual or made known to the individual by us during the course of the individual's relationship with us be kept confidential and not disclosed to third parties. Our agreements with employees as well as our personnel policies also generally provide that any inventions conceived by the individual in the course of rendering services to us shall be our exclusive property or that we may obtain full rights to such inventions at our election. However, we may not obtain these agreements in all circumstances, and individuals with whom we have these agreements may not comply with their terms. In the event of unauthorized use or disclosure of our trade secrets or proprietary information, these agreements, even if obtained, may not provide meaningful protection, particularly for our trade secrets or other confidential information. To the extent that our employees, consultants or contractors use technology or know-how owned by third parties in their work for us, disputes may arise between us and those third parties as to the rights in related inventions. To the extent that an individual who is not obligated to assign rights in intellectual property to us is rightfully an inventor of intellectual property, we may need to obtain an assignment or a license to that intellectual property from that individual, or a third party or from that individual's assignee. Such assignment or license may not be available on commercially reasonable terms or at all.

Adequate remedies may not exist in the event of unauthorized use or disclosure of our proprietary information. The disclosure of our trade secrets would impair our competitive position and may materially harm our business, financial condition and results of operations. Costly and time consuming litigation could be necessary to enforce and determine the scope of our proprietary rights, and failure to maintain trade secret protection could adversely affect our competitive business position. In addition, others may independently discover or develop our trade secrets and proprietary information, and the existence of our own trade secrets affords no protection against such independent discovery.

As is common in the biotechnology and pharmaceutical industries, we employ individuals who were previously or concurrently employed at research institutions and/or other biotechnology or pharmaceutical companies, including our competitors or potential competitors. We may be subject to claims that these employees, or we, have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers, or that patents and applications we have filed to protect inventions of these employees, even those related to one or more of our product candidates, are rightfully owned by their former or concurrent employer. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management.

Obtaining and maintaining our patent protection depends on compliance with various procedural, documentary, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for noncompliance with these requirements.

Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents and/or applications will be due to the USPTO and various non-U.S. patent offices at various points over the lifetime of our patents and/or applications. Additionally, the USPTO and various non-U.S. patent offices require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. There are situations in which noncompliance can result in abandonment

or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. If such an event were to occur, it could have a material adverse effect on our business.

Certain of our current and former employees and patents are subject to Finnish law and therefore may be eligible to receive compensation based on our future income related to intellectual property invented or coinvented by these employees.

We are based in Finland, and therefore we are subject to Finnish employment law. According to the Finnish Act on the Right in Employee Inventions, which regulates the ownership of, and compensation for, inventions made by employees, several of our employees may be eligible to receive compensation based on our future income related to intellectual property invented or coinvented by these employees.

If we are required to pay additional compensation or face other disputes under the Finnish Act on the Right in Employee Inventions, our results of operations could be adversely affected.

Our internal computer systems, or those of our collaborators or other contractors or consultants, may fail or suffer security breaches, which could result in a material disruption of our product development programs.

Our internal computer systems and those of our current and any future collaborators and other contractors or consultants are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. While we have not experienced any such material system failure, accident or security breach to date, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our development programs and our business operations, whether due to a loss of our trade secrets or other proprietary information or other similar disruptions. For example, the loss of clinical trial data from completed or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability, our competitive position could be harmed and the further development and commercialization of our product candidates could be delayed.

Risks Related to Our Business and Industry

Our relationships with health care professionals, institutional providers, principal investigators, consultants, customers (actual and potential) and third-party payors are, and will continue to be, subject, directly and indirectly, to federal and state health care fraud and abuse, false claims, marketing expenditure tracking and disclosure, government price reporting, and health information privacy and security laws. If we are unable to comply, or have not fully complied, with such laws, we could face penalties, including, without limitation, civil, criminal, and administrative penalties, damages, fines, exclusion from government-funded health care programs, such as Medicare and Medicaid, and the curtailment or restructuring of our operations.

Our business operations and activities may be directly or indirectly subject to various federal and state fraud and abuse laws, including, without limitation, the federal Anti-Kickback Statute and the federal False Claims Act. If we obtain FDA approval for any of our product candidates and begin commercializing those products in the United States, our potential exposure under such laws will increase significantly, and our costs associated with compliance with such laws are also likely to increase. These laws may impact, among other things, our current activities with principal investigators and research subjects, as well as proposed and future sales, marketing and education programs. In addition, we may be subject to patient privacy regulation by the federal government and state governments in which we conduct our business. The laws that may affect our ability to operate include, but are not limited to:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in

kind, to induce or reward either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made, in whole or in part, under a federal health care program such as Medicare and Medicaid;

- the federal false statements statute prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement in connection with the delivery of or payment for health care benefits, items or services;
- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which imposes criminal and civil liability for executing a scheme to defraud any health care benefit program or making false statements relating to health care matters;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 and their respective implementing regulations, which impose requirements on certain covered health care providers, health plans, and health care clearinghouses as well as their respective business associates that perform services for them that involve the use, or disclosure of, individually identifiable health information, relating to the privacy, security and transmission of individually identifiable health information without appropriate authorization;
- the federal physician self-referral law, commonly known as the Stark Law, which prohibits a physician from making a referral to an entity for certain designated health services reimbursed by Medicare or Medicaid if the physician or a member of the physician's family has a financial relationship with the entity, and which also prohibits the submission of any claims for reimbursement for designated health services furnished pursuant to a prohibited referral;
- the federal transparency requirements under the Health Care Reform Law will require manufacturers of drugs, devices, biologics and medical supplies to report to the Department of Health and Human Services information related to payments and other transfers of value to physicians and teaching hospitals and physician ownership and investment interests;
- federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers;
- federal government price reporting laws, changed by the ACA to, among other things, increase the minimum Medicaid rebates owed by most manufacturers under the Medicaid Drug Rebate Program and offer such rebates to additional populations, that require us to calculate and report complex pricing metrics to government programs, where such reported prices may be used in the calculation of reimbursement and/or discounts on our marketed drugs (participation in these programs and compliance with the applicable requirements may subject us to potentially significant discounts on our products, increased infrastructure costs, and potentially limit our ability to offer certain marketplace discounts);
- the Foreign Corrupt Practices Act, a U.S law which regulates certain financial relationships with foreign government officials (which could include, for example, certain medical professionals); and
- analogous state and foreign laws and regulations.

In the European Union, the Data Protection Directive, or DPD, imposes strict regulations and establishes a series of requirements regarding the storage of personally identifiable information on computers or recorded on other electronic media. This has been implemented by all European Union member states through national laws. DPD provides for specific regulations requiring all non-European Union countries doing business with European Union member states to provide adequate data privacy protection when receiving personal data from persons in any of the European Union member states. In

addition, the use and disclosure of personal health and other private information is subject to regulation in other jurisdictions in which we do business or expect to do business in the future. Those jurisdictions may attempt to apply such laws extraterritorially or through treaties or other arrangements with European governmental entities. We cannot assure you that our privacy and security policies and practices will be found sufficient to protect us from liability or adverse publicity relating to the privacy and security of personal information.

In addition, the regulatory approval and commercialization of any of our product candidates outside the United States will also likely subject us to foreign equivalents of the health care laws mentioned above, among other foreign laws.

The ACA, among other things, amended the intent standard of the federal Anti-Kickback Statute and criminal health care fraud statutes to a stricter standard such that a person or entity no longer needs to have actual knowledge of this statute or specific intent to violate it. In addition, the ACA codified case law that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal False Claims Act.

Efforts to ensure that our business arrangements will comply with applicable health care laws may involve substantial costs. It is possible that governmental and enforcement authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law interpreting applicable fraud and abuse or other health care laws and regulations. If we are unable to comply, or have not fully complied, with such laws, we could face penalties, including, without limitation, civil, criminal, and administrative penalties, damages, fines, exclusion from government funded health care programs, such as Medicare and Medicaid, and the curtailment or restructuring of our operations.

We may become exposed to costly and damaging liability claims, either when testing our product candidates in the clinic or at the commercial stage; and our product liability insurance may not cover all damages from such claims.

We are exposed to potential product liability and professional indemnity risks that are inherent in the research, development, manufacturing, marketing and use of pharmaceutical products. Currently we have licensed Selincro to Lundbeck for commercial sale. In addition, the current and future use of product candidates by us in clinical trials, and the sale of any approved products in the future, may expose us to liability claims. These claims might be made by patients that use the product, health care providers, pharmaceutical companies or others selling such products. Any claims against us, regardless of their merit, could be difficult and costly to defend and could materially adversely affect the market for our product candidates or any prospects for commercialization of our product candidates.

Although the clinical trial process is designed to identify and assess potential side effects, it is always possible that a drug, even after regulatory approval, may exhibit unforeseen side effects. If any of our product candidates were to cause adverse side effects during clinical trials or after approval of the product candidate, we may be exposed to substantial liabilities. Physicians and patients may not comply with any warnings that identify known potential adverse effects and patients who should not use our product candidates.

We purchase liability insurance in connection with each of our clinical trials. It is possible that our liabilities could exceed our insurance coverage. We intend to expand our insurance coverage to include the sale of commercial products if we obtain marketing approval for any of our product candidates. However, we may not be able to maintain insurance coverage at a reasonable cost or obtain insurance coverage that will be adequate to satisfy any liability that may arise. If a successful product liability claim or series of claims is brought against us for uninsured liabilities or in excess of insured liabilities, our assets may not be sufficient to cover such claims and our business operations could be impaired.

Should any of the events described above occur, this could have a material adverse effect on our business, financial condition and results of operations, including, but not limited to:

- decreased demand for Selincro, or our current or future product candidates;
- injury to our reputation;
- withdrawal of clinical trial participants;
- initiation of investigations by regulators;
- costs to defend the related litigation;
- a diversion of management's time and our resources;
- substantial monetary awards to clinical trial participants or patients;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;
- loss of revenue;
- exhaustion of any available insurance and our capital resources;
- the inability to commercialize our products or product candidates; and
- a decline in the price of our shares or the ADSs.

We will be highly dependent upon consumer perceptions of us and the safety and quality of our products. We could be adversely affected if we are subject to negative publicity. We could also be adversely affected if any of our products or any similar products distributed by other companies prove to be, or are asserted to be, harmful to patients. Because of our dependence on consumer perceptions, any adverse publicity associated with illness or other adverse effects resulting from patients' use or misuse of our products or any similar products distributed by other companies could have a material adverse impact on our financial condition or results of operations.

Price controls may be imposed in certain markets, which may adversely affect our future profitability.

In some countries, particularly member states of the European Union, the pricing of prescription drugs is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after receipt of marketing approval for a product. In addition, there can be considerable pressure by governments and other stakeholders on prices and reimbursement levels, including as part of cost containment measures. Political, economic and regulatory developments may further complicate pricing negotiations, and pricing negotiations may continue after reimbursement has been obtained. Reference pricing used by various countries and parallel distribution, or arbitrage between low-priced and high-priced countries, can further reduce prices. In some countries, we may be required to conduct a clinical trial or other studies that compare the cost-effectiveness of our product candidates to other available therapies in order to obtain or maintain reimbursement or pricing approval. Publication of discounts by third-party payors or authorities may lead to further pressure on the prices or reimbursement levels within the country of publication and other countries. If reimbursement of our products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our business could be adversely affected.

The impact of recent health care reform legislation and other changes in the health care industry and in health care spending on us is currently unknown, and may adversely affect our business model.

Our revenue prospects could be affected by changes in health care spending and policy in the United States, Europe and other countries. We operate in a highly regulated industry and new laws, regulations or judicial decisions, or new interpretations of existing laws, regulations or decisions, related to health care availability, the method of delivery or payment for health care products and services could negatively impact our business, operations and financial condition.

The United States and state governments continue to propose and pass legislation designed to reduce the cost of health care. In March 2010, the U.S. Congress enacted the Patient Protection and Affordable Care Act and the Health Care and Education Reconciliation Act, which include changes to the coverage and reimbursement of drug products under government health care programs such as:

- increasing drug rebates under state Medicaid programs for brand name prescription drugs and extending those rebates to Medicaid managed care;
- extending discounted rates on drug products available under the Public Health Service pharmaceutical pricing program to additional hospitals and other providers;
- assessing a fee on manufacturers and importers of brand name prescription drugs reimbursed under certain government programs, including Medicare and Medicaid; and
- requiring drug manufacturers to provide a 50% discount on Medicare Part D brand name prescription drugs sold to Medicare beneficiaries whose prescription drug costs cause the beneficiaries to be subject to the Medicare Part D coverage gap (i.e., the so-called “donut hole”).

It is likely that federal and state legislatures within the United States and foreign governments will continue to consider changes to existing health care legislation. We cannot predict the reform initiatives that may be adopted in the future or whether initiatives that have been adopted will be repealed or modified. The continuing efforts of the government, insurance companies, managed care organizations and other payors of health care services to contain or reduce costs of health care may adversely affect:

- the demand for any products for which we may obtain regulatory approval;
- our ability to set a price that we believe is fair for our products;
- our ability to obtain coverage and reimbursement approval for a product;
- our ability to generate revenues and achieve or maintain profitability; and
- the level of taxes that we are required to pay.

In addition, other legislative changes have been proposed and adopted since the 2010 health care reform legislation. The Budget Control Act of 2011, as amended, or the Budget Control Act, includes provisions intended to reduce the federal deficit. The Budget Control Act resulted in the imposition of 2% reductions in Medicare payments to providers beginning in 2013. Recent legislation extends reductions through 2023. Any significant spending reductions affecting Medicare, Medicaid or other publicly funded or subsidized health programs that may be implemented, and/or any significant taxes or fees that may be imposed on us, as part of any broader deficit reduction effort or legislative replacement to the Budget Control Act, could have an adverse impact on our anticipated product revenues.

We and our contract manufacturers and our suppliers could be subject to liabilities, fines, penalties or other sanctions under environmental, health and safety laws and regulations if we or they fail to comply with such laws or regulations or otherwise incur costs that could have a material adverse effect on the success of our business.

We currently rely on and expect to continue to rely on third parties for the manufacturing and supply of active pharmaceutical ingredient, or API, and drug products of our product candidates, including tozadenant, SYN120 and BTT1023. These third parties are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, transportation, use, storage, treatment and disposal of hazardous materials and wastes. Although we have auditing rights with all our CMOs for production of API and drug products, we do not have control over a manufacturer's or supplier's compliance with environmental, health and safety laws and regulations. Liabilities they incur pursuant to these laws and regulations could result in significant costs or in certain circumstances, an interruption in operations, any of which could adversely affect our business and financial condition if we are unable to find an alternate supplier in a timely manner.

We currently do not operate any manufacturing facility or laboratories to produce hazardous materials. With respect to any hazardous materials or waste which we are currently, or in the future will be, handling, using, storing or disposing of, we cannot eliminate the risk of contamination or injury from these materials or wastes, including at third-party disposal sites. In the event of such contamination or injury, we could be held liable for any resulting damages and liability. We also could incur significant costs associated with civil or criminal fines and penalties for failure to comply with applicable environmental, health and safety laws. Although we maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees, this insurance may not provide adequate coverage against potential liabilities. In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our research, development or production efforts. Failure to comply with these laws and regulations may also result in substantial fines, penalties or other sanctions.

Risks Related to Employee Matters and Managing Growth

If we fail to attract and keep senior management and key scientific personnel, we may be unable to successfully develop our products, conduct our clinical trials and commercialize our product candidates.

We are highly dependent on the members of our senior management, which consists of, Timo Veromaa, our CEO, David Cook, our CFO, Stephen Bandak, our CMO and Mehdi Paborji, our COO. The loss of the services of any of these persons could impede the achievement of our research, development and commercialization objectives. Also, each of these persons may terminate their employment with us at any time, subject to their individual employment terms and conditions. We do not maintain "key person" insurance for any of our executives or other employees.

Recruiting and retaining qualified scientific, clinical, manufacturing, sales and marketing personnel will also be critical to our success. We may not be able to attract and retain these personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. We also experience competition for the hiring of scientific and clinical personnel from universities and research institutions. In addition, sometimes we may rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our research and development and commercialization strategy. Our consultants and advisors, including our scientific co-founders, may be employed by employers other than us and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us.

We may encounter difficulties in managing our growth and expanding our operations successfully.

As we seek to advance our product candidates through clinical trials and commercialization, we plan to determine the most appropriate commercial strategy, which may involve setting up our own infrastructure, partnering with another commercial company, or a combination of both to provide these capabilities for us. As our operations expand, we expect that we will need to manage additional relationships with various strategic partners, suppliers and other third parties. Future growth will impose significant added responsibilities on members of management. Our future financial performance and our ability to commercialize our product candidates and to compete effectively will depend, in part, on our ability to manage any future growth effectively. To that end, we must be able to manage our development efforts and clinical trials effectively and hire, train and integrate additional management, administrative and, if necessary, sales and marketing personnel. Due to our limited financial resources, we may not be able to accomplish these tasks, and our failure to accomplish any of them could prevent us from successfully growing our company or disrupt our operations.

Risks Related to the American Depositary Shares, Our Shares and This Offering

We do not know whether a market will develop for the ADSs or what the market price of the ADSs will be and, as a result, it may be difficult for you to sell your ADSs.

If a market for the ADSs does not develop or is not sustained, it may be difficult for you to sell your ADSs at an attractive price, or at all. Certain of our existing investors and members of our board of directors have indicated an interest in purchasing up to an aggregate of \$17 million of ADSs in this offering at the public offering price. However, because indications of interest are not binding agreements or commitments to purchase, these entities and persons may determine to not purchase any ADSs in this offering. It is also possible that these entities and persons and additional existing investors could indicate an interest in purchasing more of the ADSs. In addition, the underwriters could determine to sell fewer ADSs to any of these entities or persons than such entities or persons indicate an interest in purchasing or to not sell any ADSs to these entities and persons. In addition, the underwriters may place the remaining portion of this offering with a limited number of investors. Therefore, trading of the ADSs may be very limited. Further, an inactive market may also impair our ability to raise capital by selling our shares and may impair our ability to enter into strategic partnerships or acquire companies or products by using our shares as consideration. We cannot predict the prices at which the ADSs will trade. It is possible that in one or more future periods, our results of operations may be below the expectations of public market analysts and investors and, as a result of these and other factors, the price of the ADSs may fall.

The market price of the ADSs may be highly volatile, and you may not be able to resell your ADSs at or above the initial public offering price.

The initial public offering price for the ADSs will be determined by negotiations between us and the representatives of the underwriters and may not be indicative of prices that will prevail in the trading market. Because of our relatively small public float the ADSs may be less liquid than the shares of companies with broader public ownership and trading of a relatively small volume of ADSs may have a greater impact on the market price for the ADSs than would be the case if our public float were larger. The market price of the ADSs may fluctuate significantly in response to numerous factors, many of which are beyond our control, including:

- results and timing of clinical trials of our and our competitors' product candidates;
- failure of any of our product candidates, if approved, to achieve commercial success;
- competition from existing products or new products that may emerge;

- delays in entering into strategic relationships with respect to development and/or commercialization of our product candidates or entry into strategic relationships on terms that are not deemed to be favorable to us;
- commencement or termination of any licensing arrangement;
- issues in manufacturing our product candidates or future approved products;
- the passage of legislation or other regulatory developments affecting us or our industry;
- regulatory actions with respect to our products or our competitors' products;
- public concern relating to the commercial value or safety of any of our product candidates;
- changes to coverage policies or reimbursement levels by commercial third-party payors and government payors and any announcements relating to coverage policies or reimbursement levels;
- lawsuits threatened or filed against us;
- disputes or other developments related to proprietary rights, including patents, litigation matters, and our ability to obtain intellectual property protection for our technologies;
- failure to adequately protect our trade secrets;
- additions and departures of key personnel;
- announcement or expectation of additional financing efforts;
- our inability to raise additional capital or the terms on which we raise it;
- period-to-period fluctuations in our financial condition and results of operations, including the timing of receipt of any milestone or other payments under commercialization or licensing agreements;
- publication of research reports by securities analysts about us or our competitors or our industry;
- our failure or the failure of our competitors to meet projections of the investment community or guidance that we or our competitors may give to the market;
- fluctuations in the valuation of companies perceived by investors to be comparable to us;
- strategic decisions by us or our competitors, such as acquisitions, divestitures, spin-offs, joint ventures, strategic investments or changes in business strategy;
- share price and volume fluctuations attributable to inconsistent trading volume levels of our shares;
- speculation in the press or investment community;
- sales of our shares or of the ADSs by us, our insiders or our other shareholders;
- changes in accounting principles;
- terrorist acts, acts of war or periods of widespread civil unrest;
- natural disasters and other calamities;
- changes in market conditions for biopharmaceutical stocks;
- changes in general market and economic conditions; and
- other risk factors discussed in this section.

In addition, the stock market in general has experienced substantial price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of particular companies affected. These broad market and industry factors may materially harm the market price of the ADSs, regardless of our operating performance. As a result of this volatility, you may not be able to sell your shares at or above the initial public offering price. As we operate in a single industry, we are especially vulnerable to these factors to the extent that they affect our industry or our products, or to a lesser extent our markets. In the past, securities class action litigation has often been initiated against companies following periods of volatility in their stock price. This type of litigation could result in substantial costs and divert our management's attention and resources, and could also require us to make substantial payments to satisfy judgments or to settle litigation.

If securities or industry analysts do not publish research or publish inaccurate or unfavorable research about our business, the price of our shares and the ADSs and trading volume could decline.

The trading market for the ADSs depends in part on the research and reports that securities or industry analysts publish about us or our business. If no or few securities or industry analysts cover us, the trading price for the ADSs and our shares would likely be negatively impacted. If one or more of the analysts who covers us downgrades the ADSs or our shares or publishes incorrect or unfavorable research about our business, the price of the ADSs or our shares would likely decline. If one or more of these analysts ceases coverage of us or fails to publish reports on us regularly, or downgrades the ADSs our shares, demand for the ADSs our shares could decrease, which could cause the price of the ADSs or trading volume to decline.

You will incur immediate and substantial dilution as a result of this offering.

If you purchase ADSs in this offering, you will incur immediate and substantial dilution of €(7.58) (\$8.84) per ADS, after giving effect to the sale by us of the 3,761,418 ADSs (representing 300,913,440 shares) offered by us in the offering and the automatic conversion of all outstanding convertible notes issued in connection with the Convertible Notes Financings upon the completion of this offering, and considering an offering price of \$14.888 per ADS, based on a share to ADS ratio of 80 to 1 and an exchange rate of \$1.1279 per euro, after deducting the underwriting discounts and commissions and estimated offering expenses payable by us. Dilution for this purpose represents the difference between the price per ADS paid by new investors and net tangible book value per ADS immediately after the completion of the offering and the automatic conversion of all outstanding convertible notes issued in connection with the Convertible Notes Financings upon the completion of this offering. As a result of the dilution to investors purchasing ADSs in this offering, investors may receive significantly less than the purchase price paid in this offering, if anything, in the event of our liquidation. For more information on the dilution you may suffer as a result of investing in this offering, see "Dilution."

We do not currently intend to pay dividends on our securities and, consequently, your ability to achieve a return on your investment will depend on appreciation in the price of our shares and the ADSs. In addition, any distribution of dividends must be in accordance with the rules and restrictions applying under Finnish law.

We have not declared or paid any cash dividends on our shares since our incorporation and do not currently intend to pay cash dividends on our shares in the foreseeable future, as we currently have significant cumulative losses and so do not have distributable reserves. Currently, we have not adopted a dividend policy. We currently intend to retain all available funds and any future earnings to fund the development and expansion of our business. Therefore, you are not likely to receive any dividends on your ADSs for the foreseeable future and the success of an investment in ADSs will depend upon any future

appreciation in its value. Consequently, investors may need to sell all or part of their holdings of ADSs after price appreciation, which may never occur, as the only way to realize any future gains on their investment. There is no guarantee that the ADSs will appreciate in value or even maintain the price at which our shareholders have purchased the ADSs. Investors seeking cash dividends should not purchase the ADSs.

Further, under the Finnish Companies Act, a company may distribute only the unrestricted equity less the funds to be left undistributed according to the articles of association, if any. In addition, repayment of the capital and accrued interests of our capital loans may restrict our ability to pay dividends in the future. Our capital loans and their terms and conditions have been described in “Management’s Discussion and Analysis of Financial Condition and Results of Operations — Capital Resources and Liquidity.”

In addition, exchange rate fluctuations may affect the amount of euros that we are able to distribute, and the amount in U.S. dollars that our shareholders receive upon the payment of cash dividends or other distributions we declare and pay in euros, if any. These factors could harm the value of the ADSs, and, in turn, the U.S. dollar proceeds that holders receive from the sale of the ADSs.

The dual listing of our shares and the ADSs following this offering may adversely affect the liquidity and value of the ADSs.

Following this offering and after the ADSs are traded on the NASDAQ, our shares will continue to be listed on the Finnish Stock Exchange. Trading of the ADSs or shares in these markets will take place in different currencies (U.S. dollars on the NASDAQ and euros on the Finnish Stock Exchange), and at different times (resulting from different time zones, different trading days and different public holidays in the United States and Finland). The trading prices of our shares on these two markets may differ due to these and other factors. Any decrease in the price of our shares on the Finnish Stock Exchange could cause a decrease in the trading price of the ADSs on the NASDAQ. Investors could seek to sell or buy our shares to take advantage of any price differences between the markets through a practice referred to as arbitrage. Any arbitrage activity could create unexpected volatility in both our share prices on one exchange, and the shares available for trading on the other exchange. In addition, holders of ADSs will not be immediately able to surrender their ADSs and withdraw the underlying shares for trading on the other market without effecting necessary procedures with the depositary. This could result in time delays and additional cost for holders of ADSs. We cannot predict the effect of this dual listing on the value of our shares and the ADSs. However, the dual listing of our shares and the ADSs may reduce the liquidity of these securities in one or both markets and may adversely affect the development of an active trading market for the ADSs in the United States. Although our shares will initially continue to be listed on the Finnish Stock Exchange following this offering, we may decide at some point in the future to delist our shares from the Finnish Stock Exchange, and our shareholders may approve such delisting. We cannot predict the effect such delisting of our shares on the Finnish Stock Exchange would have on the market price of the ADSs on the NASDAQ. Furthermore, in connection with any distributions of payments under the deposit agreement, the depositary may convert foreign currency itself or through any of its affiliates and, in those cases, acts as principal for its own account and not as an agent, fiduciary or broker on behalf of any other person and earns revenue, including, without limitation, fees and spreads that it will retain for its own account. The depositary makes no representation that the exchange rate used or obtained in any currency conversion will be the most favorable rate that could be obtained at the time or as to the method by which that rate will be determined, subject to its obligations under the deposit agreement.

We have broad discretion in the use of the net proceeds from the offering and may not use them effectively.

Our management will have broad discretion in the application of the net proceeds that we receive from this offering as well as of our existing liquid assets, including applications for working capital, possible acquisitions and other general corporate purposes, and we may spend or invest these proceeds in a way with which our shareholders disagree. The failure by our management to apply these funds effectively could harm our business and financial condition. Pending their use, we may invest the net proceeds from the offering in a manner that does not produce income or that loses value. These investments may not yield a favorable return to our investors.

A significant portion of our shares may be sold into the public market in the near future, which could cause the market price of the ADSs or shares to drop significantly, even if our business is doing well.

Future sales of our shares or the ADSs in the public market after this offering and the availability of shares for future sale could adversely affect the market price of the ADSs prevailing from time to time. As described in the section entitled “Shares and American Depositary Shares Eligible for Future Sale,” certain of our shares currently outstanding will not be available for sale shortly after this offering due to contractual restrictions on transfers of shares. However, sales of substantial numbers of ADSs or shares, or the perception that these sales could occur, could adversely affect prevailing market prices for the ADSs and could impair our future ability to raise equity capital.

We have entered into a registration rights agreement with certain of the investors in the Convertible Notes financings pursuant to which we have agreed under certain circumstances to file a registration statement to register the resale of the shares and ADSs held by them or shares issuable upon exercise of the warrants held by them, as well as to cooperate in certain public offerings of such shares and ADSs. In addition, the shares subject to our equity incentive plans and the shares reserved for future delivery under such plans will become eligible for sale in the public market in the future, subject to certain legal and contractual limitations. Following this offering, we intend to file one or more registration statements on Form S-8 with the U.S. Securities and Exchange Commission, or the SEC, covering ADSs (equivalent to shares) available for future issuance under our equity incentive plans. Upon effectiveness of such registration statements, any shares subsequently issued under such plans will be eligible for sale in the public market, except to the extent that they are restricted by the lock-up agreements referred to above and subject to compliance with Rule 144 in the case of our affiliates. Sales of a large number of the shares issued under these plans in the public market could have an adverse effect on the market price of the ADSs. See “Shares and American Depositary Shares Eligible for Future Sale” for a more detailed description of sales that may occur in the future. If these additional shares are sold, or if it is perceived that they will be sold in the public market, the trading price of the ADSs could decline substantially.

Fluctuations in the exchange rate between the U.S. dollar and the euro may increase the risk of holding the ADSs.

Our shares currently trade on the Finnish Stock Exchange and are denominated in euros, while the ADSs that we expect will trade on the NASDAQ will be denominated in U.S. dollars. Fluctuations in the exchange rate between the U.S. dollar and the euro may result in temporary differences between the value of the ADSs and the value of our shares, which may result in heavy trading by investors seeking to exploit such differences. In addition, as a result of fluctuations in the exchange rate between the U.S. dollar and the euro, the U.S. dollar equivalent of the proceeds that a holder of the ADSs would receive upon the sale in Finland of any shares withdrawn from the depositary and the U.S. dollar equivalent of any cash dividends paid in euros on our shares represented by the ADSs could also decline.

Holders of the ADSs are not treated as shareholders of our company.

By participating in this offering you will become a holder of ADSs with underlying shares in a Finnish public limited liability company. Holders of the ADSs are not treated as shareholders of us, unless they withdraw the shares underlying the ADSs from the depositary. The depositary is the holder of the shares underlying the ADSs. Holders of ADSs therefore do not have any rights as shareholders of our company, other than the rights that they have pursuant to the deposit agreement, see “Description of American Depositary Shares.”

You may not be able to exercise your right to vote the shares underlying your ADSs.

Holders of ADSs may exercise voting rights with respect to the shares represented by the ADSs only in accordance with the provisions of the deposit agreement. You may instruct the depositary to vote the number of whole deposited shares your ADSs represent. The depositary will notify you of general meetings of shareholders or other solicitations of consents and arrange to deliver our voting materials to you if we ask it to. Those materials will describe the matters to be voted on and explain how you may instruct the depositary how to vote. For instructions to be valid, they must reach the depositary by a date set by the depositary.

You may instruct the depositary to vote the shares underlying your ADSs. Otherwise, you will not be able to exercise your right to vote, unless you withdraw the shares underlying the ADSs you hold. We cannot assure you that you will receive the voting materials in time to ensure that you can instruct the depositary to vote your shares. In addition, the depositary and its agents are not responsible for failing to carry out voting instructions or for the manner of carrying out voting instructions provided that any such failure is in good faith. This means that you may not be able to exercise your right to vote and there may be nothing you can do if your shares are not voted as you requested. If we do not tell the depositary to ask for your instructions, you can still instruct the depositary how to vote, and the depositary may vote as you instruct, but it is not required to do so.

Our management may have the right to vote the shares underlying your ADSs

Under the deposit agreement, if the depositary asks for your instructions how to vote the shares underlying your ADSs but does not receive those instructions by a specified date, the depositary may give a proxy to our management to vote those shares. This provision may tend to increase the power of our management as against shareholders and make it more difficult for ADSs holders and our shareholders to exercise effective control over our board of directors and other matters submitted to a vote by shareholders.

Your right as a holder of ADSs to participate in any future preemptive subscription rights issues or to elect to receive dividends in shares may be limited, which may cause dilution to your holdings.

Under Finnish law, the existing shareholders have a preemptive right to subscribe for shares offered in proportion to the amount of shares in their possession in connection with any offering of shares. However, a general meeting of shareholders may vote, by a majority which represents at least two-thirds of the votes cast and two-thirds of the shares represented at the meeting, to waive this preemptive right provided that, from the company's perspective, there is a weighty financial reason for the waiver.

Certain non-Finnish shareholders may not necessarily be able to exercise their preemptive subscription rights in our future offerings due to the legislation and regulations of their home country. For example, ADS holders in the United States will not be entitled to exercise or sell such rights unless we register the rights and the securities to which the rights relate under the Securities Act or an exemption from the registration requirements is available. In addition, the deposit agreement provides that the depositary need not make rights available to you unless the distribution to ADS holders of both the rights and any related securities are either registered under the Securities Act or exempted from registration under the Securities Act. We are

under no obligation to file a registration statement with respect to any such rights or securities or to endeavor to cause such a registration statement to be declared effective. Moreover, we may not be able to establish an exemption from registration under the Securities Act. Accordingly, ADS holders may be unable to participate in our rights offerings and may experience dilution in their holdings. In addition, if the depositary is unable to sell rights that are not exercised or not distributed or if the sale is not lawful or reasonably practicable, it will allow the rights to lapse, in which case you will receive no value for these rights.

You may be subject to limitations on the transfer of your ADSs and the withdrawal of the underlying shares.

Your ADSs are transferable on the books of the depositary. However, the depositary may close its books at any time or from time to time when it deems expedient in connection with the performance of its duties. The depositary may refuse to deliver, transfer or register transfers of your ADSs generally when our books or the books of the depositary are closed, or at any time if we or the depositary think it is advisable to do so because of any requirement of law, government or governmental body, or under any provision of the deposit agreement, or for any other reason subject to your right to cancel your ADSs and withdraw the underlying shares. Temporary delays in the cancellation of your ADSs and withdrawal of the underlying shares may arise because the depositary has closed its transfer books or we have closed our transfer books, the transfer of shares is blocked to permit voting at a shareholders' meeting or we are paying a dividend on our shares. In addition, you may not be able to cancel your ADSs and withdraw the underlying shares when you owe money for fees, taxes and similar charges and when it is necessary to prohibit withdrawals in order to comply with any laws or governmental regulations that apply to ADSs or to the withdrawal of shares or other deposited securities.

As a foreign private issuer, we are permitted to adopt certain home country practices in relation to corporate governance matters that differ significantly from NASDAQ corporate governance listing standards. These practices may afford less protection to shareholders than they would enjoy if we complied fully with corporate governance listing standards.

We are a "foreign private issuer," as defined in the SEC's rules and regulations. The NASDAQ Listing Rules include certain accommodations in the corporate governance requirements that allow foreign private issuers to follow "home country" corporate governance practices in lieu of the otherwise applicable corporate governance standards of NASDAQ. The application of such exceptions requires that we disclose the NASDAQ Listing Rules that we do not follow and describe the Finnish corporate governance practices we do follow in lieu of the relevant NASDAQ corporate governance standard. If and when the ADSs are listed on NASDAQ, we intend to continue to follow Finnish corporate governance practices in lieu of the corporate governance requirements of NASDAQ in certain respects. In accordance with the Finnish Companies Act, our articles of association do not provide quorum requirements generally applicable to general meetings of shareholders. To this extent, our practice varies from the requirement of NASDAQ Listing Rule 5620(c), which requires an issuer to provide in its bylaws for a generally applicable quorum, and that such quorum may not be less than one-third of the outstanding voting stock. Although we must provide shareholders with an agenda and other relevant documents for the general meeting of shareholders, Finnish law does not have regulatory regime for the solicitation of proxies and the solicitation of proxies is not a generally required in Finland, thus our practice will vary from the requirement of NASDAQ Listing Rule 5620(b). In addition, we have opted out of shareholder approval requirements for the issuance of securities in connection with certain events such as the acquisition of stock or assets of another company, the establishment of or amendments to equity-based compensation plans for employees, a change of control of us and certain private placements. To this extent, our practice varies from the requirements of NASDAQ

Rule 5635, which generally requires an issuer to obtain shareholder approval for the issuance of securities in connection with such events. Finnish law does not require the implementation of a remuneration committee. Although we do have a remuneration committee, our practice will vary from NASDAQ Listing Rule 5620(d) which sets forth certain requirements as to the responsibilities, composition and independence of a compensation committee. Accordingly, our shareholders may not have the same protection afforded to shareholders of companies that are subject to these NASDAQ requirements.

For an overview of our corporate governance principles, see “Description of Share Capital and Articles of Association—Corporate governance.”

We may lose our foreign private issuer status in the future, which could result in significant additional cost and expense.

While we currently qualify as a foreign private issuer, the determination of foreign private issuer status is made annually on the last business day of an issuer’s most recently completed second fiscal quarter.

In the future, we would lose our foreign private issuer status if we fail to meet the requirements necessary to maintain our foreign private issuer status as of the relevant determination date. Our foreign private issuer status will be tested on June 30 of each year. We expect that we will maintain our status on June 30, 2015, but in the future we may lose the status if, for example, more than 50% of our executive officers or members of our board of directors are residents or citizens of the United States.

The regulatory and compliance costs to us under U.S. securities laws as a U.S. domestic issuer may be significantly more than costs we incur as a foreign private issuer. If we are not a foreign private issuer, we will be required to file periodic reports and registration statements on U.S. domestic issuer forms with the SEC, which are more detailed and extensive in certain respects than the forms available to a foreign private issuer. We would be required under current SEC rules to prepare our financial statements in accordance with U.S. Generally Accepted Accounting Principles, or U.S. GAAP, rather than IFRS. Such conversion of our financial statements to U.S. GAAP would involve significant time and cost, and we would still be required to prepare financial statements in accordance with IFRS under Finnish Stock Exchange requirements. In addition, we may lose our ability to rely upon exemptions from certain corporate governance requirements on United States stock exchanges that are available to foreign private issuers such as the ones described above and exemptions from procedural requirements related to the solicitation of proxies.

We are eligible to be treated as an “emerging growth company,” as defined in the JOBS Act, and we cannot be certain if the reduced disclosure requirements applicable to emerging growth companies will make the ADSs less attractive to investors.

We are an emerging growth company, as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act. For as long as we continue to be an emerging growth company, we may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies, including (1) the ability to include only two years of audited financial statements and only two years of related Management’s Discussion and Analysis of Financial Condition and Results of Operations disclosure; (2) an exemption from the auditor attestation requirement in the assessment of our internal control over financial reporting pursuant to the Sarbanes-Oxley Act of 2002, as amended, or the Sarbanes-Oxley Act; and (3) to the extent that we no longer qualify as a foreign private issuer, (a) reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements; and (b) exemptions from the requirements of holding a nonbinding advisory vote on executive compensation, including golden parachute compensation.

We may take advantage of these provisions for up to five years or such earlier time that we are no longer an emerging growth company. We would cease to be an emerging growth company if we have more than \$1.0 billion in annual revenue, have more than \$700 million in market value of our shares held by non-affiliates, or issue more than \$1.0 billion of nonconvertible debt over a three-year period. We may choose to take advantage of some but not all of these reduced burdens. For example, Section 107 of the JOBS Act provides that an emerging growth company can use the extended transition period provided in Section 7(a)(2)(B) of the Securities Act of 1933, as amended, or the Securities Act, for complying with new or revised accounting standards. Given that we currently report and expect to continue to report under IFRS, as issued by the International Accounting Standards Board, or IASB, we have irrevocably elected not to avail ourselves of this extended transition period and, as a result, we will adopt new or revised accounting standards on the relevant dates on which adoption of such standards is required by the IASB. We have taken advantage of reduced reporting requirements in this prospectus. Accordingly, the information contained herein may be different than the information you receive from other public companies in which you hold equity securities.

The rights of shareholders in companies subject to Finnish corporate law differ in material respects from the rights of shareholders of corporations incorporated in the United States.

We are a Finnish company with limited liability. Our corporate affairs are governed by our articles of association. The rights of shareholders and the responsibilities of members of our board of directors are in many ways different from the rights and obligations of shareholders in companies governed by the laws of United States jurisdictions.

Our bylaws and Finnish corporate law contain provisions that may delay or discourage a takeover attempt.

Provisions contained in our articles of association and Finnish corporate laws could make it more difficult for a third party to acquire us, even if doing so might be beneficial to our shareholders. In addition, under Finnish law, certain measures are possible and permissible that may reduce the likelihood of a company becoming subject to a public tender offer. These may include provisions in the articles of association concerning, for example, the maximum number of votes that a shareholder can cast at a shareholders' meeting, increased majority voting requirements for certain types of shareholder decisions, or a duty to make an offer to purchase outstanding shares at a price specified in the articles of association to all other shareholders upon exceeding a certain ownership threshold. We have not currently adopted any specific provisions in our articles of association that may have the effect of making a takeover of us more difficult or less attractive but there is no guarantee that our shareholders will not adopt such provisions in the future which may delay or discourage a takeover attempt.

U.S. investors may have difficulty enforcing civil liabilities against our company and directors and senior management and the experts named in this prospectus.

We are incorporated under the laws of Finland. Some of our assets are located outside the United States and certain of our directors and members of senior management reside outside of the United States. As a result, it may not be possible for investors to effect service of process within the United States upon such persons or to enforce against them or us in U.S. courts' judgments predicated upon the civil liability provisions of the federal securities laws of the United States. Foreign courts may refuse to hear a United States securities law claim because foreign courts may not be the most appropriate forums in which to bring such a claim. Even if a foreign court agrees to hear a claim, it may determine that the law of the jurisdiction in which the foreign court resides, and not U.S. law, is applicable to the claim.

Further, if U.S. law is found to be applicable, the content of applicable U.S. law must be proved as a fact, which can be a time-consuming and costly process, and certain matters of procedure would still be governed by the law of the jurisdiction in which the foreign court resides. We have been advised by Hannes Snellman Attorneys Ltd, our Finnish counsel, that there is currently no treaty between the United States and Finland providing for reciprocal recognition and enforceability of judgments rendered in connection with civil and commercial disputes and, accordingly, a final judgment rendered by a U.S. court based on civil liability would not be enforceable in Finland as such. However, a U.S. court's judgment may carry evidentiary value in any proceedings for civil liability brought in the Finnish courts. See "Service of Process and Enforcement of Judgments."

If we fail to maintain an effective system of internal control over financial reporting, we may not be able to accurately report our financial results or prevent fraud. As a result, shareholders could lose confidence in our financial and other public reporting, which would harm our business and the trading price of our shares.

Effective internal controls over financial reporting are necessary for us to provide reliable financial reports and, together with adequate disclosure controls and procedures, are designed to prevent fraud. Any failure to implement required new or improved controls, or difficulties encountered in their implementation could cause us to fail to meet our reporting obligations. In addition, any testing by us conducted in connection with Section 404 of the Sarbanes-Oxley Act of 2002, or any subsequent testing by our independent registered public accounting firm, may reveal deficiencies in our internal controls over financial reporting that are deemed to be material weaknesses or that may require prospective or retroactive changes to our financial statements, or identify other areas for further attention or improvement. Inferior internal controls could also cause investors to lose confidence in our reported financial information, which could have a negative effect on the trading price of our shares.

For as long as we are an "emerging growth company" under the JOBS Act, our independent registered public accounting firm will not be required to attest to the effectiveness of our internal controls over financial reporting pursuant to Section 404. We could be an "emerging growth company" for up to five years. An independent assessment of the effectiveness of our internal controls could detect problems that our management's assessment might not. Undetected material weaknesses in our internal controls could lead to financial statement restatements and require us to incur the expense of remediation.

We may be classified as a "passive foreign investment company," or PFIC, in 2015 or any future years. U.S. investors may suffer adverse U.S. federal income tax consequences if we are a PFIC for any taxable year.

Under the Internal Revenue Code of 1986, as amended, or the Code, we will be a PFIC for any taxable year in which, after the application of certain "look-through" rules with respect to subsidiaries, either (i) 75% or more of our gross income consists of "passive income" or (ii) 50% or more of the average quarterly value of our assets consist of assets that produce, or are held for the production of, "passive income." Passive income generally includes interest, dividends, rents and royalties (except to the extent derived in the active conduct of a trade or business) and the excess of gain over losses from disposition of assets which produce passive income. Whether we will be a PFIC in 2015 or any future years depends on the composition of our income and assets, and the relative fair market value of our assets from time to time, which has varied, and we expect will continue to vary, substantially over time. Because (i) we currently own, and will own after the completion of this offering, a substantial amount of passive assets, including cash, and (ii) the valuation of our assets that generate non-passive income for PFIC purposes, including our intangible assets, is uncertain and may vary substantially over time, it is uncertain whether we will be, and there can be no assurance that we will not be, a PFIC in 2015 or any future years. In addition, we may, directly or indirectly, hold equity interests in other entities, including certain of our subsidiaries, that are PFICs, or Lower-tier PFICs.

If we were a PFIC for any taxable year during which a U.S. investor holds ADSs, we generally would continue to be treated as a PFIC with respect to that U.S. investor for all succeeding years during which the U.S. investor holds ADSs, even if we ceased to meet the threshold requirements for PFIC status. Such a U.S. investor may be subject to adverse tax consequences, including (i) the treatment of all or a portion of any gain on disposition as ordinary income, (ii) the application of a deferred interest charge on such gain and the receipt of certain dividends and (iii) compliance with certain reporting requirements.

For further discussion of the adverse U.S. federal income tax consequences if we are classified as a PFIC, see “Taxation — Material U.S. Federal Income Tax Considerations for U.S. Holders.”

Failure by a Finnish resident investor to file a transfer tax notice with the Finnish tax authorities will result in a transfer tax payable by such Finnish resident investor.

The initial public offering of the ADSs is expected to be carried out as a sale of existing ADSs by the underwriters and not as an issue of new ADSs. Therefore, as no Finnish intermediary will be involved in the sale of the ADSs, any investors resident in Finland for tax purposes will have an obligation to file with the Finnish tax authorities a transfer tax notification. Such filing obligation does not exist with respect to investors not resident in Finland for tax purposes. Should an investor resident in Finland for tax purposes not comply with this filing obligation, the sale of ADSs will not qualify for the transfer tax exemption and Finnish transfer tax will be payable by the investor at a rate of 1.6%.

PRESENTATION OF FINANCIAL AND OTHER INFORMATION

Unless otherwise indicated in this prospectus, all references in this prospectus to “\$,” “dollars” and “USD” mean U.S. dollars, all references to “€” and “euros” mean euros, and are to the currency introduced at the start of the third stage of European Economic and Monetary Union pursuant to the Treaty establishing the European Community and all references to “CHF” mean Swiss Franc. Unless otherwise indicated, throughout this prospectus and solely for convenience conversions from one currency to another:

- relating to payments made or received on or before March 31, 2015 were made at the rate used in preparation of the relevant financial statements; and
- relating to future payments were made at the euro to dollars rate of €1.00=\$1.1279, the official rate quoted by the European Central Bank on June 10, 2015.

These conversions should not be considered representations that any such amounts have been, could have been or could be converted into such other currency at that or any other exchange rate as at that or any other date.

Financial Statements

We report under IFRS as issued by the IASB. We present our consolidated financial statements in euros and in accordance with IFRS.

This prospectus contains our audited consolidated financial statements as of and for the years ended December 31, 2014 and 2013 and our unaudited condensed consolidated financial statements as of March 31, 2015 and for the three-month periods ended March 31, 2015 and 2014, which have been prepared in accordance with IFRS as issued by IASB.

Market Share and Other Information

This prospectus contains industry, market and competitive position data that are based on industry publications and studies conducted by third parties as well as our own internal estimates and research. This information involved a number of assumptions and limitations, and you are cautioned not to give undue weight to this information. These industry publications and third-party studies generally state that the information that they contain has been obtained from sources believed to be reliable, although they do not guarantee the accuracy or completeness of such information.

Rounding

The figures presented in this prospectus, including the financial information, have been subject to rounding adjustments. Accordingly, in certain instances, the sum of the numbers in a column or row may not conform exactly to the total figure given for that column or row. In addition, certain percentages presented in this prospectus reflect calculations based upon the underlying figures prior to rounding and, accordingly, may not conform exactly to the percentages that would be derived if the relevant calculations were based upon the rounded numbers.

CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING STATEMENTS

This prospectus contains statements that constitute forward-looking statements. Many of the forward-looking statements contained in this prospectus can be identified by the use of forward-looking words such as “anticipate,” “believe,” “could,” “expect,” “should,” “plan,” “intend,” “estimate” and “potential,” among others.

Forward-looking statements appear in a number of places in this prospectus and include, but are not limited to, statements regarding our intent, belief or current expectations. Forward-looking statements are based on our management’s beliefs and assumptions and on information currently available to our management. Such statements are subject to risks and uncertainties, and actual results may differ materially from those expressed or implied in the forward-looking statements because of various factors, including, but not limited to, those identified under the section entitled “Risk Factors” in this prospectus. These risks and uncertainties include factors relating to:

- our operation as a development stage company with a history of net losses;
- our dependence on cash generation from milestones and royalties in connection with sales of Selincro and other sources of non-dilutive funding;
- the adequacy of our capital resources to successfully complete the development and commercialization of our product candidates;
- our ability to raise additional capital, if required;
- our dependence on the success of tozadenant and our other product candidates, which are still in clinical development and may eventually prove unsuccessful;
- the substantial value allocated to our intangible assets and goodwill resulting from business combinations and potential for impairment;
- uncertainties as to timelines and outcomes in the clinical drug development process;
- uncertainty surrounding whether any of our product candidates will receive regulatory approval, which is necessary before they can be commercialized;
- development and marketing of competing products that are more effective, safer or less expensive than our product candidates;
- our dependence on licenses for development and commercialization rights to our products, product candidates or technologies;
- our dependence on the success of our strategic partnerships and collaborations;
- our reliance on third parties to conduct our nonclinical and clinical trials and perform other tasks for us;
- our reliance on third-party suppliers and other third parties for production of our product candidates;
- our ability to obtain and maintain sufficient intellectual property protection for our product or product candidates;
- our ability to attract and keep senior management and key scientific personnel; and
- other risk factors discussed under “Risk Factors.”

Forward-looking statements speak only as of the date they are made, and we do not undertake any obligation to update them in light of new information or future developments or to release publicly any revisions to these statements in order to reflect later events or circumstances or to reflect the occurrence of unanticipated events.

MARKET INFORMATION

Our shares have been trading on the Finnish Stock Exchange under the symbol “BTH1V” since October 31, 2002.

The following table sets forth for the periods indicated the reported high and low closing sale prices per ordinary share in euros and the average daily trading volume on the Finnish Stock Exchange.

<u>Period</u>	<u>High</u>	<u>Low</u>	<u>Average Daily Trading Volume</u>
Annual			
2010	€0.58	€0.31	357,340
2011	€0.73	€0.38	961,802
2012	€0.53	€0.33	333,332
2013	€0.45	€0.27	631,682
2014	€0.36	€0.19	498,417
Quarterly			
First Quarter 2013	€0.45	€0.36	651,975
Second Quarter 2013	€0.40	€0.33	517,178
Third Quarter 2013	€0.36	€0.32	357,784
Fourth Quarter 2013	€0.36	€0.27	1,021,910
First Quarter 2014	€0.36	€0.22	496,473
Second Quarter 2014	€0.25	€0.22	387,628
Third Quarter 2014	€0.25	€0.19	608,003
Fourth Quarter 2014	€0.22	€0.19	490,919
First Quarter 2015	€0.23	€0.18	625,317
Month Ended			
December 2014	€0.21	€0.19	611,313
January 2015	€0.20	€0.19	318,452
February 2015	€0.23	€0.19	1,023,114
March 2015	€0.19	€0.18	542,651
April 2015	€0.18	€0.16	883,883
May 2015	€0.17	€0.14	852,159
June 2015 (through June 10, 2015)	€0.17	€0.17	500,654

USE OF PROCEEDS

We expect to receive total estimated net proceeds of approximately \$49.1 million (€43.5 million), based on the public offering price of \$14.888 per ADS and an exchange rate of \$1.1279 per euro, and after deducting the estimated underwriting discounts and commissions and expenses of the offering that are payable by us (\$49.7 million (€44.1 million) if the underwriters exercise in full their option to purchase additional ADSs).

As of March 31, 2015, our liquid assets amounted to €27.8 million. We define “liquid assets” as cash and cash equivalents together with our financial assets at fair value through profit or loss, which consists of money market funds. We intend to use the net proceeds from this offering, together with a portion of our current liquid assets (which subsequent to March 31, 2015 includes €30.3 million in net proceeds from the Convertible Notes Financings) to fund our Phase 3 double-blind clinical trial (and extension) of tozadenant in Parkinson’s through completion, which we expect to require an investment of approximately €75 million, including all related studies that will be performed. We intend to fund the SYN120 Phase 2a clinical trial in Parkinson’s dementia and the BTT1023 Phase 2 clinical trial in PSC, which we expect to cost approximately €5 million in total, and other working capital requirements, with our remaining liquid assets, milestone and royalty revenues from Lundbeck for Selincro, and already identified non-dilutive sources.

Our expected use of the net proceeds from this offering represents our current intentions based upon our present plans and business conditions, which could change in the future as our plans and business conditions evolve. As of the date of this prospectus, we cannot predict with certainty all of the particular uses for the net proceeds to be received upon the completion of this offering or the amounts that we will actually spend on the uses set forth above. The amounts and timing of our actual expenditures depend on numerous factors, including the ongoing status of and results from our clinical trials and other studies, the level and timing of milestones and royalties received from Lundbeck for our marketed product, Selincro, and any unforeseen cash needs. As a result, our management will have broad discretion in applying the net proceeds of this offering and investors will be relying on our judgment regarding the application of the net proceeds of this offering. In addition, we might decide to postpone or not pursue other clinical trials or preclinical activities if the net proceeds from this offering and our other sources of cash are less than expected.

Pending their use, we intend to invest the net proceeds from this offering in a variety of capital preservation investments, including money market deposits and investment funds that will be designated as financial assets at fair value through profit and loss in our consolidated statement of financial position.

We will not receive any proceeds from ADSs sold by the selling shareholder pursuant to the underwriters' option to purchase additional ADSs.

DIVIDENDS AND DIVIDEND POLICY

We have not declared or paid any cash dividends on our shares since our incorporation and do not currently intend to pay cash dividends on our shares in the foreseeable future, as we do not expect to have distributable reserves that would enable us to pay a dividend, in the foreseeable future. Currently, we have not adopted a dividend policy. We intend to retain all available funds and any future earnings to fund the development and expansion of our business.

Each of our shares confers equal rights to share in the distribution of our funds. Under the Finnish Companies Act (624/2006), as amended, or the Finnish Companies Act, the annual general meeting of shareholders decides on the distribution of dividends, if any, on the basis of the proposal of our board of directors in connection with the adoption of our audited financial statements. Any material changes in a company's financial situation after the preparation of the financial statements is required to be taken into account in the distribution of dividends. Pursuant to the Finnish Companies Act, the distribution of dividends shall be based on the latest adopted and audited financial statements and a company may also pay interim dividends based on the earnings of the current financial year in accordance with the audited financial statements adopted by an extraordinary general meeting of shareholders. A company may distribute only the unrestricted equity less the funds to be left undistributed according to the articles of association, if any. No funds may be distributed if at the time of deciding on the distribution it is known or it should be known that the company is insolvent or that the distribution will result in insolvency. A dividend or other distribution of assets may not exceed the amount proposed or approved by our board of directors. However, if shareholders holding a minimum of one-tenth of all shares so demand at an annual general meeting of shareholders prior to a decision regarding the use of the profit, and sufficient distributable funds are available, the profit to be distributed shall equal at least half of the profit of the financial year after deduction of items to be left undistributed under the articles of association, if any. According to the Finnish Companies Act, shareholders may not, however, request a distribution of profit exceeding 8% of shareholders' equity. The dividend for the financial year potentially distributed prior to the annual general meeting of shareholders shall be deducted from the distributable amount. The payment of any dividend requires the approval of the majority of the votes cast at the annual general meeting of shareholders. According to the Finnish Companies Act, the annual general meeting of shareholders may also authorize our board of directors to resolve on the distribution of dividends on the basis of adopted financial statements. Such authorization is required to define the maximum amount of dividends to be distributed thereunder and may not remain in effect after the following annual general meeting of shareholders.

Even if our board of directors decides to propose dividends in the future, the form, frequency and amount of such dividends will depend upon our future operations and earnings, capital requirements and surplus, general financial condition, contractual restrictions and other factors our board of directors may deem relevant.

Repayment of the capital and accrued interests of our capital loans may restrict our ability to pay dividends in the future. Our capital loans and their terms and conditions have been described in "Management's Discussion and Analysis of Financial Condition and Results of Operations — Capital Resources and Liquidity." We did not have any distributable assets as at March 31, 2015 and had retained earnings which was an accumulated deficit of €160.8 million at March 31, 2015. See also "Description of Share Capital and Articles of Association — Shareholders' Rights — Dividend and Other Distribution of Funds" and "Description of American Depositary Shares."

CAPITALIZATION

Investors should read this table together with our consolidated financial statements, including the notes thereto, included in this prospectus, as well as “Use of Proceeds,” “Selected Financial and Other Information” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations.”

	As at March 31, 2015		
	Actual	Pro Forma(1)	Pro Forma As Adjusted(2)
	(€ thousands)		
Cash and cash equivalents	6,315	36,662	80,177
Financial assets at fair value through profit or loss	21,513	21,513	21,513
Non-current debt(3)	30,376	30,376	30,376
Shareholders’ equity			
Share capital (ordinary shares, no nominal value, 455,468,174 shares outstanding on an actual and a pro forma basis (including 3,695,284 treasury shares); 977,281,615 shares outstanding on a pro forma as adjusted basis (including 3,695,284 treasury shares))	193,285	223,700	267,214
Reserve for invested unrestricted equity	5,389	5,389	5,389
Other reserves	17,210	17,210	17,210
Retained earnings	(160,789)	(160,789)	(160,789)
Total shareholders’ equity	55,095	85,510	129,024
Total capitalization(4)	85,471	115,886	159,400

- (1) The unaudited pro forma balance sheet data gives effect to the Convertible Notes Financings and the automatic conversion of the convertible notes issued in the Convertible Notes Financings into shares. For pro forma purposes, we have preliminarily evaluated the accounting under IAS 32 for the convertible notes and warrants and expect that the subscription price will be recorded in full in equity as share capital in accordance with the Finnish Companies Act, net of transaction costs, as the instruments will be settled in our shares based on a fixed conversion ratio. As a result, the net proceeds from the convertible notes will result in an increase of cash of approximately €30.3 million with a corresponding amount recorded in share capital at issuance.
- (2) The unaudited pro forma as adjusted balance sheet data gives effect to the following transactions: (i) the Convertible Notes Financings; (ii) the automatic conversion of the convertible notes issued in connection with the Convertible Notes Financings upon the completion of this offering into shares; and (iii) the issuance and sale of 3,761,418 ADSs representing 300,913,440 shares in this offering by us at an initial public offering price of \$14.888 per ADS, a share to ADS ratio of 80 to 1 and an exchange rate of \$1.1279 per euro, after deducting estimated underwriting discounts and commissions and offering expenses payable by us, as set forth under “Use of Proceeds”; and excludes the underwriters’ option to purchase additional ADSs. The automatic conversion of the convertible notes into shares will not impact cash.

The pro forma as adjusted information is presented for informational purposes only and is not necessarily indicative of what our financial position and results would have been had these transactions actually occurred at such date nor is it indicative of our future financial position or performance.

The pro forma as adjusted data does not reflect the effects of the conversion of the warrants, which are exercisable into 220,440,001 of our shares for an exercise price of €0.17 and proceeds of €37.5 million.

- (3) Non-current debt comprises non-current financial liabilities relating to debt of €20.7 million, and related accrued accumulated interest on that debt of €9.6 million and a finance lease of €0.1 million as of March 31, 2015.

- (4) Total capitalization consists of non-current debt and total shareholders' equity.

The table above does not reflect the effects of:

- a maximum of 2,824,772 shares issuable upon exercise of options outstanding pursuant to our Swiss option scheme, at a weighted-average exercise price of €0.24 per share, and which will be settled from the current treasury shares held by us;
- a maximum of 2,678,000 shares issuable upon the exercise of options outstanding pursuant to our stock option plan 2011, at an exercise price of €0.01 per share, and of which a maximum of 720,500 shares will be settled from the current treasury shares held by us;
- a maximum of 945,000 shares issuable upon the settlement of share units outstanding pursuant to our equity incentive plan 2011, at a subscription price of nil, a maximum of 150,000 shares of which will be settled from the current treasury shares held by us;
- a maximum of 7,412,000 shares issuable upon the exercise of options outstanding pursuant to our stock option plan 2014, at an exercise price of €0.01 per share, of which a maximum of 4,320,000 are subject to a market-related performance condition at the time of vesting;
- a maximum of 6,328,750 shares issuable upon the settlement of share units outstanding pursuant to our equity incentive plan 2014, at a subscription price of the euro equivalent to \$0.01 per share, of which 2,520,000 share units are subject to a market-related performance condition at the time of settlement;
- a maximum of 9,409,250 shares issuable upon the exercise of share options and settlement of share units that may be, but have not yet been, granted pursuant to our stock option plan 2014 and our equity incentive plan 2014, at a subscription price of €0.01 and the euro equivalent of \$0.01 respectively;

- the number of shares that would be issuable upon the exercise of our right to offer shares to be subscribed or purchased by YA Global Master SPV Ltd. pursuant to the Standby Equity Distribution Agreement, or the SEDA, which at March 31, 2015, could be for a maximum value of €20.0 million; for more information on the SEDA, see “Description of Share Capital and Articles of Association — Share Capital — Standby Equity Distribution Agreement”;
- 828,000 shares issuable upon conversion of the outstanding convertible capital loan as of March 31, 2015, at a conversion rate of €1.8688 per share for 540,000 of the shares and €2.3359 for 288,000 of the shares; and
- a maximum of 220,400,001 shares issuable upon the exercise of warrants outstanding as of May 28, 2015 at an exercise price of €0.17 per share.

DILUTION

If you invest in the ADSs, your ownership interest will be diluted to the extent of the difference between the initial public offering price per ADS paid by purchasers of the ADSs and the pro forma as adjusted net tangible book value per ADS immediately after the completion of this offering. At March 31, 2015, we had a net tangible book value of €(5,223,000) (\$5,619,426), corresponding to a net tangible book value of €(0.01) (\$0.01) per share or €(0.92) (\$0.99) per ADS based on a share to ADS ratio of 80 to 1. Net tangible book value per share represents the amount of our total assets less our total liabilities, excluding goodwill and other intangible assets, divided by the total number of our shares outstanding at March 31, 2015.

At March 31, 2015, we had a pro forma net tangible book value of €25,114,785 (\$27,020,997), corresponding to a net tangible book value of €0.04 (\$0.04) per share or €2.97 (\$3.20) per ADS based on a share to ADS ratio of 80 to 1. Pro forma net tangible book value per share represents the amount of our total assets less our total liabilities, excluding goodwill and other intangible assets, divided by the total number of our shares outstanding at March 31, 2015, after giving pro forma effect to the Convertible Notes Financings and the automatic conversion of all convertible notes issued in the Convertible Notes Financings into shares.

After giving effect to the sale by us of the 3,761,418 ADSs (representing an aggregate of 300,913,440 shares) offered by us in the offering, based on an offering price of \$14.888 per ADS, a share to ADS ratio of 80 to 1 and an exchange rate of \$1.1279 per euro, after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us, our pro forma as adjusted net tangible book value at March 31, 2015 would have been approximately €68,638,317 (\$73,847,965), representing €0.07 (\$0.08) per share or €5.62 (\$6.05) per ADS. This represents an immediate increase in pro forma as adjusted net tangible book value of €0.03 (\$0.04) per share or €2.65 (\$2.85) per ADS to existing shareholders and an immediate dilution in net tangible book value of €0.09 (\$0.11) per share or €(7.58) (\$8.84) per ADS to new investors purchasing ADSs in this offering. Dilution for this purpose represents the difference between the price per ADS paid by these purchasers and the net tangible book value per ADS immediately after the completion of this offering, giving effect to the Convertible Notes Financings and the automatic conversion of all outstanding convertible notes issued in the Convertible Notes Financings into shares.

The following table illustrates this dilution to new investors purchasing ADSs in the offering:

Initial public offering price per ADS	€13.20	\$14.89
Net tangible book value per ADS at March 31, 2015	(0.92)	(0.99)
Increase in net tangible book value per ADS attributable to the Convertible Notes Financings and the automatic conversion of all outstanding convertible notes issued in the Convertible Notes Financings	3.89	4.18
Pro forma net tangible book value per ADS before this offering	2.97	3.20
Increase in pro forma net tangible book value per ADS attributable to new investors	2.65	2.85
Pro forma as adjusted net tangible book value per ADS after the offering	€ 5.62	\$ 6.05
Dilution per ADS to new investors	€(7.58)	\$ (8.84)
Percentage of dilution in net tangible book value per ADS for new investors	57%	59%

If the underwriters exercise their option in full to purchase additional ADSs from us in this offering, the pro forma as adjusted net tangible book value per ADS after the offering would be €5.64 (\$6.26) per ADS, the increase in the net tangible book value per would be €2.67 (\$3.06) per ADS and the dilution to new investors purchasing ADSs in this offering would be €(7.56) (\$8.63) per ADS.

The following table sets forth, at March 31, 2015, on a pro forma as adjusted basis for this offering, the Convertible Notes Financings and the automatic conversion of all outstanding convertible notes issued in connection with the Convertible Notes Financings, the consideration paid to us in cash for shares (shares expressed as ADSs (translated into US dollars at \$1.1279 per euro) in the table below) purchased from us by our existing shareholders and ADSs purchased from us by new investors participating in this offering, based on an offering price of \$14.888 per ADS, after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable per ADS:

	ADSs Purchased from Us		Total Consideration		Average Price per ADS
	Number	Percent	Amount	Percent	
Existing shareholders	8,454,602	69%	\$ 93,611,657	63%	\$11.07
New investors	3,761,418	31%	\$ 55,999,991	37%	\$14.89
Total	<u>12,216,020</u>	<u>100%</u>	<u>\$149,611,648</u>	<u>100%</u>	<u>—</u>

Except as otherwise indicated herein, the discussion and tables above assume that 977,281,615 shares will be outstanding after this offering, based on 455,968,174 of our shares outstanding as of March 31, 2015, including 452,272,890 shares with voting rights and 3,695,284 treasury shares that are held by us and do not have voting rights, and includes 300,913,440 shares to be issued and sold by us in this offering and 220,400,001 shares to be issued by us upon the automatic conversion of all outstanding convertible notes issued in connection with the Convertible Notes Financings upon the completion of this offering, but excludes:

- a maximum of 2,824,772 shares issuable upon exercise of options outstanding pursuant to our Swiss option scheme, at a weighted-average exercise price of €0.24 per share, and which will be settled from the current treasury shares held by us;
- a maximum of 2,678,000 shares issuable upon the exercise of options outstanding pursuant to our stock option plan 2011, at an exercise price of €0.01 per share, and of which a maximum of 720,500 shares will be settled from the current treasury shares held by us;
- a maximum of 945,000 shares issuable upon the settlement of share units outstanding pursuant to our equity incentive plan 2011, at a subscription price of nil, a maximum of 150,000 shares of which will be settled from the current treasury shares held by us;

- a maximum of 7,412,000 shares issuable upon the exercise of options outstanding pursuant to our stock option plan 2014, at an exercise price of €0.01 per share, of which a maximum of 4,320,000 shares are subject to a market-related performance condition at the time of vesting;
- a maximum of 6,328,750 shares issuable upon the settlement of share units outstanding pursuant to our equity incentive plan 2014, at a subscription price of the amount of euros corresponding to \$0.01 per share, of which 2,520,000 share units are subject to a market-related performance condition at the time of settlement;
- a maximum of 9,409,250 shares issuable upon the exercise of share options and settlement of share units that may be, but have not yet been, granted pursuant to our stock option plan 2014 and our equity incentive plan 2014, at a subscription price of €0.01 and the euro equivalent of \$0.01 respectively;
- the number of shares that would be issuable upon the exercise of our right to offer shares to be subscribed or purchased by YA Global Master SPV Ltd. pursuant to the Standby Equity Distribution Agreement, or the SEDA, which at March 31, 2015, could be for a maximum value of €20.0 million; for more information on the SEDA, see “Description of Share Capital and Articles of Association — Share Capital — Standby Equity Distribution Agreement”;
- 828,000 shares issuable upon conversion of the outstanding convertible capital loan as of March 31, 2015, at a conversion rate of €1.8688 per share for 540,000 of the shares and €2.3359 for 288,000 of the shares; and
- a maximum of 220,400,001 shares issuable upon the exercise of warrants outstanding as of May 28, 2015 at an exercise price of €0.17 per share.

Certain of our existing investors and members of our board of directors have indicated an interest in purchasing up to an aggregate of \$17 million of the ADSs in this offering at the public offering price. However, because indications of interest are not binding agreements or commitments to purchase, these entities and persons may determine to not purchase any ADSs in this offering. It is also possible that these entities and persons and additional existing investors could indicate an interest in purchasing more of the ADSs. In addition, the underwriters could determine to sell fewer ADSs to any of these entities or persons than such entities or persons indicate an interest in purchasing or to not sell any ADSs to these entities and persons. The foregoing discussion and tables do not reflect any potential purchases by these entities and persons.

EXCHANGE RATES

The following table sets forth, for the periods indicated, the high, low, average and period-end exchange rates for U.S. dollars expressed in euros. As of June 10, 2015, the exchange rate as reported by the European Central Bank was \$1.00 = €0.8866. The rates set forth below are provided solely for your convenience and may differ from the actual rates used in the preparation of our consolidated financial statements and other financial data included in this prospectus.

	<u>Period-End</u>	<u>Average for</u> <u>Period</u>	<u>Low</u>	<u>High</u>
	<u>€</u>	<u>€</u>	<u>€</u>	<u>€</u>
		(€ per \$)		
Year Ended December 31:				
2010	0.748	0.754	0.687	0.837
2011	0.773	0.718	0.672	0.776
2012	0.758	0.778	0.743	0.827
2013	0.725	0.753	0.724	0.783
2014	0.824	0.754	0.717	0.824
Month Ended:				
December 31, 2014	0.824	0.811	0.798	0.824
January 31, 2015	0.885	0.861	0.830	0.893
February 28, 2015	0.890	0.881	0.874	0.890
March 31, 2015	0.929	0.923	0.891	0.947
April 31, 2015	0.892	0.928	0.892	0.948
May 31, 2015	0.912	0.897	0.876	0.921
June (through June 10, 2015)	0.887	0.896	0.884	0.914

SELECTED FINANCIAL AND OTHER INFORMATION

The consolidated statements of comprehensive income data for each of the years ended December 31, 2014 and 2013 and the summary consolidated statement of financial position data as of December 31, 2014 have been derived from our audited consolidated financial statements included elsewhere in this prospectus. The consolidated statements of comprehensive income data for each of the three-month periods ended March 31, 2015 and 2014 and the summary consolidated statement of financial position data as of March 31, 2015 have been derived from our unaudited condensed consolidated financial statements included elsewhere in this prospectus. The unaudited condensed financial statements have been prepared on the same basis as the audited financial statements and, in the opinion of management, reflect all adjustments necessary to state fairly our results of operations for the three months ended March 31, 2015 and 2014 and our financial position as of March 31, 2015. The summary consolidated financial information below should be read in conjunction with our consolidated financial statements, including the notes thereto, included elsewhere in this prospectus as well as the “Presentation of Financial and Other Information” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations” sections of this prospectus.

Our audited consolidated financial statements for the years ended December 31, 2014 and 2013 and our unaudited condensed consolidated financial statements for the three-month periods ended March 31, 2015 and 2014 have been prepared in accordance with IFRS as issued by the IASB.

Our historical results are not necessarily indicative of our future results. The summary financial information below does not contain all the information included in our financial statements. In addition, our historical results for the three months ended March 31, 2015 are not necessarily indicative of results to be expected for a full year or any other interim period.

Consolidated Statements of Comprehensive Income Data

	Year Ended December 31,		Three Months Ended March 31,	
	2014	2013	2015	2014
(€ thousands, except per share data)			(unaudited)	
Revenue	14,901	27,712	871	5,096
Research and development expenses	(17,192)	(17,807)	(4,766)	(4,803)
Impairment of in-process research and development assets	(27,605)	—	—	—
General and administrative expenses	(7,326)	(8,971)	(1,730)	(1,950)
Other operating income	1,132	565	—	135
Operating (loss) income	(36,090)	1,499	(5,625)	(1,522)
Interest income	—	37	1	—
Interest expenses	(687)	(726)	(151)	(152)
Other net financial income (expenses)	1,612	2,841	(119)	(45)
(Loss) income before taxes	(35,165)	3,651	(5,894)	(1,719)
Income tax benefit	—	2,195	—	—
Net (loss) income	(35,165)	5,846	(5,894)	(1,719)
Other comprehensive income (loss)				
Remeasurements of post-employment benefit obligations	(81)	—	—	—
Currency translation differences	6,593	(2,629)	8,181	315
Total comprehensive (loss) income	(28,653)	3,217	2,287	(1,404)
Net (loss) income attributable to equity holders of the parent	(35,165)	5,846	(5,894)	(1,719)
Total comprehensive (loss) income attributable to equity holders of the parent	(28,653)	3,217	2,287	(1,404)
(Loss) earnings per share (EPS) basic & diluted(1)	(0.08)	0.01	(0.01)	(0.00)

- (1) Basic and diluted (loss) earnings per share are the same in all periods because outstanding options, share units and the convertible loan would have been anti-dilutive for the year ended December 31, 2014 and for the three months ended March 31, 2015 and 2014; and dilutive shares had no impact to EPS after rounding for the year ended December 31, 2013.

Consolidated Statements of Financial Position Data

(in thousands of €)	At December 31,		At March 31, 2015 (unaudited)
	2014	2013	
ASSETS			
Intangible assets	47,356	68,744	53,721
Goodwill	5,799	5,315	6,597
Other assets	977	1,686	1,072
Total non-current assets	54,132	75,745	61,390
Accounts receivables, other receivables and prepaid expenses	1,806	575	5,357
Financial assets at fair value through profit or loss	24,941	33,457	21,513
Cash and cash equivalents	7,452	10,221	6,315
Total current assets	34,199	44,253	33,185
Total assets	88,331	119,998	94,575
EQUITY AND LIABILITIES			
Share capital	193,285	193,285	193,285
Reserve for invested unrestricted equity	5,378	5,252	5,389
Other reserves	9,029	2,517	17,210
Retained earnings	(155,069)	(120,688)	(160,789)
Total shareholders' equity	52,623	80,366	55,095
Non-current financial liabilities	20,690	20,690	20,690
Pension benefit obligation	670	569	670
Other non-current liabilities	9,671	8,918	9,842
Non-current deferred revenues	2,000	2,972	2,000
Total non-current liabilities	33,031	33,149	33,202
Current deferred revenues	—	743	—
Accounts payable and other current liabilities	2,677	5,740	6,278
Total current liabilities	2,677	6,483	6,278
Total liabilities	35,708	39,632	39,480
Total shareholders' equity and liabilities	88,331	119,998	94,575

MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion and analysis of our financial condition and results of operations should be read together with our audited consolidated financial statements and the notes thereto, each included elsewhere in this prospectus, as well as the information presented under "Presentation of Financial and Other Information" and "Selected Financial and Other Information." The following discussion is based on our financial statements prepared in accordance with International Financial Reporting Standards, or IFRS, as issued by the International Accounting Standards Board, or IASB, which might differ in material respects from generally accepted accounting principles in other jurisdictions. This discussion and analysis contains forward-looking statements, which are subject to risks and uncertainties. Investors should also familiarize themselves with the sections entitled "Risk Factors" and "Cautionary Statement Regarding Forward-Looking Statements" of this prospectus. As a result of many factors, including factors described in the aforementioned sections, our actual results could differ materially from the results described herein or implied by the forward-looking statements contained in the following discussion and analysis.

Overview

We are a biopharmaceutical company primarily focused on developing therapeutics for central nervous system disorders. Our pipeline includes product candidates designed to address unmet medical needs in Parkinson's disease and related dementia, other neurodegenerative indications, and primary sclerosing cholangitis, an orphan fibrotic liver disease. In addition, we have successfully developed a product for alcohol dependence that is being commercialized by Lundbeck and is a source of further potential milestone payments and ongoing royalties.

We are preparing to commence a pivotal Phase 3 clinical trial of our lead product candidate, tozadenant, that we believe could form the basis for its approval in the United States as an adjunctive treatment to levodopa in Parkinson's. Levodopa, the most widely prescribed treatment for Parkinson's, loses effectiveness in most patients over time. Parkinson's patients often experience a reemergence of debilitating symptoms on a daily basis as their levodopa doses wear off. Tozadenant is an oral, selective adenosine A_{2a} receptor antagonist that aims to address this wearing off effect. In a 420-patient Phase 2b trial, tozadenant displayed clinically important and statistically significant effects across prespecified primary and multiple secondary endpoints at a number of doses. In addition, tozadenant has been found to be generally safe and well tolerated in our ten clinical trials conducted to date.

We also have two additional development-stage product candidates: SYN120 for Parkinson's dementia and Alzheimer's; and BTT1023 for primary sclerosing cholangitis, an orphan fibrotic liver disease. In addition, under our license and commercialization agreement with H. Lundbeck A/S, or Lundbeck, for Selincro, our product for alcohol dependence, we have received €22.0 million in upfront and milestone payments to date and are eligible to receive additional regulatory and commercial milestone payments and ongoing royalties.

We have primarily funded our operations through private placements of equity securities, non-convertible and convertible capital loans, long-term research and development loans, development milestone payments, commercial milestone payments under our license and commercialization agreement with Lundbeck, or the Lundbeck License Agreement, and, most recently, royalties under the Lundbeck License Agreement. In addition, a number of trials of our product candidates have been partially or wholly funded through non-dilutive funding, which may or may not flow through our financial statements.

In January 2011, we entered into an agreement to acquire Synosia Therapeutics Holding AG, or Synosia, a company that had been formed by certain former executives of F. Hoffmann-La Roche Ltd., or

Roche, that had licensed a number of central nervous system focused assets from Roche, including tozadenant and SYN120. From the acquisition of Synosia in 2011 through March 31, 2015, we raised gross proceeds of €57.0 million from private placements of equity securities. In addition, between 1998 and 2011, we received gross proceeds of €19.7 million from non-convertible capital loans from the Finnish Funding Agency for Technology and Innovation, or Tekes, €4.4 million from long-term research and development loans from Tekes and €1.7 million from a convertible capital loan from shareholders and venture capital investors, of which €3.3 million of the non-convertible capital loans and €1.7 million of the long-term research and development loans have been forgiven. We refer to the non-convertible capital loans and research and development loans from Tekes as the Tekes loans. Through March 31, 2015, we have also received €23.8 million in milestone and royalty payments from Lundbeck for Selincro and a total of €36.2 million from UCB Pharma S.A., or UCB, in connection with tozadenant.

As of March 31, 2015, our liquid assets amounted to €27.8 million. We define “liquid assets” as cash and cash equivalents together with our financial assets at fair value through profit or loss, which consist of money market funds. As of March 31, 2015, our cash and cash equivalents were €6.3 million and our financial assets at fair value through profit or loss were €21.5 million.

With the exception of the year ended December 31, 2013, we have never been profitable and have incurred losses in each year since inception. Although we made a profit in 2013, this was primarily due to a non-refundable development milestone payment received from UCB for tozadenant, which cannot be expected to recur in the future. Our net result was a €35.2 million loss and a €5.8 million profit for the years ended December 31, 2014 and 2013, respectively and for the three months ended March 31, 2015 and 2014, we incurred net losses of €5.9 million and €1.7 million, respectively. As of March 31, 2015 we had retained earnings, which were an accumulated deficit, of €160.8 million. Substantially all of our losses have resulted from funding our research and development programs and general and administrative costs associated with our operations.

We currently expect to earn revenue primarily under the Lundbeck License Agreement, pursuant to which we are eligible to receive royalties on sales of Selincro, as well as milestone payments upon achievement of specified regulatory and commercial milestones. We believe that the net proceeds of this offering, together with our current liquid assets and the milestone and royalty revenues that we expect to receive from Lundbeck for Selincro, will enable us to fund our Phase 3 double-blind clinical trial (and extension) of tozadenant in Parkinson’s through completion, as well as our portion of the funding for the SYN120 Phase 2a clinical trial in Parkinson’s dementia and BTT1023 Phase 2 clinical trial in primary sclerosing cholangitis, or PSC.

Collaboration and License Agreements

We have entered into strategic collaborations and license agreements for some of our products and product candidates. As part of our business development strategy, we aim to increase the number of our strategic collaborations in order to derive further value from our platforms and more fully exploit their potential.

Certain key terms of our current material collaboration and license agreements are summarized below. For further details, see “Business — Collaborations.”

Lundbeck License Agreement

In November 2006, we entered into an option agreement, or the Option Agreement, to negotiate a license and commercialization agreement with Lundbeck and subsequently entered into the Lundbeck License Agreement in May 2007. Pursuant to the Lundbeck License Agreement we granted Lundbeck an exclusive, royalty-bearing, sublicensable worldwide license under certain patents and know-how related to

Selincro owned by or exclusively licensed to us, to develop, manufacture and commercialize Selincro for any purpose. Lundbeck is responsible for the manufacturing and commercialization of Selincro products, as well as registration, maintenance and defense of all trademarks related to such products.

Pursuant to the Option Agreement in November 2006, Lundbeck made an upfront payment to us of €10.0 million. Pursuant to the Lundbeck License Agreement, Lundbeck initially made an upfront payment to us of €2.0 million in May 2007 and agreed to make milestone payments to us upon the achievement of specified regulatory and commercial milestones as well as royalties on sales of Selincro. As of March 31, 2015, we have received €10.0 million in milestone payments, including €2.0 million milestones on the first commercial sale in each of the United Kingdom (May 2013), Italy (September 2013), Spain (July 2014), Germany (August 2014) and France (September 2014). In addition, we are required to reimburse Lundbeck for performing additional studies in certain countries in order to obtain and maintain regulatory approval to market and sell Selincro products in such countries. As of March 31, 2015, we have contributed €2.1 million to such studies. In October 2013, Lundbeck entered into an agreement with Otsuka Pharmaceutical Co., Ltd., or Otsuka, to develop and commercialize Selincro in Japan. Lundbeck and Otsuka will jointly finalize and fully fund the clinical program for Selincro in Japan, and it is expected that the first Phase 3 clinical trial will be initiated during 2015. For further information on the Lundbeck License Agreement, see “Business — Collaborations — Lundbeck License Agreement.”

UCB Collaboration Agreement and UCB Termination and Transition Agreement

Prior to our acquisition of Synosia in February 2011, in August 2010, Synosia entered into a license and collaboration agreement, or the UCB Collaboration Agreement, with UCB, to develop and commercialize tozadenant. Pursuant to the UCB Collaboration Agreement, UCB was granted a licensing option. Following a review of the tozadenant Phase 2 data in February 2013, UCB exercised its option in relation to tozadenant and paid us a non-refundable development milestone payment of \$20.0 million (€15.3 million) following completion of the Phase 2b clinical trial. Until the end of March 2014, UCB funded further development of tozadenant amounting to €13.3 million. In March 2014, we received a notice from UCB informing us of its intent to terminate the UCB Collaboration Agreement for convenience, effective March 20, 2014. In August 2014, we and UCB entered into a termination and transition agreement, or the UCB Termination and Transition Agreement, pursuant to which we and UCB agreed to undertake a series of transitional activities to facilitate the handover of tozadenant development activities and associated regulatory documentation back to us. UCB has now met all of its obligations under the UCB Termination and Transition Agreement and has provided additional Phase 3 development funding, of which we had received €3.1 million through March 31, 2015. We are required to pay UCB a percentage of any future consideration we receive from tozadenant, up to a maximum of €3.1 million. For further information on the UCB Collaboration Agreement and the UCB Termination and Transition Agreement, see “Business — Collaborations — UCB Collaboration Agreement and UCB Termination and Transition Agreement.”

Roche License Agreement

We are party to a license agreement with Roche Palo Alto LLC, Hoffman-La Roche Inc. and F. Hoffman-La Roche Ltd., collectively, the Roche Entities, and such agreement, the Roche License Agreement, pursuant to which we obtained exclusive, royalty-bearing, worldwide licenses in respect of tozadenant and SYN120. Pursuant to the Roche License Agreement, we are obligated to make certain milestone payments to the Roche Entities on the achievement of specified regulatory and commercial milestones. We are also obligated to pay the Roche Entities royalties on net sales of licensed products. For further information on the Roche License Agreement, see “Business—Collaborations—Roche License Agreement.”

Medarex License Agreement

In November 2006, we entered into a license and commercialization agreement, as amended, or the Medarex License Agreement, with Medarex, Inc. or Medarex, to develop and commercialize BTT1023 worldwide. Pursuant to the Medarex License Agreement, we obtained an exclusive, royalty-bearing license under certain patents rights and know-how controlled by Medarex, to develop and commercialize BTT1023 and products containing BTT1023 worldwide. We also obtained a non-exclusive, worldwide, royalty-free license to use Medarex's patent rights and know-how relating to the production of VAP-1 antibodies solely for the purpose of manufacturing BTT1023 or products containing BTT1023.

We have paid Medarex \$1 million in upfront license fees, \$1.08 million for research and development costs, as well as \$1.35 million for the supply of materials for a Phase 1 clinical trial. We are further obligated to pay Medarex up to an aggregate of \$8.6 million upon the occurrence of certain regulatory milestones for each product developed under the Medarex License Agreement, of which \$0.5 million has already been paid. We are also required to pay Medarex up to an aggregate of \$11.5 million if we achieve specified sales milestones, as well as a tiered mid-single digit royalty on net sales of products containing BTT1023 worldwide. Such royalties are payable on a country-by-country and product-by-product basis until the later of either the expiration of the last to expire of any patent or patent application controlled by Medarex that covers the applicable product in the applicable country, or 15 years from the first commercial sale of the applicable product in the applicable country. For further information on the Medarex License Agreement, see "Business—Collaborations—Medarex License Agreement."

Financial Operations Overview

Revenue

In the periods presented, we earned revenue under the Lundbeck License Agreement, the UCB Collaboration Agreement and the UCB Termination and Transition Agreement as described below.

Under the Lundbeck License Agreement, we have recognized revenue from commercial milestone and royalty payments. During the years ended December 31, 2014 and 2013, we received milestone payments totaling €10.0 million in connection with launches of Selincro in the five major EU markets: the United Kingdom (May 2013), Italy (September 2013), Spain (July 2014), Germany (August 2014) and France (September 2014) and royalties of €0.9 million, €0.2 million and €0.7 million on sales of Selincro during the years ended December 31, 2014 and 2013 and the three months ended March 31, 2015, respectively. Royalties received are dependent upon the sales made by Lundbeck in each period. The milestone payments are non-refundable and are recognized when a milestone has been achieved, we have no further performance obligations in respect of the milestone and it will be possible to collect the milestone with reasonable assurance. Royalty revenue is recognized on an accrual basis in accordance with the Lundbeck License Agreement providing that it is probable that economic benefits will flow to us and the amount of revenue can be measured reliably.

Under the UCB Collaboration Agreement and the UCB Termination and Transition Agreement, we also recognized revenue from a non-refundable development milestone payment following the completion of the Phase 2b clinical trial and Phase 3 development milestones. The non-refundable development milestone payment and development funding payments are recognized upon receipt as revenue when a milestone has been achieved and we have no further performance obligations. In February 2013, UCB exercised its option in relation to tozadenant and paid us a non-refundable Phase 2 development milestone payment of \$20.0 million (€15.3 million) following the completion of the Phase 2b clinical trial, and by March 31, 2015, we had received €3.1 million in development funding under the UCB Termination and Transition Agreement. During the years ended December 31, 2014 and 2013, we received €5.1 million and

€8.3 million, respectively, in development milestones under the UCB Collaboration Agreement, which prior to UCB's informing us of their intention to return their rights to tozadenant to us, were recognized in proportion to the development activities performed to date.

We expect that our revenues in the near to medium term will mainly derive from the Lundbeck License Agreement.

Research and Development Expenses

Our research and development activities are central to our business model. Product candidates in later stages of clinical development generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials. We expect our research and development expenses to increase for the foreseeable future as our product candidates progress in clinical trials. Our research and development expenses consist principally of:

- salaries for research and development staff and related expenses, including employee benefits;
- costs for production of the compounds by contract manufacturers;
- fees and other costs paid to contract research organizations in connection with the performance of clinical trials;
- an allocation of general and administrative costs related to the research and development activities; and
- depreciation and amortization of tangible and intangible fixed assets used to develop our product candidates.

Our current research and development activities mainly relate to the following key programs, listed together with the next stage of clinical development for each product candidate:

Tozadenant: Phase 3 clinical trial of tozadenant in Parkinson's expected to be ready to start recruiting patients by the middle of 2015.

SYN120: Phase 2a clinical trial of SYN120 in Parkinson's dementia, which is currently recruiting patients.

BTT1023: Phase 2 clinical trial of BTT1023 in PSC, which was open to patient recruitment at the end of the first quarter of 2015.

Our research and development expenses may vary from period to period based on the timing of our research and development activities, including the timing of initiation of clinical trials and enrollment of patients in clinical trials. Research and development expenses are expected to increase as we advance the clinical development of our current product candidates, in particular the commencement of the Phase 3 clinical program for tozadenant in Parkinson's.

The successful development of our product candidates is highly uncertain. At this time we cannot reasonably estimate the nature, timing and estimated costs of the efforts that will be necessary to complete the development of, or the period, if any, in which material net cash inflows may commence from, any of our product candidates. This is due to numerous risks and uncertainties associated with developing drugs, including the uncertainty of:

- the scope, rate of progress, results and cost of our clinical trials, nonclinical testing, and other related activities;
- the cost of manufacturing clinical supplies, and establishing commercial supplies, of our product candidates and any products that we may develop;

- the number and characteristics of product candidates that we pursue;
- the cost, timing, and outcomes of regulatory approvals;
- the cost and timing of establishing sales, marketing, and distribution capabilities; and
- the terms and timing of any collaborative, licensing, and other arrangements that we may establish, including any required milestone and royalty payments thereunder and any non-dilutive funding that we may receive.

A change in the outcome of any of these variables with respect to the development of tozadenant or our other product candidates could mean a significant change in the costs and timing associated with the development of the applicable product candidate. For example, if the FDA or other regulatory authority were to require us to conduct clinical trials beyond those which we currently anticipate will be required for the completion of clinical development of a product candidate, we could be required to expend significant additional financial resources and time on the completion of clinical development of such product candidate.

Impairment of In-Process Research and Development Assets

In-process research and development assets acquired in a business combination are capitalized on our balance sheet at their fair values at date of acquisition and are subject to annual impairment testing until ready for use. An impairment of an in-process research and development intangible asset may be triggered if the clinical program for an asset does not proceed as expected, a different clinical development pathway is pursued than initially intended, the asset is partnered or out-licensed utilizing a transaction structure that changes the timing or amount of our future economic rights to the asset, or some of the economic value from the asset is realized. An impairment is recognized as a non-cash impairment charge to the statement of comprehensive income. During the year ended December 31, 2014, we recognized impairment charges totaling €27.6 million in relation to nepicastat, which was fully written down as a result of the receipt of top-line data that did not meet its primary efficacy endpoint in respect of the Phase 2a trial, and SYN120, which was written down to its recoverable amount, as a result of a revision to our plans to develop SYN120 initially for Parkinson's dementia, which has smaller commercial potential than Alzheimer's. If in the future we commence a trial of SYN120 for Alzheimer's, for example, the impairment relating to SYN120 could be reversed.

General and Administrative Expenses

Our general and administrative expense consists principally of:

- salaries for general and administrative staff and related expenses, including employee benefits and travel expenses;
- business development expenses;
- professional fees for auditors and other consulting expenses not related to research and development activities;
- professional fees for lawyers not related to the protection and maintenance of our intellectual property;
- cost of facilities, communication and office expenses;
- IT expenses; and
- depreciation and amortization of tangible and intangible fixed assets not related to research and development activities.

Other Operating Income

Other operating income consists primarily of grant income, rent from our investment property and proceeds on the sale of the investment property.

Interest Income

Our policy is to invest funds in low-risk investments, which primarily consist of money market funds and interest-bearing savings and deposit accounts. Savings and deposit accounts generate a small amount of interest income. We expect to continue this investment philosophy.

Interest Expenses

Our interest expenses consist primarily of non-cash interest in respect of the Tekes loans and the convertible capital loan.

Other Net Financial Income (Expenses)

Other net financial income (expense) primarily relates to all non-interest related items and comprises net foreign exchange gains (losses) that arise from our intercompany borrowings, unrealized and realized gains from money market funds, that are reflected as financial assets recorded at fair value in profit and loss, and gain on extinguishment of debt related to the forgiveness of a portion of the Tekes loans in 2013.

Taxes

As we currently have cumulative operating losses in each of our companies, we do not generally pay any corporate income taxes. We do not recognize deferred tax assets on our cumulative operating losses because of the uncertainty as to whether they could be utilized.

Segment Reporting

We operate in one reportable segment, which comprises the development of pharmaceutical products. Our Chief Executive Officer reviews our consolidated operating results regularly to make decisions about resource allocation and to assess overall performance.

Results of Operations

Comparison of the Years Ended December 31, 2014 and 2013

	Year Ended December 31,		
	2014	2013	Change
	(€ thousands)		%
Revenue	14,901	27,712	(46.2)
Research and development expenses	(17,192)	(17,807)	(3.5)
Impairment of in-process research and development assets	(27,605)	—	—
General and administrative expenses	(7,326)	(8,971)	(18.3)
Other operating income	1,132	565	100.4
Operating (loss) income	(36,090)	1,499	(2,507.6)
Interest income	—	37	—
Interest expenses	(687)	(726)	(5.4)
Other net financial income (expenses)	1,612	2,841	(43.3)
(Loss) income before taxes	(35,165)	3,651	(1,063.2)
Income tax benefit	—	2,195	—
Net (loss) income	(35,165)	5,846	(701.5)
Other comprehensive income (loss)			
Remeasurements of post-employment benefit obligations	(81)	—	—
Currency translation differences	6,593	(2,629)	350.8
Total comprehensive (loss) income	(28,653)	3,217	(990.7)

Revenue

The table below presents a breakdown of our revenue for the years ended December 31, 2014 and 2013:

	Year Ended December 31,	
	2014	2013
	(€ thousands)	
Commercial milestone payments from Lundbeck license agreement	6,000	4,000
Royalties from Lundbeck license agreement	923	155
Phase 2 development milestones from UCB collaboration agreement	—	15,286
Phase 3 development milestones from UCB collaboration agreement	5,047	8,271
Phase 3 development funding income from UCB	2,931	—
Total	14,901	27,712

Revenue decreased 46.2% or €12.8 million to €14.9 million for the year ended December 31, 2014 compared to €27.7 million for the year ended December 31, 2013. During the year ended December 31, 2014, revenue consisted of European commercial milestones and royalties received for Selincro from Lundbeck and development milestones and development funding for tozadenant from UCB. The decrease in revenue was primarily due to the payment of the non-refundable Phase 2 development milestone payment from UCB in the amount of €15.3 million in 2013 and a decrease by €3.2 million from 2013 to 2014 in Phase 3 development milestones for tozadenant from UCB before it returned its rights to us. This decrease was offset by an increase in revenue from Lundbeck for Selincro, both in respect of a commercial milestone, with an increase of €2.0 million, and royalties, with an increase of €0.8 million.

Research and Development Expenses

The table below lists our research and development expenses by project for the years ended December 31, 2014 and 2013, including certain projects that have been discontinued, namely NRL-1 and nepicastat.

Project	Year Ended December 31,		
	2014	2013	Change
	(€ thousands)		%
Tozadenant	8,769	11,923	(26.5)
SYN120	2,454	730	236.2
BTT1023	1,338	158	746.8
NRL-1	1,347	2,034	(33.8)
Selincro	1,506	447	236.9
Nepicastat	196	—	—
Other research and development expenses	1,582	2,515	(37.1)
Total	17,192	17,807	(3.5)

Research and development expenses decreased 3.5% or €0.6 million to €17.2 million for the year ended December 31, 2014 as compared to €17.8 million for year ended December 31, 2013. The decrease in research and development expenses was due to a change in the stage of various development products, particularly lower costs on tozadenant following UCB's decision to return its rights to us.

Impairment of In-process Research and Development Assets

During the year ended December 31, 2014, we recognized impairment charges totaling €27.6 million in relation to nepicastat, which was fully written down, and SYN120, which was written down to its recoverable amount, as a result of a revision to our plans to develop SYN120 initially for Parkinson's dementia, which has smaller commercial potential than Alzheimer's. There were no such impairments during the year ended December 31, 2013.

General and Administrative Expenses

General and administrative expenses decreased 18.3% or €1.7 million to €7.3 million for the year ended December 31, 2014 as compared to €9.0 million for the year ended December 31, 2013. The decrease in general and administrative expenses was largely due to a decrease in fees related to business development activities.

Other Operating Income

Other operating income for the year ended December 31, 2014 amounted to €1.1 million, an increase of €0.5 million from €0.6 million for the year ended December 31, 2013. Other operating income in 2013 only included rental income from an investment property in Germany, which was sold in September 2014. During the year ended December 31, 2014, it included rental income up to the date of the sale of the investment property and the profit from the sale of the property, as well as grant income from Michael J. Fox Foundation for Parkinson's Research recognized in respect of the SYN120 Parkinson's dementia clinical trial.

Operating (Loss) Income

Operating loss for the year ended December 31, 2014 was €36.1 million. This represented a decrease of €37.6 million from the €1.5 million of operating income we generated for the year ended December 31,

2013. The change was mainly attributable to the higher revenues generated in 2013, in particular the UCB development milestone payment of €15.3 million following the completion of the Phase 2b clinical trial and impairment charges of €27.6 million in respect of nepicastat and SYN120 during the year ended December 31, 2014.

Interest Income

Interest income was less than €0.1 million for both the years ended December 31, 2014 and 2013. The slight decrease between the two years is due to the proportion of liquid assets held as cash and cash equivalents and changes in interest rates.

Interest Expenses

Interest expenses consist of non-cash interest expenses accrued on the Tekes loans and the convertible capital loan. Interest rates remained broadly stable and as a result interest expense was €0.7 million for both the years ended December 31, 2014 and 2013.

Other Net Financial Income (Expenses)

Other net financial income (expenses) comprises all non-interest related items and decreased by 43.3% to €1.6 million for the year ended December 31, 2014, compared to €2.8 million for the year ended December 31, 2013. The year ended December 31, 2013 included a gain of €3.2 million in respect of extinguishment of debt in relation to the forgiveness of Tekes loans (there was no corresponding gain in the year ended December 31, 2014), which was partially offset by a net increase in foreign exchange gains and losses of €1.9 million during the period.

Income (Loss) before Taxes

For the reasons described above, loss before taxes was €35.2 million for the year ended December 31, 2014, compared to income before taxes of €3.7 million for the year ended December 31, 2013, a change of €38.9 million.

Income Tax Benefit

There was no income tax benefit for the year ended December 31, 2014, whereas in the year ended December 31, 2013 there was an income tax benefit of €2.2 million that primarily related to a reduction in the deferred tax liability that arose in Switzerland in connection with the Synosia acquisition in 2011.

Net Income (Loss)

For the reasons described above, the net loss for the year ended December 31, 2014 amounted to €35.2 million, compared to net income of €5.8 million for the year ended December 31, 2013.

Items Included in Other Comprehensive Income (Loss)

The items included in other comprehensive income (loss) include remeasurements of post-employment benefit obligations and currency translation differences. The remeasurements of post-employment benefit obligations only occurred in the year ended December 31, 2014 and were a loss of €0.1 million. The currency translation differences reflected in other comprehensive income (loss) was a gain of €6.6 million for the year ended December 31, 2014, an increase of €9.2 million, as compared to a loss of €2.6 million for the year ended December 31, 2013.

Total Comprehensive (Loss) Income

Total comprehensive loss for the year ended December 31, 2014 was €28.7 million, compared to total comprehensive income of €3.2 million for the year ended December 31, 2013.

Comparison of the Quarters Ended March 31, 2015 and 2014

	Quarter Ended March 31,		
	2015	2014	Change
	(in thousands of €)		%
Revenue	871	5,096	(82.9)
Research and development expenses	(4,766)	(4,803)	0.8
General and administrative expenses	(1,730)	(1,950)	11.3
Other operating income	—	135	N/A
Operating loss	(5,625)	(1,522)	(269.6)
Interest income	1	—	—
Interest expenses	(151)	(152)	0.7
Other net financial income (expenses)	(119)	(45)	(164.4)
Loss before taxes	(5,894)	(1,719)	(242.9)
Income tax benefit	—	—	—
Net loss	(5,894)	(1,719)	(242.9)
Other comprehensive income			
Currency translation differences	8,181	315	2,497.1
Total comprehensive income (loss)	2,287	(1,404)	262.9

Revenue

The table below presents a breakdown of our revenue for the quarters ended March 31, 2015 and 2014:

	Year Ended March 31,	
	2015	2014
	(€ thousands)	
Royalties from Lundbeck Agreement	658	49
Phase 3 development milestones from UCB collaboration agreement	—	5,047
Phase 3 development funding income from UCB	213	—
Total	871	5,096

Revenue decreased 82.9% or €4.2 million to €0.9 million for the quarter ended March 31, 2015 compared to €5.1 million for the quarter ended March 31, 2014. The decrease in revenue was primarily due to the payment of the Phase 3 development milestones from UCB under the Collaboration Agreement of €5.0 million in 2014, which did not recur in 2015 due to the termination of the agreement. This was partially offset by an increase in royalties from Lundbeck for Selincro of €0.6 million and €0.2 million from Phase 3 development funding income from UCB which did not arise in 2014.

Research and Development Expenses

The table below lists our research and development expenses by project in the periods presented, including certain projects that have been discontinued, namely NRL-1 and nepicastat.

	Quarter Ended March 31,		
	2015	2014	Change
	(in thousands of €)	(in thousands of €)	%
Project			
Tozadenant	3,351	2,923	14.6
SYN120	597	81	637.0
BTT1023	210	257	(18.3)
NRL-1	—	1,141	n/a
Selincro	118	49	140.8
Nepicastat	—	12	n/a
Other research and development expenses	490	340	44.1
Total	4,766	4,803	(0.8)

Research and development expenses remained the same at €4.8 million for the quarters ended March 31, 2015, and 2014. However, there was a difference in the mix of the various development products. The main changes in the components of research and development expenses in the first quarter of 2015 compared with the first quarter of 2014 include an increase of €0.4 million for tozadenant and €0.5 million for SYN120. These increases were mainly offset by the cessation of costs in connection with the termination of development activity and return of NRL-1. NRL-1 research and development expenses amounted to €1.1 million in the first quarter of 2014.

General and Administrative Expenses

General and administrative expenses decreased 11.3% or €0.3 million to €1.7 million for the quarter ended March 31, 2015 as compared to €2.0 million for the quarter ended March 31, 2014.

Other Operating Income

Other operating income for the quarter ended March 31, 2014 amounted to €0.1 million of rental income from an investment property in Germany that was sold in September 2014. There was no other operating income during the quarter ended March 31, 2015.

Operating Loss

Operating loss for the quarter ended March 31, 2015 was €5.6 million. This represented an additional loss of €4.1 million from the loss of €1.5 million for the quarter ended March 31, 2014. The change was mainly due to the higher revenues generated in 2014 from the Phase 3 development milestones under the UCB collaboration agreement that did not recur in 2015.

Interest Income

Interest income was minimal for both of the quarters ended March 31, 2015 and 2014.

Interest Expenses

Interest expenses consist of non-cash interest expenses accrued on the Tekes loans and the convertible capital loans and remained broadly stable and as a result, interest expense was €0.2 million for both the quarters ended March 31, 2015 and 2014.

Other Net Financial Income (Expenses)

Other net financial income (expenses) mainly comprises net foreign exchange losses and was a greater net expense of €0.1 million for the quarter ended March 31, 2015, compared to €0.05 million for the quarter ended March 31, 2014.

Loss before Taxes

For the reasons described above, loss before taxes was €5.9 million for the quarter ended March 31, 2015, compared to €1.7 million for the quarter ended March 31, 2014, a change of €4.2 million.

Income Tax Benefit

There was no income tax benefit for either of the quarters ended March 31, 2015 and 2014.

Net Loss

For the reasons described above, the net loss for the quarter ended March 31, 2015 amounted to €5.9 million, compared to a net loss of €1.7 million for the quarter ended March 31, 2014.

Other Comprehensive Income (Loss)

Other comprehensive income comprises currency translation differences, which mainly arises from the translation of in-process R&D assets and goodwill. It was a gain of €8.2 million for the quarter ended March 31, 2015, an increase of €7.9 million, as compared to a gain of €0.3 million for the quarter ended March 31, 2014. The movement for the quarter ended March 31, 2015 was due to the significant devaluation of the Euro against the United States Dollar and Swiss Franc.

Total Comprehensive Income (Loss)

Total comprehensive income for the quarter ended March 31, 2015 was €2.3 million, compared to a total comprehensive (loss) of €1.4 million for the quarter ended March 31, 2014.

Liquidity and Capital Resources

Our primary use of cash is to fund research and development costs. With the exception of the year ended December 31, 2013, we have never been profitable and have incurred losses in each year since inception. Although we made a profit in the 2013 fiscal year, this was primarily due to a non-refundable development milestone payment by UCB for tozadenant which cannot be expected to recur in the future. Substantially all of our losses have resulted from funding our research and development programs and general and administrative costs associated with our operations. As of March 31, 2015, we had retained earnings which was an accumulated deficit of €160.8 million and liquid assets of €27.8 million.

We have mainly funded our operations through private placements of equity securities and convertible notes, non-convertible and convertible capital loans, long-term research and development loans, development milestone and development funding payments under research and development collaboration agreements, regulatory and commercial milestone payments under the Lundbeck License Agreement and, most recently, royalties under the Lundbeck License Agreement. In addition, a number of trials of our product candidates have been partially or wholly funded through non-dilutive funding, which may or may not flow through our financial statements.

Cash Flows

Comparison of the Years Ended December 31, 2014 and 2013

The following table sets forth our primary sources and uses of our liquid assets for each of the periods set forth below:

	Year Ended December 31,	
	2014	2013
	(€ thousands)	
Net cash from (used in):		
Operating activities	(14,092)	10,577
Investing activities	10,874	(14,065)
Financing activities	126	370
Net decrease in cash and cash equivalents	(3,092)	(3,118)
Effects of changes in exchange rates	323	(214)
Net decrease in cash and cash equivalents, after the impact of exchange rates	(2,769)	(3,332)
Net (decrease) increase in financial assets at fair value through profit and loss . . .	(8,516)	13,163
Net (decrease) increase in liquid assets	(11,285)	9,831

Liquid assets totaled €32.4 million as at December 31, 2014, as compared to €43.7 million as at December 31, 2013. The decrease of €11.3 million was mainly due to utilization of cash flow for financing our operating activities. We invested part of our liquid assets into money market funds, which are reported as “Financial assets at fair value through profit or loss” (€24.9 million as at December 31, 2014). Deposits with original maturities of less than three months are reported in the “Cash and cash equivalents,” which totaled €7.5 million as at December 31, 2014.

Operating Activities

Our net cash outflow from operating activities for the year ended December 31, 2014 was €14.1 million, a decrease of €24.7 million, as compared to a net cash inflow of €10.6 million in the same period in 2013, mainly due to the receipt of a non-refundable development milestone payment of €15.3 million from UCB in the first quarter of 2013 and a net cash outflow from working capital of €6.4 million in 2014.

Investing Activities

Net cash inflow from investing activities was €10.9 million for the year ended December 31, 2014, an increase of €25.0 million, as compared to the net cash outflow €14.1 million used in the same period in 2013, mainly due to net investments out of/into financial assets at fair value through profit and loss as required to meet our operating cash flows in each year.

Financing Activities

Net cash inflow from financing activities was €0.1 million for the year ended December 31, 2014, a decrease of €0.3 million compared to €0.4 million in the year ended December 31, 2013 due to a reduction in proceeds from share issues under employee equity plans.

Comparison of the Quarters Ended March 31, 2015 and 2014

The following table sets forth our primary sources and uses of our liquid assets for each of the quarters set forth below:

	Quarter Ended March 31,	
	2015	2014
	(in thousands of €)	
Net cash provided by (used in):		
Operating activities	(5,384)	(5,409)
Investing activities	3,945	(175)
Financing activities	11	3
Net decrease in cash and cash equivalents	(1,428)	(5,581)
Effects of changes in exchange rates	291	31
Net decrease in cash and cash equivalents, after the impact of exchange rates	(1,137)	(5,550)
Net decrease in financial assets held at fair value through profit and loss	(3,428)	(496)
Net decrease in liquid assets	<u>(4,565)</u>	<u>(6,046)</u>

Liquid assets totaled €27.8 million as at March 31, 2015, as compared to €32.4 million as at December 31, 2014. The decrease of €4.6 million was mainly due to utilization of cash flow for financing our operating activities. We invested part of our liquid assets into money market funds, which are reported as “Financial assets at fair value through profit or loss” (€21.5 million as at March 31, 2015). Deposits with maturity of less than three months are reported in the “Cash and cash equivalents,” which totaled €6.3 million as at March 31, 2015.

Operating Activities

Our net cash outflow from operating activities for the quarter ended March 31, 2015 was €5.4 million, a slight decrease compared to a net cash outflow of €5.4 million during the same period in 2014. Although the net loss for the quarter ended March 31, 2015 was higher than in the same period in 2014, there was a favorable working capital movement in 2015 compared to 2014 as there was no change in deferred revenue during the three months ended March 31, 2015 and accounts payable increased as at March 31, 2015.

Investing Activities

Net cash inflow from investing activities was €3.9 million for the quarter ended March 31, 2015, an increase of €4.1 million, as compared to the net cash outflow €0.2 million in the same period in 2014. The large inflow was mainly due to proceeds from the sale of financial assets at fair value through profit and loss required to meet our operating cash flows in 2015 that did not occur in 2014.

Financing Activities

Net cash inflow from financing activities was below €0.1 million for the quarters ended March 31, 2015 and 2015 and related solely to proceeds from share issues in respect of employee equity plans.

Cash and Funding Sources

Our main sources of funding during the periods presented were revenue received from UCB in relation to tozadenant and royalties from Lundbeck in relation to Selincro sales. We have not raised any equity or debt financing during any of the periods presented.

We have no ongoing material financial commitments, such as lines of credit or guarantees, that are expected to affect our liquidity over the next five years, other than research and development loans, some of which are due for repayment as described below.

Funding Requirements

We believe that the net proceeds of this offering, together with our current liquid assets and the milestone and royalty revenues that we expect to receive from Lundbeck for Selincro, will enable us to fund our Phase 3 double-blind clinical trial (and extension) of tozadenant in Parkinson's through completion, as well as our portion of the funding for the SYN120 Phase 2a clinical trial in Parkinson's dementia and BTT1023 Phase 2 clinical trial in PSC. We intend to fund the remaining portion from non-dilutive sources. We have based this estimate on assumptions that may prove to be incorrect, and we could use our capital resources sooner than we currently expect. Our future funding requirements will depend on many factors, including but not limited to:

- the level of Selincro sales achieved by Lundbeck and its ability to obtain regulatory approvals in additional countries, which will affect the amount of milestones and royalties that we receive;
- the rate of enrollment, progress and cost of our clinical trials and other related activities;
- the cost of manufacturing clinical supplies and establishing commercial supplies of our product candidates;
- the cost, timing and outcomes of our clinical trials, which may meet their primary end-points or not; and
- the terms and timing of any collaborative, licensing, and other arrangements that we may establish, including any required milestone and royalty payments thereunder and any non-dilutive funding that we may receive.

For more information as to the risks associated with our future funding needs, see "Risk Factors."

We have no ongoing material financial commitments, such as lines of credit or guarantees, that are expected to affect our liquidity over the next five years, other than research and development loans, some of which are due for repayment as described below.

Contractual Obligations and Commitments

The following table sets forth information relating to our contractual obligations and commitments as at December 31, 2014.

	Payments due by period				Total(1)(2)
	Less than 1 year	Between 1 and 3 years	Between 3 and 5 years	More than 5 years	
	(€ thousands)				
Convertible capital loan(3)(4)	—	—	—	1,682	1,682
Non-convertible capital loans(3)(4)	—	—	—	16,318	16,318
Research and development loans(4)	—	538	1,614	538	2,690
Operating lease commitments	843	1,356	581	—	2,780

- (1) As of December 31, 2014, we also had outstanding contractual payment obligations (contracted commitments), primarily for contract research work services related to ongoing clinical development programs, totaling €0.2 million. These contractual commitments have not been included in this table.

- (2) We have entered into various license agreements that contingently trigger one-off payments upon achievement of certain milestones, the payment of royalties and certain other payments. If all the milestone triggering events were to be achieved, the aggregate amount of milestone payments due would be approximately \$114 million. Because the achievement and timing of these payments are uncertain, our commitments under these agreements have not been included in this table. We anticipate that approximately \$1.5 million of these milestone payments may become due within the next year. See “—Collaboration and License Agreements.”
- (3) The convertible capital loan and the non-convertible capital loans have a stated maturity in less than one year. However, the repayment of these loans and payment of accrued interest thereon is governed by a restrictive condition, according to which the loan principal must only be repaid if our consolidated restricted equity is fully covered. Accrued interest must only be paid if the consolidated entity has sufficient funds for profit distribution as of the most recently ended fiscal year. Interest accrues in the interim. All capital loans are therefore classified as long-term debt.
- (4) The amounts do not include interest costs at the loans’ applicable interest rates.

Convertible Capital Loan

We have an outstanding convertible capital loan that was issued originally in 1999 to certain shareholders and venture capital organizations with a notional amount of €2.5 million. The interest rate is 10% per annum. The repayment of the loan and interest is governed by a restrictive condition, according to which the capital may only be returned if our consolidated restricted equity for the last financial period is sufficient to pay back the loan. Interest on the convertible capital loan shall be paid only if we have (on a consolidated basis) sufficient funds for profit distribution as of the most recently ended fiscal year. The loan also accrues interest from the fiscal years in which our financial statements do not present sufficient funds available for profit distribution. As at December 31, 2014, the carrying value of the convertible capital loan was €1.7 million and accumulated accrued interest on the convertible capital loan amounted to €3.4 million (€3.2 million at December 31, 2013) and is recorded in “Other non-current liabilities” on the balance sheet. The convertible capital loan can also be converted at any time, at the option of the holder, into 828,000 of our shares under the terms of the agreement at a conversion rate of €1.8688 per share for 540,000 of the shares and €2.3359 for 288,000 of the shares.

Non-Convertible Capital Loans

As of December 31, 2014, we had outstanding a total of 14 non-convertible capital loans granted by Tekes in an aggregate amount of €16.3 million, following the forgiveness of two loans (carrying value €1.1 million) in 2013. The proceeds from the loans have been fully used to fund a number of research & development projects. The majority of the loans outstanding at December 31, 2014 were drawn prior to 2009, and the maturities range from eight to ten years from drawdown. The interest rate per annum for these loans is the base rate set by the Ministry of Finance minus 1%, subject to a minimum rate of 3%. As the base rate has been lower than the minimum of 3%, the interest rate for these loans has been 3% for both periods presented. Further, these loans and accumulated accrued interest are not repayable until our restricted equity is fully covered or we (on a consolidated basis) have distributable funds. Restricted equity is fully covered when our distributable funds are greater than zero. Distributable funds (or unrestricted equity) of the Company comprises retained earnings (accumulated deficit), reserve for invested unrestricted equity and other reserves (unrestricted) and as of December 31, 2014 (the last financial period) and totaled a debit of €140.1 million. Since we have not had distributable funds since the withdrawal of these loans, interest recorded through the financial expenses are accrued and presented under other non-current liabilities in the balance sheet as we do not expect to have distributable funds in foreseeable future. The accumulated accrued interest on the non-convertible capital loans amounted to €6.0 million at December 31, 2014 (€5.5 million at December 31, 2013).

Research and Development Loans

As of December 31, 2014, we had €2.7 million of research and development loans granted by Tekes. Research and development loans amounting to €1.7 million were extinguished in 2013 following Tekes' decision to forgive the loans. Research and development loans are granted to a defined product development project and cover a contractually defined portion of the project's research and development expenses. The interest rate for these loans is the base rate set by the Ministry of Finance minus 3%, subject to a minimum rate of 1%. As the base rate has been lower than the minimum of 1%, the interest rate for these loans has been 1% for both periods presented. Repayment of these loans is required to be completed between 2017 and 2021, or a later date if agreed with Tekes, thereafter loan principal is payable in equal installments over a five-year period.

Operating Lease Commitments

Operating lease commitments comprise rent commitments for leasehold properties and lease commitments for motor vehicles, machines and equipment with leases of three to five years. Our operating leases are non-cancellable and they do not include redemption or extension options.

Other Commitments

As of December 31, 2014, we also had outstanding contractual payment obligations (contracted commitments), primarily for contract research work services related to ongoing clinical development programs, totaling €0.2 million.

We have entered into various license agreements that contingently trigger one-off payments upon achievement of certain milestones and royalty payments in the future. Because the achievement and timing of these milestones and net sales is not fixed and determinable, our commitments under these agreements have not been included in the Contractual Obligations and Commitments table above. See “— Collaboration and License Agreements.”

Subsequent Events

Convertible Notes Financings

Pursuant to certain agreements entered into between us and the other parties identified therein in April and May 2015, certain new investors and existing shareholders subscribed for €33.1 million aggregate principal amount of our convertible promissory notes and received warrants exercisable for our shares on May 28, 2015, which we refer to as the Convertible Notes Financings. An aggregate of 220,400,001 convertible notes were issued to the subscribers, and each convertible note has a conversion price of €0.15 per share. The convertible notes may be converted by their holders at any time prior to repayment. The convertible notes will automatically convert upon completion of this offering. The convertible notes do not bear any interest unless an event of default has occurred and continues for ten business days, whereupon the convertible notes would accrue interest at a rate of 8% per year thereafter during the continuance of the event of default. An aggregate of 220,400,001 warrants were issued to the subscribers, and each warrant entitles the holder to subscribe for one share at a subscription price of €0.17. The warrants, irrespective of the consummation of this offering, entitle the holder to subscribe for our shares from November 1, 2015 until November 1, 2020. See “Description of Share Capital and Articles of Association—Share Capital—Warrants” for a description of the warrants. Under the terms and conditions of the convertible notes, the issuance of securities resulting in our raising an amount greater than \$95 million in gross proceeds from this offering, including the underwriters' option to purchase additional shares from us in connection with this offering, from the issuance of convertible notes in the Convertible Notes Financings, and from any other

offerings of our securities from the date of the relevant subscription agreement for the Convertible Notes Financings through the date of the completion of this offering, would constitute an event of default, which could result in the requisite noteholders declaring the convertible notes immediately due and payable. As a result, we intend to raise no more than \$95 million in aggregate from this offering and the sale of the convertible notes in the Convertible Notes Financings.

Off-Balance Sheet Arrangements

As of the date of this prospectus, we do not have any, and during the periods presented, we did not have any, significant off-balance sheet liabilities.

Quantitative and Qualitative Disclosures About Market Risk

We are exposed to several financial risks caused by, for example, the following factors: changes to market prices in debt and capital markets and fluctuation of exchange rates and interest rates. Our risk management principles focus on the unpredictability of the financial markets and aim at minimizing any undesired impacts on our financial result. Our Board of Directors defines our general risk management principles and provides operational guidelines concerning specific areas including but not limited to foreign exchange risk, interest rate risk, credit risk, use of derivatives and investment of our liquid assets.

Market Risk

Foreign Exchange Risk

We operate internationally but are only exposed to translation risk from our investments in foreign operations, the U.S. dollar being the most significant currency. We are not exposed to significant transaction risk, as we and our subsidiaries mainly operate in our functional currencies. As of March 31, 2015, we had cash and cash equivalents of €3.2 million in U.S. dollars, €0.05 million in Swiss Francs and €0.1 million in Pounds Sterling and money market funds of €1.8 million in U.S. dollars.

We have granted an intercompany loan (€41.0 million as at March 31, 2015) to our U.S. subsidiary that qualifies for part of the net investment, and exchange differences reflected as net gains / (losses) from foreign exchange in the statement of comprehensive (loss) income.

We may need to consider transfer of balances between currencies as appropriate to manage the currency in which revenue is received and expenses are incurred. However, we have a policy not to hedge translation risk.

Proceeds from this offering in U.S. dollars will be held in U.S. dollars, as the majority of the costs for the tozadenant Phase 3 program are expected to be incurred in that currency.

Interest Rate Risk

Our interest rate risk arises from borrowings from Tekes and private investors. Borrowings carry fixed interest rates and hence do not expose us to variable interest rate risk. Our loans from Tekes are mainly tied to the base rate defined by the Finnish Ministry of Finance, which is reset rarely, with a floor at 3% for the non-convertible capital loans and 1% for the research and development loans. During the periods presented, the interest rate level has been below the floor, so we have accrued for the floor interest of 3% or 1%, respectively, on the Tekes loans. Hence an increase in base rates would not have any material impact on our profit or loss. Further, accumulated accrued interest is not payable until we are profitable and have sufficient funds for profit distribution. Surplus cash is invested in short term money market funds, and they also expose us mainly to fair value interest rate risk.

Credit and Counterparty Risk

Deposit and security receivables from banks expose us to credit risk. The banks we use for our deposits are among the most reputable financial institutions in the United States and Europe. We invest liquid assets in low risk securities with high ratings and in interest bearing bank accounts. Management monitors the sufficiency of our liquid assets and exposure to credit risk regularly.

We preferentially work with counterparties with good credit ratings. We currently derive a significant proportion of our collaborative income from a small group of partners. This risk of concentration of creditors is partly mitigated by the fact that our collaboration partners are typically large and internationally reputable pharmaceutical companies which are financially sound. These collaborations are governed by contractual relationships that typically address and describe remedies for situations in which our interests and the interests of the partner are no longer in line. In addition, we aim to collaborate on different development programs with as many partners as possible in order to spread the risk of creditor concentration.

Critical Accounting Estimates and Judgments

In the application of our accounting policies, our management is required to make judgments, estimates and assumptions about the carrying amounts of assets and liabilities that are not readily apparent from other sources. The estimates and associated assumptions are based on historical experience and other factors that are considered to be relevant. Actual results may differ from these estimates.

The estimates and assumptions are reviewed on an on-going basis. Revisions to accounting estimates are recognized in the period in which the estimate is revised if the revision affects only that period or in the period of the revisions and future periods if the revision affects both current and future periods.

While our significant accounting policies are more fully described in the notes to our consolidated financial statements appearing elsewhere in this prospectus, we believe that the following accounting policies are the most critical to aid you in fully understanding and evaluating our financial condition and results of operations.

Revenue Recognition

We recognize revenue from collaboration and licensing agreements with pharmaceutical companies that may include licenses, development and approval milestone payments, development funding income, commercial milestone payments and royalties. These agreements often require significant analysis and judgment by management in order to determine the appropriate method of revenue recognition.

Where such arrangements can be divided into separate units of accounting (each unit constituting a separate earnings process), the arrangement consideration is allocated to the different units based on their relative fair values and recognized over the respective performance period. This analysis requires considerable estimates and judgments, including estimates of the relative fair values of the various elements included in such agreements and the estimated length of the respective performance periods. Depending upon how such judgment is exercised, the timing and amount of revenue recognized could differ significantly. Revenue in the various accounting units containing elements is recognized when the criteria for revenue recognition regarding the elements of that accounting unit have been met according to their type and only to the extent of the consideration that is not contingent upon completion or performance of the remaining elements in the contract.

Revenues on licenses are recognized when, in the judgment of management, significant risks and rewards of ownership have been transferred to the buyer and where we do not retain either the continuing managerial involvement to the degree usually associated with ownership or effective control.

Non-refundable development, approval and commercial milestone payments are recognized when a milestone has been achieved and we have no further performance obligations. This is normally when we are informed by the partner that the milestone has been achieved.

Any milestone payments that have been received but for which the earnings process has not been completed are reported as deferred revenue (a liability) in the balance sheet. Any change in the estimated development period may lead to an adjustment of the recognition amount and time. In case the estimated development schedule were to be delayed, the annual income would lessen since the amount of the total revenue would be allocated over a longer period of time.

In certain agreements, where development milestones are primarily received to reimburse development costs for specific development activities, revenue is recognized as the lower of the non-refundable cash received under the agreement and that based on the percentage of completion method. This is based on the efforts and costs incurred to date in relation to the total estimated costs to complete the contract. Any change in the estimated costs to complete could cause a change in the amount of revenue that should have been recognized to date.

Impairment of Intangible Assets

We have significant investments in intangible assets that have an indefinite useful life, such as goodwill, or intangible assets not ready to use, such as acquired in-process research and development assets, are not subject to amortization and are tested annually for impairment, or whenever events or changes in circumstances indicate that the carrying amount may not be recoverable.

An impairment loss is recognized for the amount by which the asset's carrying amount exceeds its recoverable amount. The recoverable amount is the higher of an asset's fair value less cost of disposal and value in use. Our impairment review methodology applied is based on the fair value less cost of disposal. The fair value of the asset is determined from the discounted future net cash flows expected to be derived from the asset or, in the case of goodwill, the cash generating unit. The discounted future net cash flows of development assets are adjusted for the probability of future development success; the discount rate used reflects the time value of money and appropriate risk premiums for the asset. The fair value less cost of disposal is then compared to the carrying amount of the asset. An impairment charge is recognized in the consolidated statement of comprehensive income for the amount by which the asset's carrying amount exceeds its fair value less cost of disposal.

During the year ended December 31, 2014, we recognized impairment charges totaling €27.6 million in relation to two of our in-process research and development assets; for the remaining in-process research and development asset and goodwill we determined that no adjustment to carrying values was required. Nepicastat was fully written down to nil as a result of the receipt of the top-line data that did not meet its primary efficacy endpoint in respect of the Phase 2a trial, and SYN120 was written down to its recoverable amount as a result of a revision to our plans to develop SYN120 initially for Parkinson's dementia, which has a smaller commercial potential than Alzheimer's. If in the future we commence a trial of SYN120 for Alzheimer's, for example, the impairment relating to SYN120 could be reversed. Key assumptions regarding impairment testing, including the impairments recognized in 2014, are discussed in note 11 to the consolidated financial statements included elsewhere in this prospectus.

During the year ended December 31, 2013, we reviewed the carrying amounts of our intangible assets and goodwill and determined that no adjustments to carrying values were required.

The determination of the fair values requires management to make a number of estimates and assumptions related to future expectations of success and to use discount rates and other inputs that are relevant to the specific assets. Should we be required to recognize future impairments in the consolidated

statement of comprehensive income as a result of the impairment testing, this could have a material effect on our results and financial position, although this would not have any impact on our cash or liquid asset balances.

Research and Development Expenses

The stage of a particular development asset generally forms the basis for the decision whether costs incurred on research and development projects can be capitalized or not. In general, our view is that research and development expenses may not be capitalized until marketing approval has been received from the relevant regulatory agencies, as this is considered to be the first point at which it may be appropriate to conclude that future revenues can be generated. Expenses before that point are recognized as they are incurred in the consolidated statement of comprehensive income and when a project reaches that point, it is reviewed at each reporting period to assess whether in management's judgment it meets the capitalization criteria. Given the current stage of the development of our products, no development expenditures have yet been capitalized.

As of each balance sheet date, we estimate the level of service performed by our vendors or other counterparties and the associated costs incurred for the services performed. As part of the process of preparing our consolidated financial statements, we are required to estimate our accrued expenses, which are predominantly in respect of research and development activities. This process involves reviewing quotations and contracts, identifying services that have been performed on our behalf, estimating the level of service performed and the associated cost incurred for the service when it has not yet been invoiced or notified of the actual cost; in most cases, this is done by discussion with the vendors. The majority of our service providers invoice us monthly in arrears for services performed. We make estimates of their accrued expenses at each balance sheet date in our financial statements based on the facts and circumstances known to us at that date. Although we do not expect our estimates to be materially different from the amounts actually incurred, our understanding of the status and timing of services performed relative to actual status and timing may vary and could result in us reporting amounts that are too high or too low in a particular period. When the actual amounts are known, any difference is recognized in the consolidated statement of comprehensive income.

Share-based Payments

Option rights and share units have been measured at their fair value, using market based inputs, at the grant date, and are recognized as an expense in the consolidated statement of comprehensive income over the vesting period. A Black-Scholes pricing model is used to value the option rights and share units that have been granted, and critical judgments need to be exercised in determining the appropriate assumptions to include in the model, as well as to determine the most appropriate way of recognizing the compensation expense. Our shares are listed on the Finnish Stock Exchange and therefore, the market based inputs used to fair value the option rights and share units include company-specific historical share price and volatility information. The key assumptions in the model are detailed in note 19 to our consolidated financial statements included elsewhere in this prospectus.

At each balance sheet date, we review and update, as appropriate, each of the underlying assumptions, such as the expected number of options and share units that are expected to become exercisable. The impact of any changes in the estimates or assumptions is recorded in the statement of comprehensive income and a corresponding adjustment to equity.

Deferred Income Taxes

We are subject to income taxes in Finland, the United States, Switzerland and Germany. Significant judgment is required in determining the use of net operating loss carry forwards and the taxation of up-front

and milestone payments for income tax purposes. There are many transactions and calculations for which the ultimate tax determination is uncertain. Where the final tax outcome of these matters is different from the amounts that were initially recorded, such differences may impact the current and deferred income tax assets and liabilities in the period in which such determination is made.

As at December 31, 2014, we had accumulated tax loss carryforwards of €120.6 million, which are potentially available to offset against future profits. Our policy is to recognize deferred tax assets arising from unused tax losses or tax credits only to the extent the relevant fiscal entity has sufficient taxable temporary differences or there is convincing other evidence that sufficient taxable profits will be available against which the unused tax losses or unused tax credits can be utilized by the fiscal entity. Estimation of the level of future taxable profits is therefore required in order to determine the appropriate carrying value of the deferred tax asset at each balance sheet date. Management's judgment is currently that sufficient convincing other evidence is not available and a deferred tax asset is, therefore, not recognized.

Recent Accounting Pronouncements

The following standards have been issued, but are not effective until after December 31, 2014, and are considered relevant for us. We are currently assessing their potential impact on our accounting policies, financial position and performance.

IFRS 9: Financial Instruments

IFRS 9: "Financial instruments" addresses the classification, measurement and recognition of financial assets and financial liabilities. The complete version of IFRS 9 was issued in July 2014. It replaces the guidance in International Accounting Standards, or IAS, 39 that relates to the classification and measurement of financial instruments. IFRS 9 retains, but simplifies, the mixed measurement model and establishes three primary measurement categories for financial assets: amortized cost, fair value through other comprehensive income (loss) and fair value through profit and loss. The basis of classification depends on the entity's business model and the contractual cash flow characteristics of the financial asset. Investments in equity instruments are required to be measured at fair value through profit or loss with the irrevocable option to present changes in fair value in other comprehensive income (loss) not recycling. There is a new expected credit losses model that replaces the incurred loss impairment model used in IAS 39. For financial liabilities there were no changes to classification and measurement except for the recognition of changes in own credit risk in other comprehensive income (loss) and for liabilities designated at fair value through profit or loss. IFRS 9 relaxes the requirements for hedge effectiveness by replacing the bright line hedge effectiveness tests. It requires an economic relationship between the hedged item and hedging instrument and for the "hedged ratio" to be the same as the one management actually uses for risk management purposes. Contemporaneous documentation is still required, but is different to that currently prepared under IAS 39. The standard is effective for accounting periods beginning on or after January 1, 2018. Early adoption is permitted. We are assessing the impact of IFRS 9.

IFRS 15: Revenue from Contracts with Customers

IFRS 15: "Revenue from contracts with customers" deals with revenue recognition and establishes principles for reporting useful information to users of financial statements about the nature, amount, timing and uncertainty of revenue and cash flows arising from an entity's contracts with customers. Revenue is recognized when a customer obtains control of a good or service and thus has the ability to direct the use of, and obtain the benefits from, the good or service. The standard replaces IAS 18 "Revenue" and IAS 11 "Construction contracts" and related interpretations. The standard is effective for annual periods beginning on or after January 1, 2017 and earlier application is permitted. We are assessing the impact of IFRS 15.

JOBS Act Exemptions

On April 5, 2012, the Jumpstart Our Business Startups Act of 2012, or the JOBS Act, was signed into law. The JOBS Act contains provisions that, among other things, reduce certain reporting requirements for an “emerging growth company.” As an emerging growth company, we are electing to take advantage of not providing an auditor attestation report on our system of internal controls over financial reporting. These exemptions will apply for a period of five years following the completion of our initial public offering or until we no longer meet the requirements of being an “emerging growth company,” whichever is earlier. We would cease to be an emerging growth company if we have more than \$1.0 billion in annual revenue, have more than \$700 million in market value of our shares held by non-affiliates or issue more than \$1.0 billion of non-convertible debt over a three-year period.

BUSINESS

Overview

We are a biopharmaceutical company primarily focused on developing therapeutics for central nervous system disorders. Our pipeline includes product candidates designed to address unmet medical needs in Parkinson's disease and related dementia, other neurodegenerative indications and primary sclerosing cholangitis, an orphan fibrotic liver disease. In addition, we have successfully developed a product for alcohol dependence that is being commercialized by Lundbeck and is a source of further potential milestone payments and ongoing royalties.

We are preparing to commence a pivotal Phase 3 clinical trial of our lead product candidate, tozadenant, that we believe could form the basis for its approval as an adjunctive treatment to levodopa in Parkinson's. Levodopa, the most widely prescribed treatment for Parkinson's, loses effectiveness in most patients over time. Parkinson's patients often experience a reemergence of debilitating symptoms on a daily basis as their levodopa doses wear off. Tozadenant is an oral, selective adenosine A_{2a} receptor antagonist that aims to address this wearing off effect. In a 420-patient Phase 2b trial, tozadenant displayed clinically important and statistically significant effects across prespecified primary and multiple secondary endpoints at a number of doses. In addition, tozadenant has been found to be generally safe and well tolerated in our ten clinical trials conducted to date.

Parkinson's disease is the second most common neurodegenerative disorder worldwide, affecting an estimated 6.3 million sufferers, including at least one million people in the United States. At least one million people who suffer from Parkinson's live in the United States. The symptoms that these patients face, such as tremors or stiffness of the face and limbs, slowness of movement and impaired coordination worsen over time and can severely affect patients' quality of life. Ultimately, Parkinson's patients are often forced to stop working and become increasingly dependent on caregivers in their homes or in specialized facilities. Levodopa is the standard treatment for Parkinson's, and an estimated 70% to 80% of Parkinson's patients receive levodopa at any given time. The periods when levodopa doses wear off and patients experience a reemergence of symptoms are commonly referred to as OFF episodes. Within four to six years of commencing treatment with levodopa, an estimated 40% of Parkinson's patients will experience OFF episodes, increasing by an additional 10% per year after that. We believe that tozadenant has the potential for use as an adjunctive therapy in combination with levodopa and other drugs indicated for the treatment of Parkinson's symptoms to reduce the duration of OFF episodes.

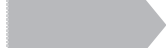
We believe tozadenant is an attractive lead product candidate based on the following:

- Late stage innovative product that has demonstrated meaningful benefit for Parkinson's patients, including those receiving multiple medications.
- Phase 2b clinical trial showed statistically significant effectiveness, including decreasing the duration of OFF episodes; and the U.S. Food and Drug Administration, or the FDA, has indicated it could qualify as the first of two pivotal trials.
- Pivotal Phase 3 clinical trial in preparation that we believe together with existing data could form the basis for approval.
- Well tolerated in more than 500 unique exposures, including two clinical trials in patients with Parkinson's and eight in healthy volunteers.
- Potential to be the first drug with a new mechanism of action for the treatment of Parkinson's introduced to North America and Europe in over 20 years.

- Novel mechanism of action complementary to other treatments for Parkinson's.
- Exclusive, worldwide license to develop and commercialize tozadenant products.

Our Product Portfolio

In addition to tozadenant, we have a commercial and development stage portfolio, as summarized below:

Portfolio	Indication	Phase 1	Phase 2	Phase 3	Marketed	Status
<u>Development Product Candidates</u>						
Tozadenant	Parkinson's Disease					• Enrollment for pivotal Phase 3 trial expected to begin mid-2015
SYN120	Parkinson's Disease Dementia					• Currently enrolling patients for Phase 2a trial with top-line data expected by YE 2016
	Alzheimer's Disease					• Phase 2 trial ready (funding dependent)
BTT1023	Primary Sclerosing Cholangitis					• Currently enrolling patients for Phase 2 proof of concept trial in with interim data expected YE 2016
<u>Commercial Product</u>						
Selincro	Alcohol Dependence					• Launched in 29 European countries by our partner Lundbeck

SYN120 is our oral product candidate to treat both cognitive deficits and psychosis, which frequently coincide in neurodegenerative diseases such as Parkinson's and Alzheimer's. We have completed single and multiple ascending dose Phase 1 trials of SYN120, an oral dual antagonist of the 5HT₆ and 5HT_{2a} receptors, in healthy volunteers. In these trials, doses well above the anticipated therapeutic dose were well tolerated. An 80-patient Phase 2a randomized, double-blind, placebo-controlled trial of SYN120 in Parkinson's dementia, largely funded by the Michael J. Fox Foundation for Parkinson's Research, or the Michael J. Fox Foundation, is being conducted by the Parkinson Study Group, which began recruiting patients at the end of 2014. Top-line data is expected by the end of 2016.

BTT1023 is our product candidate for the orphan disease primary sclerosing cholangitis, or PSC, a chronic and progressive fibrotic liver disease for which there is no FDA-approved treatment. We have partnered with the U.K. National Institute of Health Research to fund a Phase 2 proof of concept trial of BTT1023 in PSC, which is being conducted in collaboration with the University of Birmingham. Interim data is expected by the end of 2016. BTT1023 has received orphan drug designation for the treatment of PSC in Europe. We intend to pursue orphan drug designation for BTT1023 in the United States.

Our marketed product, Selincro, an orally administered opioid receptor ligand used in alcohol dependence therapy, received European marketing authorization in 2013 and has been introduced across Europe in 29 countries by our partner H. Lundbeck A/S, or Lundbeck, a Danish pharmaceutical company specializing in central nervous system products. Under our November 2006 option agreement with Lundbeck, or the Option Agreement, and our license and commercialization agreement with Lundbeck, or the Lundbeck License Agreement, we have received €22.0 million in milestone payments to date and are eligible to receive additional regulatory and commercial milestone payments and ongoing royalties on sales of Selincro.

Strategy

Our goal is to be a leading global specialty central nervous system company focused on diseases with unmet medical needs. Key elements of our strategy are:

- **Advance development of tozadenant through regulatory approval.** We are preparing to commence a pivotal Phase 3 trial of tozadenant, which we believe could form the basis for its approval in the United States as an adjunctive treatment to levodopa in Parkinson's patients experiencing end-of-dose wearing off episodes. We believe that tozadenant could serve as a significant enhancement to existing maintenance therapies. We have an exclusive, worldwide, royalty-bearing license to exploit tozadenant and intend to conduct a Phase 3 clinical trial, which we believe will qualify as the second of two pivotal trials. We expect to commence this Phase 3 double-blind trial in the third quarter of 2015 and subsequently file for registration, initially in the United States, after adequate safety data has been obtained from the open-label trial of the Phase 3 program.
- **Leverage our expertise in drug development to advance product candidates in our pipeline.** In addition to tozadenant, we are currently conducting a Phase 2a trial of SYN120 in Parkinson's dementia and expect to announce top-line data by the end of 2016. We may also conduct an additional Phase 2 clinical trial of SYN120 in Alzheimer's if we obtain additional funding. We began enrolling patients for the Phase 2 trial of BTT1023 in PSC in the first quarter of 2015, and interim data is expected by the end of 2016. BTT1023 has received orphan drug designation for the treatment of PSC in Europe. We intend to pursue orphan drug designation for BTT1023 in the United States. We believe our expertise in drug development and experience identifying, acquiring, developing and out-licensing clinical assets will allow us to continue to apply our core competencies to advance our product candidates successfully.
- **Selectively establish partnerships and collaborations to derive near-term value from our existing assets.** We have successfully worked with the Michael J. Fox Foundation and the Parkinson Study Group to fund and conduct our ongoing Phase 2a trial of SYN120 in Parkinson's dementia and are partnering with the U.K. National Institute of Health Research to fund a Phase 2 clinical trial of BTT1023 in PSC that is being conducted in collaboration with the University of Birmingham. We actively evaluate potential collaborators for licensing, sales and distribution of certain of our product candidates during their development lifecycle in order to maximize the financial benefit to us. In particular, if the Phase 2 clinical trial of BTT1023 in PSC is successful, we intend to monetize this asset by seeking a collaboration partner for development of this product candidate through Phase 3 and for product commercialization.
- **Continue to take advantage of non-dilutive sources of funding to fund ongoing and future trial costs and expenses.** We have in the past used and intend to continue to use non-dilutive sources of funding to advance product candidates in our pipeline and maximize return for our shareholders. We intend to use cash generated from milestone payments and our royalty stream on sales of Selincro from Lundbeck to fund ongoing and future trials. We have successfully gained access to non-dilutive funding to support our Phase 2 clinical programs in SYN120 and BTT1023. We intend to continue to pursue additional sources of non-dilutive funding through our relationships with government, not-for-profit organizations and other third party collaborators to defray our costs and preserve value for our shareholders.

Tozadenant

Overview of Parkinson's Disease

Parkinson's is the second most common neurodegenerative disorder worldwide, affecting an estimated 6.3 million sufferers, including at least one million people in the United States. At least one million people who suffer from Parkinson's live in the United States, representing an estimated one in 100 people over age 60. Its prevalence increases with age; approximately 1% of those aged 60 years or older and 4% or more of those aged 80 years or older are affected. As a result, prevalence will increase as the global population ages. The debilitating effects of Parkinson's result in a significant economic burden for patients, caregivers and the healthcare system in general. A 2013 study estimated the economic burden of Parkinson's to be at least \$14 billion in 2010 in the United States comprised of \$8.1 billion of medical expenses and \$6.3 billion of indirect costs, and this economic burden is projected to grow substantially. The Parkinson's therapeutics market size in the United States, five major EU markets, Brazil and Japan is currently estimated at approximately \$3.6 billion and is projected to rise to \$5.3 billion by 2022, and the United States is projected to have the largest Parkinson's therapeutics market share of 44% by 2022. We believe that market growth will be driven by an aging population and the introduction of new therapeutic modalities that address the significant unmet medical needs of this patient population, counterbalanced by the fact that many of the current products are, or will become, generic.

Parkinson's is a progressive neurodegenerative condition of the central nervous system that is associated with tremor of the hands, arms, legs, jaw or face, rigidity or stiffness of the limbs and trunk, bradykinesia, or slowness of movement, and postural instability and impaired balance. Symptoms may occur alone or in combination. The average age of patients at diagnosis is 60 years, and their life expectancy after diagnosis is approximately 20 years. Relatively good symptom control can be achieved in the early stages of the disease, but as it progresses motor function gradually worsens, complications of current treatments become more restrictive and within five to 10 years the majority of Parkinson's patients start to experience OFF episodes, which increase in frequency and severity during the course of their disease. Parkinson's patients are often forced to stop working and become increasingly dependent on caregivers in their homes or in specialized facilities. Parkinson's is also frequently associated with non-motor symptoms, including depression, dementia, psychosis and sleep disorders, which may be as disabling as, or more disabling than, the motor symptoms.

Dopamine is a neurotransmitter that plays an important role in the brain to allow people to have smooth, coordinated movements, and its loss makes it difficult to regulate movements. Parkinson's is caused by the death of dopaminergic neurons, cells in the brain that produce dopamine. When 60% to 80% of the dopamine-producing cells are damaged and do not produce enough dopamine, the motor symptoms of Parkinson's appear.

Current Treatment Approaches and Inherent Limitations

Currently available treatment approaches aim to compensate for reduced dopamine. Pharmacotherapy is administered to control symptoms and is characteristically modified as neurodegeneration progresses and symptoms reemerge. One of the major limitations of current Parkinson's treatment is that the therapeutic benefits diminish over time. The three currently available treatment approaches aim to supplement dopamine levels in the brain (levodopa); prolong the action of endogenous dopamine or a dopamine supplement through dopamine extenders (monoamine oxidase B or catechol O-methyltransferase inhibitors); or mimic the effect of dopamine in the brain by stimulating dopamine receptors directly (dopamine agonists).

Levodopa, the standard treatment for Parkinson's was first introduced nearly 50 years ago and is currently the most effective therapy for reducing the motor symptoms of Parkinson's. An estimated 70% to

80% of Parkinson's patients receive levodopa at any given time. Treatment with levodopa is usually highly effective in improving motor symptoms when first initiated. Any improvements in motor control and quality of life progressively diminish as these patients start to experience a shorter duration of benefit following each dose of levodopa (periods when they are in an "ON-state," also referred to as ON-time), and longer periods where their symptoms return (periods when they are in an "OFF-state," also referred to as OFF-time). Within four to six years of commencing treatment with levodopa, an estimated 40% of Parkinson's patients will experience OFF episodes, increasing by an additional 10% per year after that.

Parkinson's patients treated with levodopa often, over time, experience dyskinesia during ON-time. Dyskinesia is the occurrence of involuntary muscle movements and is generally distinguished by patients as troublesome or not depending on whether the movements adversely affect motor function. Troublesome dyskinesia may seriously negatively affect the quality of a patient's ON-time. Current adjunctive treatments to levodopa frequently further increase dyskinesia.

While there have been a number of studies conducted to evaluate the optimal sequence with which levodopa, dopamine extenders and dopamine agonists should be introduced into treatment, the treatment algorithm for the majority of patients involves addition of a new therapy to the patient's existing regimen. For example, a patient started on levodopa who subsequently experiences reappearance of symptoms may have a dopamine extender or dopamine agonist added to his or her regime. Existing therapies are rarely discontinued when new therapies are added. With continued disease progression, patients may be administered one drug from each of the three classes currently approved for the treatment of Parkinson's, and it is standard for multiple medications to be administered five to seven years after diagnosis. As a last resort, invasive surgical intervention may be required to control symptoms, including neurosurgical insertion of electrodes (deep brain stimulation) and gastrointestinal surgery to insert a permanent tube in the duodenum through which a levodopa gel can be infused from a portable pump.

Tozadenant's Mechanism of Action

Tozadenant blocks the effect of a neurotransmitter (a naturally occurring chemical messenger that transmits a signal from one neuron to another neuron) in the brain, adenosine, at the A_{2a} receptor, a receptor expressed in high concentration in the motor control part of the brain that is most affected in Parkinson's patients. Activation of the A_{2a} receptor by adenosine A_{2a} receptors has been shown to exert an antagonist effect on the action of dopamine in this brain region. Blocking of A_{2a} receptors with tozadenant serves to dampen this antagonistic effect, improving central dopaminergic balance and promoting restoration of motor function.

Completed Tozadenant Clinical Trials and Preclinical Studies

Tozadenant is an orally administered, potent and selective inhibitor of the adenosine A_{2a} receptor that we are developing for the treatment of Parkinson's. Tozadenant has been evaluated in patients with Parkinson's in two published clinical trials. Most recently, in a 420-patient Phase 2b clinical trial of tozadenant, in the 120 mg twice/day arm, OFF-time was improved in levodopa-treated Parkinson's patients from a mean OFF-time at baseline of 6.1 hours per day to 4.2 hours per day, which was an improvement of 1.9 hours over baseline, and a 1.1 hour placebo-adjusted improvement. There was a corresponding improvement in ON-time which increased by 1.2 hours compared with placebo. Notably, these clinically important improvements were not associated with increases in troublesome dyskinesia. Tozadenant also has been evaluated in healthy subjects in eight clinical trials in which safety, tolerability, pharmacokinetics and pharmacodynamics were examined. Tozadenant has been found to be generally safe and well tolerated.

The following table outlines the key attributes and trial designs and controls in the ten clinical trials conducted to date, which have included 568 unique exposures to tozadenant.

Phase	Key Attributes	Trial Design and Control
Phase 2b	Pivotal trial in Parkinson's patients	Double-blind, placebo-controlled, randomized trial of safety and efficacy of tozadenant as adjunctive therapy to levodopa
Phase 2a	Pilot trial in Parkinson's patients	Double-blind, placebo-controlled, randomized, 2-way crossover trial to explore the effects of tozadenant on clinical and functional MRI response to intravenous levodopa
Phase 1	Multiple-ascending dose trial in aged healthy volunteers	Double-blind, single center, placebo-controlled, randomized, multiple-ascending dose trial to assess safety and tolerability and to characterize pharmacokinetic and cardiovascular effects
Phase 1	Food effect and drug-drug interaction trial	Open label, single center, 3-period, food effect crossover combined with a fixed-sequence itraconazole drug-drug interaction trial
Phase 1	Single-ascending dose trial in healthy volunteers	Double-blind, single center, placebo-controlled, randomized, single-ascending dose trial to assess safety and pharmacokinetics
Phase 1	Multiple-ascending dose trial in healthy volunteers	Double-blind, single center, placebo-controlled, randomized, multiple-ascending dose trial to assess safety and pharmacokinetics
Phase 1	ADME trial	Open label, single center, single-dose trial to investigate the absorption, distribution, metabolism and excretion of radiolabeled tozadenant
Phase 1	Japanese-bridging trial	Single center, placebo-controlled single and multiple dose trial to investigate the pharmacokinetics, safety, and tolerability of tozadenant in Japanese subjects
Phase 1	Bioequivalence trial	Open label, single center, randomized, 2-treatment, 2-way crossover bioequivalence trial
Phase 1	Drug-drug interaction trial	Open label, single center, fixed-sequence 4-period pharmacokinetics trial of a single-dose of metformin and pramipexole following 5 (metformin) or 9 (pramipexole) consecutive days of twice/day tozadenant administration

Phase 2b Clinical Trial

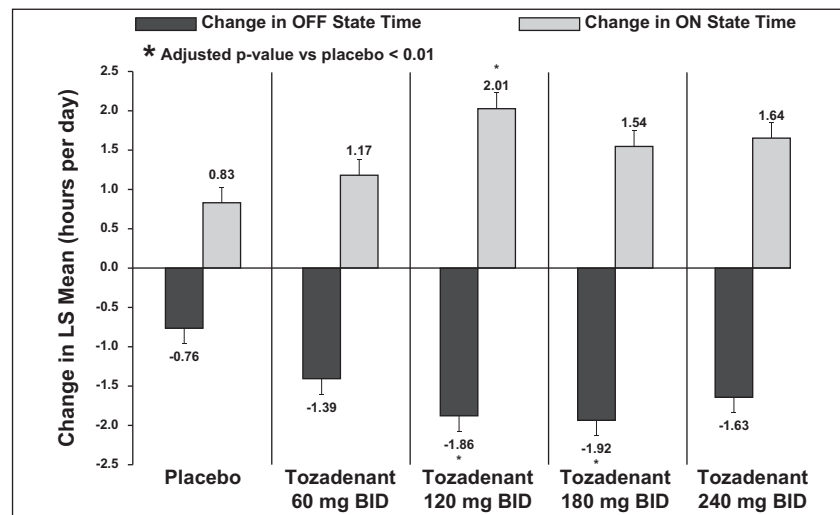
Our Phase 2b clinical trial of tozadenant was a double-blind, placebo-controlled clinical trial designed to evaluate the safety and efficacy of tozadenant as an adjunctive therapy in levodopa-treated Parkinson's patients with at least 2.5 hours of OFF-time per day. We enrolled 420 subjects at approximately 70 sites in the United States, Canada, Argentina, Chile, Romania and Ukraine, randomized to 60 mg, 120 mg, 180 mg, or 240 mg of tozadenant, in each case twice/day, or a placebo. The mean age of the patients was 63.3 years and the mean duration of Parkinson's was 8.7 years from diagnosis. The mean OFF-time at baseline was

about six hours per day. The primary endpoint of our Phase 2b trial was to assess the reduction in the mean total hours of awake time per day spent in the OFF-state over the 12-week treatment period. Our key secondary endpoints were the number of total hours spent in the ON-state while awake and the number of hours spent in the ON-state without troublesome dyskinesia. Additional secondary endpoints included a variety of scores on the Unified Parkinson's Disease Rating Scale, or UPDRS; and both clinical and patient global impression surveys.

All treatment groups demonstrated a decrease in time in the OFF-state from baseline to week 12. Statistically significant decreases (changes that mathematically were unlikely to have occurred purely by chance) in the placebo-adjusted mean changes in time in the OFF-state were observed for the 120 mg twice/day and 180 mg twice/day comparisons to placebo ($p < 0.05$, a number signifying that the differences to placebo would have occurred by chance less than one time in 20). The magnitude of the reductions in OFF-time with tozadenant doses of 120 mg and 180 mg was almost two hours over baseline and is considered to be a clinically important improvement in this population, defined as the smallest change in OFF-time that is meaningful for patients (one hour more than improvement with placebo). In addition, the reduction in time in the OFF-state was associated with an improvement (increase) in awake time in the ON-state in all treatment groups, and was highly statistically significant for the 120 mg twice/day dose (1.2 hour increase compared to placebo, $p = 0.0052$, a number signifying that the differences to placebo would have occurred by chance 52 times in 10,000).

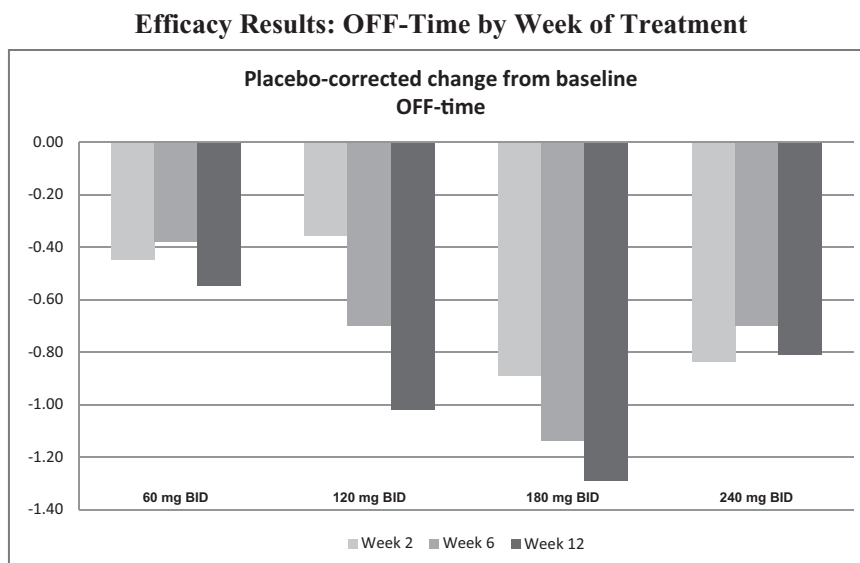
The following graph depicts the reduction of the mean total hours of awake time per day spent in the OFF-state (primary endpoint) and the increase in the total number of hours spent in the ON-state over the 12-week period (secondary endpoint).

Efficacy Results: Mean Change from Baseline to End of Week 12 in OFF-Time and ON-Time



Considerable geographic variation in the difference between tozadenant and placebo was observed on the primary endpoint among the different countries that participated in SYN115-CL02, with the United States and Canada demonstrating the largest differences to placebo compared to countries outside North America.

In addition, as shown in the following graph, tozadenant showed progressively increasing efficacy by week of treatment in the 120 mg twice/day group and the 180 mg twice/day group.

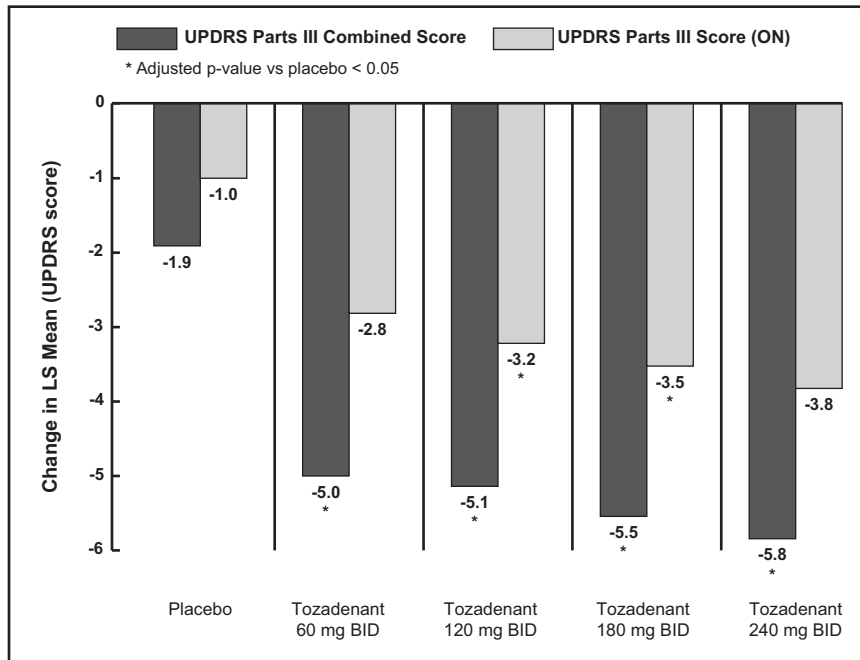


The UPDRS is a widely accepted scale to evaluate the severity and progression of Parkinson's and the complications of treatment. It is a four-part scale: Part I assesses non-motor experiences of daily living, Part II assesses motor experiences of daily living, Part III is a clinician-conducted motor examination and Part IV assesses motor complications. Combined and individual UPDRS scores have been commonly used as the primary endpoint in clinical trials evaluating the efficacy of Parkinson's treatments.

The sum of UPDRS Parts I-III was significantly reduced by at least three points ($p < 0.05$) compared with placebo in all tozadenant dose groups. UPDRS Part III scores were improved compared with placebo in both the 120 mg group (reduced by 2.2 points; $p = 0.0325$) and 180 mg group (reduced by 2.5 points; $p = 0.0325$), as well as in the 60 mg group by 1.8 points ($p = 0.0722$). The improvement in UPDRS Part III scores observed with tozadenant 180 mg twice/day is considered clinically important (defined as the smallest change in the UPDRS scores that is meaningful to patients) and demonstrate that the benefits experienced by subjects taking tozadenant were not limited to a reduction in the duration of OFF episodes.

The following graph depicts the improvements in the UPDRS scores.

Efficacy Results: UPDRS Parts I-III and Part III Change from Baseline to End of Week 12



Improvements, as measured by both the clinical global impression and patient global impression scales, were perceptible to both physicians and patients as reflected in the improved clinical global impression scores on both the severity scale and the improvement scale in all dose groups compared with placebo ($p < 0.05$ and $p < 0.01$, respectively). The Clinical Global Impression of Severity scale is a 7-point scale that requires the clinician to rate the severity of the patient's illness at the time of assessment compared with the clinician's past experience with patients who have the same diagnosis from normal to extremely ill. The Clinical Global Impression of Improvement scale is a 7-point scale that requires the clinician to assess how much the patient's illness has improved or worsened relative to a baseline state at the beginning of the intervention and rate it from very much improved to very much worse. The patient global impression scores in the 120 mg group were better than in the placebo group ($p = 0.0249$). The Patient Global Impression of Improvement scale asks the patient to rate their condition as compared with how it was prior to beginning treatment on a scale from 1 to 7.

The following sets forth the improvements in the global impression scales.

Efficacy Results: Mean Changes in Global Impression Scores from Baseline to End of Week 12

		Tozadenant (mg twice/day)			
* P-Value <0.05	Placebo N=84	60 N=85	120 N=82	180 N=85	240 N=84
Clinician Global Impression - Severity					
Change in LS mean	0.03	-0.2	-0.2	-0.2	-0.2
Adjusted p-value	—	*0.0208	*0.0076	*0.0076	*0.0208
Clinician Global Impression - Improvement					
Change in LS mean	0.4	0.8	1.1	1.0	1.0
Adjusted p-value	—	*0.0066	*<0.0001	*0.0003	*0.0066
Patient Global Impression - Improvement					
Change in LS mean	0.7	0.8	1.2	1.0	1.2
Adjusted p-value	—	0.7943	*0.0249	0.1661	0.7943

In summary, tozadenant reduced OFF-time in levodopa-treated Parkinson's patients experiencing OFF episodes. Compared with placebo, 120 mg twice/day tozadenant reduced OFF-time by 1.1 hours and increased ON-time by 1.2 hours. Clinically important improvements were not associated with increases in troublesome dyskinesia in the 120 mg dose. Notably, benefits were observed in a population of Parkinson's patients of whom more than 84% were receiving adjunctive anti-Parkinson's medications in addition to levodopa.

Tozadenant was generally well tolerated. The majority of patients in each treatment group experienced at least one treatment emergent adverse events, or TEAE, during the trial. The most frequently reported TEAEs (that is, occurring in more than 5% of patients in any treatment group, with incidence greater than placebo) were dyskinesia, nausea, dizziness, constipation, insomnia and fall. The majority of TEAEs were mild or moderate in maximum intensity. As expected with most central nervous system drugs, there was a dose-related increase in the reporting of adverse events and in the proportion of patients who discontinued early due to TEAEs, with a higher proportion (approximately 20%) of patients in the 240 mg twice/day tozadenant group discontinuing early due to TEAEs compared to the lower dose groups (approximately 8% to 12%).

A total of 24 severe adverse events, or SAEs, were reported in 13 patients. The incidence of SAEs was 1.2%, 3.7%, 2.4% and 4.8% in the 60 mg, 120 mg, 180 mg and 240 mg groups, and 3.6% in the placebo group. Of the 24 SAEs reported, 11 occurred in two of the 13 patients. Nonfatal SAEs were reported for seven patients. All nonfatal SAEs resolved except for an event of atrial fibrillation in a placebo-group patient who also had an ischemic stroke. One nonfatal SAE of acute psychosis with paranoia was assessed by the investigator as being probably related to tozadenant; and we do not intend to take any further actions based on this isolated report. Fatal SAEs of disparate causes were reported for six patients, all of whom received tozadenant. An independent blinded data monitoring committee reviewed all SAEs during the trial, and an independent expert panel reviewed the data after the trial was complete and unblinded. Both panels concluded that there was no relationship between tozadenant and the fatal SAEs. Laboratory evaluations did not indicate an adverse effect of tozadenant on safety parameters (hematology, chemistry or urinalysis) in any dose group.

Phase 2a Clinical Trial

Our Phase 2a trial of tozadenant was a double-blind, single-center, placebo-controlled, two-way crossover clinical trial in which each subject acted as his or her own control. Subjects with Parkinson's were randomized to one of two treatment sequences each of one week duration: tozadenant to placebo or placebo to tozadenant with a one week "washout" period between the treatment periods. Fourteen subjects were evaluated at doses of 60 mg twice/day and twelve at 20 mg twice/day (of whom five also participated in the evaluation of the 60 mg twice/day dose). Functional magnetic resonance imaging, or fMRI, was used to evaluate brain activity and demonstrated effects of tozadenant similar to those observed with drugs effective in the treatment of Parkinson's such as levodopa and dopamine agonists. Administration of tozadenant 60 mg twice/day for seven days was associated with improvements in several measures of bradykinesia, less sleepiness and faster reaction time on cognitive tests, as compared to placebo. Tozadenant was found to be safe and well tolerated.

Phase 1 Clinical Trials

Tozadenant has been evaluated in eight clinical trials in healthy subjects in which safety, tolerability, pharmacokinetics and pharmacodynamics were examined. Over 200 subjects participated in these clinical trials in which doses ranging from 5 mg to 480 mg were administered as either single doses or daily for up to 26 days. Tozadenant was found to be generally safe and well tolerated.

Preclinical Studies

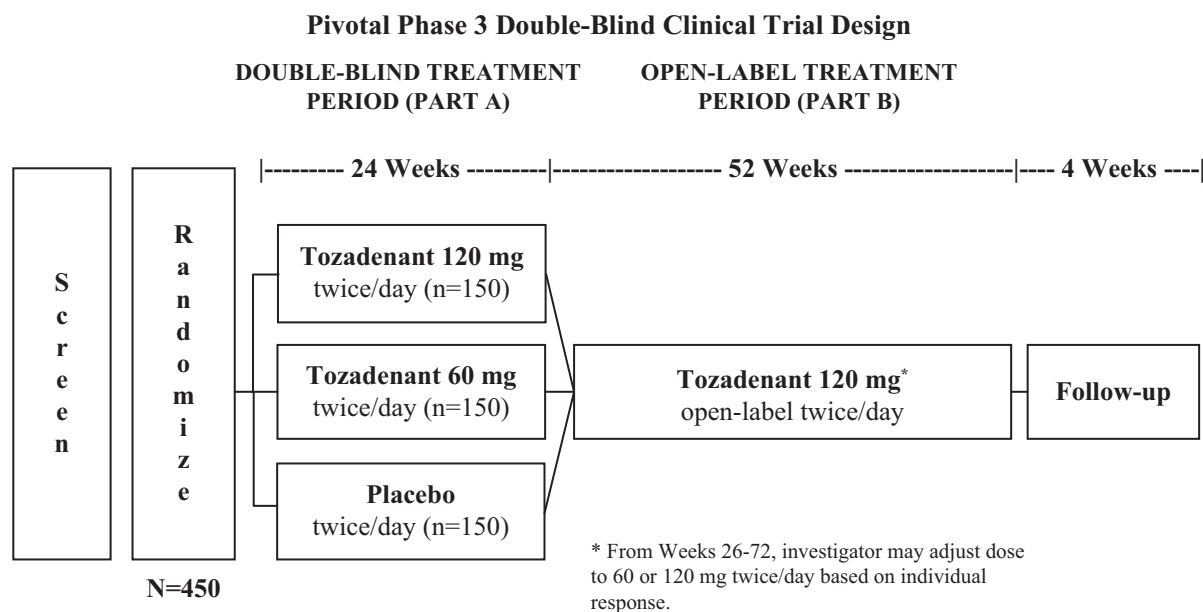
In preclinical models of Parkinson's, tozadenant has been shown to enhance the effects of levodopa on motor function without the induction of dyskinesia. Tozadenant has also demonstrated antidepressive, anxiolytic and pro-cognitive effects in relevant animal models, suggesting it may have the potential to improve the non-motor symptoms of Parkinson's. Adenosine A_{2a} antagonists have also been shown *in vitro* and in animal models of Parkinson's to have neuroprotective effects, which raises the possibility that tozadenant may have disease-modifying properties.

Planned Clinical Activity

Pivotal Phase 3 Clinical Trial

In March 2014, we participated in an End of Phase 2 meeting with the FDA at which the results of the Phase 2b clinical trial of tozadenant were reviewed. Based on the data on the primary and multiple secondary endpoints in our Phase 2b trial of tozadenant, the FDA indicated it could qualify as the first of two pivotal studies required for regulatory approval of tozadenant as an adjunctive treatment to levodopa in Parkinson's patients experiencing end-of-dose wearing off episodes. We are preparing to commence a Phase 3 trial of tozadenant and will use the primary and secondary endpoints and enrollment criteria we used in our Phase 2b clinical trial.

The Phase 3 program will consist of a double-blind trial followed by an open-label extension and, if this demonstrates safety and efficacy, a separate open-label trial to generate further information on safety. Below is the design of the study that includes the double-blind treatment phase.



The double-blind portion will be a six-month trial comparing 60 mg and 120 mg twice/day doses of tozadenant to placebo as an adjunctive therapy in 450 levodopa-treated patients with Parkinson's who are experiencing end-of-dose wearing off episodes. We plan to conduct the trial in North America and selected European countries. The primary efficacy endpoint will be the change from baseline to week 24 in the number of hours per day spent in the OFF-state, as assessed by patient-completed diaries and averaged over three consecutive days. The key secondary endpoints will be the change from baseline to week 24 in the number of hours per day spent in good ON-time, defined as the sum of ON-time without dyskinesia and ON-time with no-troublesome dyskinesias and the change from baseline to week 24 in the sum of UPDRS Parts II (motor experience of daily living subscale) and III (clinical conducted motor examination subscale) total scores. Other secondary efficacy measures will include various UPDRS and global impression measures. The trial is designed to provide adequate statistical power to detect a difference in mean response in the primary endpoint. Following the double-blind treatment period, patients will be eligible to enroll in a one-year open label treatment period, which will evaluate the safety of tozadenant during long-term administration.

If the double-blind portion of the trial described above meets its primary efficacy endpoint, we will initiate another open-label trial in 450 of a separate population of Parkinson's patients to establish the requisite number of unique patient exposures required for approval. This open label trial will also be conducted in North America and selected European sites. Patients will be dosed with 120 mg of tozadenant twice/day for 52 weeks with a 4-week follow-up period, although the investigator may adjust the dose to 60 mg or 120 mg twice/day based on individual response.

A data safety monitoring board will oversee the safety of both trials.

Subsequent to our End of Phase 2 meeting, we consulted the FDA regarding the design and adequacy of the proposed Phase 3 clinical trial to support regulatory approval of tozadenant through a Special Protocol Assessment, or SPA, to which the FDA has now agreed.

We believe, based on our correspondence with the FDA to date, a successful Phase 3 clinical program will enable submission of a new drug application, or NDA, to seek approval of tozadenant as an adjunctive treatment to levodopa in Parkinson's patients experiencing end-of-dose wearing off episodes. We also requested scientific advice from the EMA on the design of our Phase 3 clinical program of tozadenant. Based on their response, we expect EMA approval of tozadenant to be contingent on conducting studies in addition to the currently planned Phase 3 program. We plan to engage in further discussions with the EMA with respect to their requirements for the approval of tozadenant.

Planned Phase 1 Clinical Trials

As is required by the FDA for most drugs that act on the central nervous system, we plan to conduct a human abuse potential trial prior to an NDA submission. A trial of the effect of tozadenant on cardiac conduction (a thorough QT study) may also be required, depending on FDA guidance.

Development, Regulatory and Commercialization Pathway for Tozadenant

We have licensed rights to tozadenant from Roche Palo Alto LLC, Hoffman-La Roche Inc., and F. Hoffman-La Roche Ltd., collectively, the Roche Entities, which were sublicensed to UCB Pharma S.A., or UCB, in 2010. Under the license and collaboration agreement with UCB, or the UCB Collaboration Agreement, we conducted a Phase 2b clinical trial for tozadenant, which was successfully completed in 2012. Following a review of the Phase 2 data, in February 2013, UCB exercised its option in relation to tozadenant and paid us a nonrefundable development milestone payment of \$20.0 million (€15.3 million). Until the end of March 2014, UCB funded further development of tozadenant amounting to €13.3 million. In March 2014, UCB terminated the UCB Collaboration Agreement and returned its rights to us following an assessment of its early and late stage clinical development pipeline as well as its other preclinical opportunities, which according to UCB did not reflect any concerns regarding the safety or efficacy of tozadenant. The decision was made prior to the End of Phase 2 meeting with the FDA. Consequently, we currently hold an exclusive, worldwide, royalty-bearing license to develop and commercialize tozadenant products. In August 2014, we and UCB entered into a termination and transition agreement, or the UCB Termination and Transition Agreement, pursuant to which, among other things, we and UCB agreed to undertake a series of transitional activities to facilitate the handover of tozadenant development activities and regulatory documentation back to us. UCB has completed substantially all of its obligations under the UCB Termination and Transition Agreement, including the provision of additional funding and support to ensure that the development program was not delayed during the transition back to us, as well as participation with us in the End of Phase 2 meeting with the FDA at the end of March 2014.

Since the End of Phase 2 meeting with the FDA, we have progressed preparations for our planned pivotal Phase 3 clinical trial, including chemistry manufacturing and control work, non-clinical work and Phase 3 enabling pharmacological trials, and expect to begin recruiting for the Phase 3 clinical trial by the middle of 2015. Based on our discussions with the FDA at our End of Phase 2 meeting, we believe our planned Phase 3 clinical program, together with existing data, could form the basis for approval of tozadenant as an adjunctive treatment to levodopa in Parkinson's patients experiencing end-of-dose wearing off episodes. We have also requested scientific advice from the EMA with respect to the design of our Phase 3 program. Assuming that the Phase 3 clinical trial yields positive data, and long-term safety is demonstrated in open-label treatment, we intend to file for registration, initially in the United States. At this time, we plan to determine the most appropriate commercial strategy, which may involve establishing our own infrastructure, partnering with another commercial company, or a combination of both.

SYN120

Overview of Cognitive Deficits in Parkinson's Dementia and Alzheimer's

While motor symptoms are the hallmark of Parkinson's, non-motor symptoms are common and include sleep disturbance, autonomic dysfunction, mood disturbance, including anxiety and depression, and cognitive disorders including memory difficulties and dementia. Alzheimer's, the most prevalent neurodegenerative disease, is also an irreversible brain disease that causes progressive deterioration of memory and cognitive skills. Both Alzheimer's and Parkinson's dementia are associated with a decline in cognitive function that eventually results in the inability of patients to perform even the simplest tasks of daily living. Ultimately patients need full time nursing care. Alzheimer's represents a large and growing economic and social burden to society. Currently, it is estimated that there are approximately 34 million Alzheimer's patients worldwide, of which 5.3 million are in the United States. The average per-person Medicare spending for those with Alzheimer's and other dementias is three times higher than for those without these conditions. Nearly one in every five dollars spent by Medicare is on patients with Alzheimer's or another form of dementia. Globally, the market is expected to grow to \$10.1 billion by 2020.

Current Treatment Approaches and Inherent Limitations

Currently, there are no therapies that cure Parkinson's or Alzheimer's. Existing therapies for both Parkinson's dementia and Alzheimer's are targeted at improvement of symptoms. Acetylcholine is believed to play an important role in the cognitive deficits observed in both Parkinson's and Alzheimer's. It is a neurotransmitter found widely in both the central and peripheral nervous system and degeneration of the neurons responsible for its synthesis is notable in both Parkinson's and Alzheimer's. An enzyme, acetylcholinesterase, is responsible for inactivating acetylcholine after its release at the synapse and thereby terminating cholinergic transmission. A number of the currently approved products for the symptomatic treatment of Alzheimer's are inhibitors of acetylcholinesterase and therefore enhance the effects of the remaining cholinergic neurons. However, increase in cholinergic transmission in the peripheral nervous system frequently leads to adverse effects, most commonly gastrointestinal.

Mechanism of Action

SYN120 is an orally administered selective antagonist of the 5HT₆ and the 5HT_{2a} receptors that has the potential to be effective in the treatment of cognitive deficits and psychosis, which frequently coincide in neurodegenerative diseases such as Parkinson's and Alzheimer's. The 5HT₆ receptors are located exclusively in the brain and antagonism results in increased concentrations of acetylcholine and glutamate, two known pro-cognitive neurotransmitters. The localization of the 5HT₆ receptors in the brain therefore avoids stimulation of peripheral cholinergic transmission and the subsequent adverse effects. The 5HT_{2a} receptor is expressed widely through the central nervous system and is believed to play a role in the antipsychotic action of many neuroleptics. The dual mechanism of action of SYN120 has the potential to address both the cognitive and the neuropsychiatric symptoms that commonly coexist in neurodegenerative conditions such as Parkinson's and Alzheimer's.

Summary of Completed Clinical Trials and Preclinical Studies

SYN120 has been shown to improve cognition in multiple preclinical models. In addition, preclinical models have confirmed its activity at the 5HT₆ and 5HT_{2a} receptors.

SYN120 has completed Phase 1 single ascending dose and multiple ascending dose clinical trials in healthy volunteers. In the single ascending dose clinical trial, 42 subjects received single doses of 2 mg to 600 mg a day and 14 subjects received placebo. In the multiple ascending dose clinical trial 27 subjects

received doses of 100 mg to 600 mg a day for 14 days and nine subjects received placebo. The drug was well tolerated, and there were no observations that we believe would preclude further development. Importantly, there was no clinically relevant effect on cardiovascular parameters, especially corrected QT interval, which has been an issue with other compounds targeting this pathway.

We have also completed a clinical trial that determined the dose required to occupy the 5HT₆ receptor in the brain. This clinical trial used positron emission tomography imaging to determine the receptor occupancy after different doses of SYN120 with the objective of establishing the therapeutic dose. Single doses between 10 mg and 300 mg were administered to nine subjects. The results of this clinical trial showed that doses approximately five- to tenfold below the highest doses administered in the single ascending dose and multiple ascending dose clinical trials provided near-maximum occupancy of the 5HT₆ and 5HT_{2a} receptors over a 24-hour period. Because the drug was well-tolerated in the single ascending dose and multiple ascending dose trials, we anticipate the therapeutic dose to be safe and well tolerated.

Ongoing Phase 2a Clinical Trial of SYN120 in Parkinson's Dementia

In July 2014, we announced that we received a grant of up to \$2.0 million (€1.7 million) from the Michael J. Fox Foundation to investigate SYN120 in Parkinson's dementia. Pursuant to this agreement, the Michael J. Fox Foundation will largely fund an 80-patient, Phase 2a, randomized, double-blind, placebo-controlled trial of 16 weeks duration in patients with Parkinson's dementia. In addition to assessing safety and tolerability, the main focus of the trial will be to evaluate efficacy of SYN120 on cognition using the Cognitive Drug Research Computerized Cognition Battery, or the CDR system, as the primary efficacy endpoint. The CDR system is a computer based cognitive testing tool developed to assess both the enhancement and impairment of human cognitive performance. Enrollment began at the end of 2014, and top-line data is expected by the end of 2016.

BTT1023

Primary Sclerosing Cholangitis

PSC, a chronic and progressive fibrotic liver disease, has a median survival after diagnosis (without liver transplant) of 10 to 12 years. There is currently no FDA-approved treatment. PSC meets the criteria for orphan disease designation. Epidemiological studies in Northern Europe and North America have shown prevalence rates ranging from approximately 4 to 16 per 100,000 inhabitants. BTT1023 has received orphan drug designation for the treatment of PSC in Europe. We intend to pursue orphan drug designation for BTT1023 in the United States.

BTT1023 is a fully human monoclonal antibody that specifically binds to VAP-1 and prevents inflammation. VAP-1 is an endothelial cell adhesion receptor expressed on blood vessels that mediates the interactions of leukocytes in the blood with the vessel wall and assists in their migration to sites of inflammation in tissue. Recent investigation has shown that VAP-1 is involved in the process of fibrosis, which can occur in several organs and is poorly treated with current drugs.

Summary of Clinical Trials

BTT1023 has been evaluated in three clinical trials in humans: one in healthy volunteers, one in patients with rheumatoid arthritis and the third in patients with psoriasis. No serious or severe adverse events were reported in the clinical trial subjects.

We are working in collaboration with the University of Birmingham to conduct a Phase 2 proof of concept clinical trial with BTT1023 in PSC. The investigator-sponsored clinical trial has been awarded partial funding from the U.K. National Institute for Health Research. The clinical trial will be conducted at three centers in the United Kingdom. It was open for the enrollment of patients during the first quarter of

2015 and interim data is expected by the end of 2016. It is an open label, single arm trial enrolling 41 patients and will evaluate the efficacy, safety and pharmacokinetic properties of BTT1023 in patients with PSC. Patients will be treated for 11 weeks, and the primary efficacy endpoint will be reduction of elevated levels of alkaline phosphatase, a blood biomarker of bile duct inflammation.

Selincro

Overview of Alcohol Dependence, Current Treatment Approaches and Inherent Limitations of Treatment

According to a 2014 study, over 47 million people in the five major EU markets, 42 million people in the United States and 19 million people in Japan engaged in heavy episodic drinking (defined as consumption of more than 60 grams of pure alcohol, or more than six standard drinks) within the last 30 days. A recently published modelling study showed that increasing the drug-based treatment of alcohol dependency in Europe by 40% would reduce alcohol-attributable mortality by 9% for women and 13% for men, potentially saving 11,700 lives annually. Up until 2025, alcohol per capita consumption is expected to continue to increase in the United States and South-East Asia, and Europe is expected to remain the region with the highest per capita consumption in the world.

Alcohol dependence is defined as a maladaptive pattern of alcohol use, leading to clinically significant impairment or distress. Alcohol dependence diagnosis requires at least three of a number of criteria, which include among others, increased tolerance, withdrawal symptoms, frequent use of alcohol in larger amounts or over longer periods than was intended. Alcohol dependence is characterized by the physical and mental addiction to alcohol and is associated with significant medical, social and economic consequences both to individual patients and to society at large. A high drinking risk is defined by the World Health Organization as more than 60 grams of alcohol per day for men and more than 40 grams of alcohol per day for women. For reference, one standard drink equates to approximately 10 grams of alcohol. There are numerous adverse consequences to the digestive system, liver, pancreas, nervous system and heart resulting from excessive alcohol consumption. Evidence from epidemiological data has shown that every drinking day carries an increased risk of accidents, aggression, suicide and cardiac arrest, and any reduction in alcohol consumption for a person who consumes more than one standard drink per day will reduce the annual and lifetime risk of an alcohol-related death.

Selincro has been developed to reduce heavy drinking, which is a new approach, compared to traditional alcoholism treatment models, which aim to achieve total abstinence. Selincro tablets can be prescribed by general practitioners and specialists, and should be used in conjunction with psychosocial support (counseling and support groups) focused on treatment adherence and the reduction of alcohol consumption. Selincro is indicated for the reduction of alcohol consumption in adult patients with alcohol dependence who have a high drinking risk level without physical withdrawal symptoms and who do not require immediate detoxification. Treatment should be initiated only in patients who continue to have a high drinking risk level two weeks after an initial assessment. Selincro is to be taken as-needed; that is, on each day the patient perceives a risk of drinking alcohol, one tablet should be taken, preferably one to two hours prior to the anticipated time of drinking.

Mechanism of Action

Selincro is a selective opioid receptor ligand with antagonist activity at the mu (μ) and delta (δ) receptors and partial agonist activity at the kappa (κ) receptor in the opioid system. Acute alcohol intake has been shown to result in mesolimbic dopamine release (facilitated by the release of beta-endorphins), the so called reward pathway. Selincro is thought to counteract the reinforcing effects of alcohol consumption, possibly by modulating these cortico-mesolimbic functions.

Clinical Program Undertaken to Support the EU Authorization

We developed Selincro with a target indication of reducing heavy alcohol consumption, a novel alternative to traditional abstinence-oriented treatment models of alcoholism, which usually include intensive psychosocial therapy. Over 1,100 patients participated in our clinical trials in the alcohol indication. Lundbeck, to which we licensed global commercial rights to Selincro, conducted additional Phase 3 clinical trials of Selincro, and including the patients who participated in the Lundbeck trials, a total of over 3,000 patients participated in the clinical development program.

Our clinical trials included three Phase 2 and two Phase 3 trials in Finland, the United States and the United Kingdom. Lundbeck subsequently completed three additional Phase 3 clinical trials (ESENSE1, ESENSE2 and SENSE). The clinical trials were conducted across a wide range of European countries, and comprehensive data from Lundbeck's clinical trials have been published in peer-reviewed journals.

ESENSE1 and ESENSE2, 24-week efficacy trials, and SENSE, a 52-week safety trial, were designed to investigate efficacy and safety of 18 mg Selincro taken "as needed" versus placebo in patients with alcohol dependence. In these clinical trials, which enrolled 1,941 patients in total, psychosocial intervention consisted of a brief, standardized program focused on adherence and follow-up. No abstinence treatment goals were imposed.

ESENSE1, ESENSE2 and SENSE showed that Selincro, in conjunction with psychosocial intervention, reduced the monthly number of heavy drinking days, and the monthly total alcohol consumption (in grams/day) by over 60% after six months of treatment, which corresponded to an average reduction equal to nearly one bottle of wine per day from baseline.

In the clinical trials, Selincro was shown to be well tolerated. The most common adverse reactions were nausea, dizziness, insomnia and headache. The majority of these reactions were mild or moderate, associated with treatment initiation, and of short duration.

Commercialization and Current Launch Status

Selincro received European marketing authorization in the European Union in February 2013, and it is the first and only therapy approved for the reduction of alcohol consumption in alcohol dependent individuals. We have licensed global rights to Selincro to Lundbeck, who have to date introduced the product in 29 European countries. Under the terms of the Option Agreement with Lundbeck and the Lundbeck License Agreement, we are eligible to receive up to €94 million in upfront and milestone payments plus royalties on sales of Selincro. To date, we have received €22.0 million in upfront and milestone payments and are eligible to receive an additional €72 million in milestone payments upon achievement of specified regulatory and commercial milestones as well as royalties on sales for the duration of the royalty term specified under the Lundbeck License Agreement. Lundbeck is responsible for the registration, manufacturing and commercialization of Selincro.

Lundbeck filed the marketing authorization application for Selincro in December 2011 in Europe, and marketing authorization from the European Commission was received in February 2013. The product was first made available in April 2013, and by the end of 2014, Selincro had been launched in 25 European countries. Selincro is on the market in the five major EU markets. Pricing and reimbursement decisions have to date been obtained in several countries and Favorable Health Technology Assessment reports have been issued in several countries including France and the United Kingdom. The U.K. National Institute for Health and Care Excellence issued final guidance in November 2014 recommending the use of Selincro within the conditions of its marketing authorization in the National Health Service in England and Wales. The decisions have enabled Lundbeck to significantly increase its sales and marketing activities across Europe. In October 2013, Lundbeck entered into an agreement with Otsuka Pharmaceutical Co., Ltd., or

Otsuka, to develop and commercialize Selincro in Japan. Lundbeck and Otsuka will jointly finalize and fully fund the clinical program for Selincro in Japan. The first Phase 3 clinical trial was initiated in the first quarter of 2015.

Collaborations

We have entered into various licensing and commercialization agreements, including the following agreements with respect to product candidates and marketed products.

Lundbeck License Agreement

In November 2006, we entered into an option agreement, or the Option Agreement, to negotiate a license and commercialization agreement with Lundbeck, and subsequently entered into the Lundbeck License Agreement in May 2007. Pursuant to the Lundbeck License Agreement, we granted Lundbeck an exclusive, royalty-bearing, sublicensable worldwide license under certain patents and know-how related to Selincro owned by or exclusively licensed to us, to develop, manufacture and commercialize Selincro for any purpose.

Pursuant to the Option Agreement in November 2006, Lundbeck made an upfront payment to us of €10.0 million. Pursuant to the Lundbeck License Agreement, Lundbeck made an upfront payment to us in May 2007 of €2.0 million and agreed to make additional milestone payments to us upon the achievement of specified regulatory and commercial milestones. The total upfront and milestone payments contemplated by the Option Agreement and the Lundbeck License Agreement total €94 million. To date, we have received €22.0 million in upfront and milestone payments and are eligible to receive an additional potential €72.0 million in milestone payments upon the achievement of specified regulatory and commercial milestones. There have been positive reimbursement and pricing decisions in a number of key markets and we received launch milestone payments in connection with launches in: Spain in July 2014, Germany in August 2014 and France in September 2014. In addition, we are eligible to receive tiered low single digit to high-teen royalties from Lundbeck on net sales of Selincro, with the applicable royalty rate varying depending on the country of sale and the level of net sales achieved in specified territories. In some territories, we are not eligible to receive any royalties until net sales surpass a certain threshold. With respect to sales in the European Union, the applicable royalty rate ranges from low to high teens, depending on net sales levels in such year. We are eligible to receive royalties from Lundbeck on net sales of Selincro on a product-by-product and country-by-country basis until the later of either the date when there are no valid patent rights owned by us covering the licensed product or other statutory exclusivity rights covering the licensed product in force in the applicable country and May 23, 2017. In addition, if no third party commercializes a generic Selincro product in the applicable country following the expiration of the foregoing royalty term, we will receive a royalty at a reduced rate on net sales of such Selincro products in such country. The royalties payable to us under the Lundbeck License Agreement will be reduced under certain conditions, including if Selincro is no longer covered by statutory exclusivity rights or a patent claim owned by us in a particular country and certain generic competition exists in such country, or if Lundbeck is required to pay royalties pursuant to a license from a third party in order to develop or commercialize Selincro products, or if Lundbeck owns certain qualifying intellectual property rights related to Selincro products.

Lundbeck is solely responsible for all manufacturing costs and expenses, as well as commercialization activities relating to licensed products. Lundbeck is subject to certain obligations requiring it to use commercially reasonable efforts to develop and commercialize Selincro products in various countries. If Lundbeck is required to perform additional studies in certain countries in order to obtain regulatory approval to market and sell Selincro products to treat alcohol dependence in such countries, Lundbeck may offset certain development costs related to such studies against any future milestone payments and royalties payable to us.

The term of the Lundbeck License Agreement will expire on a country-by-country basis on the date of the expiration of all payment obligations with respect to each product in each country of commercialization. Following such expiration, the licenses granted to Lundbeck will be fully paid-up and royalty-free. Either party may terminate the Lundbeck License Agreement for cause in the event of a material breach which is incapable of remedy or if a material breach capable of remedy has not been cured within 90 days after written notice was provided. In addition, either party may terminate the Lundbeck License Agreement upon the occurrence of certain insolvency-related events. Upon a termination of the Lundbeck License Agreement by Lundbeck for material breach or our insolvency, Lundbeck will have a fully paid-up royalty-free license. Upon a termination of the Lundbeck License Agreement by us for material breach or insolvency of Lundbeck, the licenses granted to Lundbeck under the Lundbeck License Agreement will terminate, and we will have the exclusive right to research, develop and commercialize products containing Selincro. Lundbeck has the right to unilaterally terminate the Lundbeck License Agreement, for any reason or no reason at all, upon 90 days' written notice. In the event of Lundbeck's unilateral termination without cause, the licenses granted to Lundbeck under the Lundbeck License Agreement will terminate, and we will have the exclusive right to research, develop and commercialize products containing Selincro.

UCB Collaboration Agreement and UCB Termination and Transition Agreement

Prior to our acquisition of Synosia in February 2011, in August 2010, Synosia entered into a license and collaboration agreement, or the UCB Collaboration Agreement, with UCB, to develop and commercialize tozadenant. Pursuant to the UCB Collaboration Agreement, UCB was granted a licensing option. Following a review of the tozadenant Phase 2 data in February 2013, UCB exercised its option in relation to tozadenant and paid us a non-refundable development milestone payment of \$20.0 million (€15.3 million) following completion of the Phase 2b clinical trial. Until the end of March 2014, UCB funded further development of tozadenant amounting to €13.3 million. In March 2014, we received a notice from UCB informing us of its intent to terminate the UCB Collaboration Agreement for convenience, effective March 20, 2014. In August 2014, we and UCB entered into a termination and transition agreement, or the UCB Termination and Transition Agreement, pursuant to which we and UCB agreed to undertake a series of transitional activities to facilitate the handover of tozadenant development activities and regulatory documentation back to us. UCB has now met all of its obligations under the UCB Termination and Transition Agreement.

Under the terms of the UCB Collaboration Agreement, upon UCB's termination for convenience, all licenses that we granted to UCB terminated, and we received a nonexclusive, worldwide, perpetual, sublicensable, royalty-free license to any blocking patents controlled by UCB as of March 20, 2014 that would be infringed by the further development or exploitation of tozadenant products, solely to the extent necessary to develop and commercialize tozadenant products in the form described in UCB's regulatory filings.

Pursuant to the UCB Termination and Transition Agreement, UCB also granted us an undivided, one-half ownership interest in all know-how related to tozadenant jointly developed by us and UCB under the UCB Collaboration Agreement, as well as a worldwide, royalty-free license under UCB's intellectual property rights in certain product data and regulatory documentation to use and reference the same for the purposes of exploiting tozadenant. UCB reserved the right to use such product data and regulatory documentation, subject to certain limitations. UCB provided us with certain development funding under the UCB Termination and Transition Agreement, and we are obligated to repay such funding out of any future income we receive from tozadenant. We and UCB each agreed to release the other party from all claims arising out of the other party's development activities with respect to tozadenant prior to August 22, 2014, as well as UCB's exploitation of tozadenant prior to August 22, 2014. We also agreed to indemnify UCB against any losses in connection with third-party claims arising from the continued exploitation of tozadenant by us or our licensees.

Roche License Agreement

We are party to a license agreement with Roche Palo Alto LLC, Hoffman-La Roche Inc. and F. Hoffman-La Roche Ltd., collectively, the Roche Entities, and such agreement, the Roche License Agreement, pursuant to which we obtained exclusive, royalty-bearing, worldwide licenses under the Roche Entities' patent rights and know-how to develop, manufacture and commercialize products incorporating specified Roche Entities compounds, including tozadenant and SYN120 (classified into tiered programs). Under the amended and restated agreement, as further amended, or the Roche License Agreement, tozadenant is a Tier 2 compound and SYN120 is a Tier 1 compound. Our license with respect to products containing Tier 2 compounds, or Tier 2 products, extends to the field of any and all uses to treat or prevent human diseases and disorders. Our license with respect to products containing Tier 1 compounds, or Tier 1 products, is limited to the field of any and all uses to treat or prevent central nervous system diseases and disorders. Under the terms of the Roche License Agreement, following the completion of certain studies, the Roche Entities had the right to opt-in to obtain an exclusive right to develop and commercialize the Tier 1 products and terminate the license granted to us with respect to such Tier 1 products. In June 2012, following our completion of the specified studies, the Roche Entities notified us of their decision not to exercise its opt-in right for SYN120. Following the Roche Entities' decision not to exercise their opt-in right, we retain our licensed global development and commercialization rights to SYN120 under the Roche License Agreement.

Pursuant to the Roche License Agreement, we are obligated to make certain milestone payments to the Roche Entities on the achievement of specified regulatory and commercial milestones, totaling up to \$37 million for Tier 1 products, including SYN120 and \$29 million for Tier 2 products, including tozadenant. We are also obligated to pay the Roche Entities tiered single-digit royalties, starting in the low single digits and increasing to the high single digits, on net sales of licensed products. Our obligation to pay royalties to the Roche Entities will expire on a product-by-product and country-by-country basis upon the later of the expiration of the last-to-expire valid claim within the licensed Roche Entities patents, our patent rights or patent rights jointly owned with the Roche Entities that covers the composition, use or manufacture of the applicable product in such country or 10 years from the first commercial sale of such product in such country. We are required to exercise commercially reasonable efforts to perform the activities set forth in an agreed upon development plan for SYN120 and must use commercially reasonable efforts to develop and commercialize, either directly or through affiliates or sublicensees, SYN120 and tozadenant in the United States and Europe and in such other markets as we deem commercially reasonable.

The term of the Roche License Agreement will expire on the date of the expiration of all payment obligations of both parties under the agreement. Upon expiration of the Roche License Agreement, all licenses granted to each party that were in effect immediately prior to such expiration will be retained on a nonexclusive, fully paid, royalty-free basis. The Roche Entities may terminate the Roche License Agreement in its entirety, for any reason upon 90 days' written notice. In the event of the Roche Entities' unilateral termination of the Roche License Agreement without cause, all licenses and other rights granted by the Roche Entities to us will remain in full force and effect in accordance with their respective terms. We may also terminate the Roche License Agreement either on a program-by-program basis for certain of the programs or in its entirety, for any reason or no reason upon 90 days' written notice. In the event of our unilateral termination without cause, all licenses granted to us with respect to the compounds and products in the terminated program (or, in the case of termination of the entire agreement, all compounds and products) will terminate. Either party may terminate the Roche License Agreement for cause in the event of a breach by the other party of any material provision of the agreement if such breach has continued for 60 days after notice was provided. If the parties reasonably and in good faith disagree as to whether there has been a material breach, the party that seeks to dispute the breach may contest the allegation. In the case of such dispute, each party will attempt to reach a resolution in good faith, and if no resolution is achieved, the matter may be referred to arbitration for final settlement.

Medarex License Agreement

In November 2006, we entered into a license and commercialization agreement, as amended, or the Medarex License Agreement, with Medarex, Inc. or Medarex, to develop and commercialize BTT1023 worldwide. Pursuant to the Medarex License Agreement, we obtained an exclusive, royalty-bearing license under certain patents rights and know-how controlled by Medarex, to develop and commercialize BTT1023 and products containing BTT1023 worldwide. We also obtained a non-exclusive, worldwide, royalty-free license to use Medarex's patent rights and know-how relating to the production of VAP-1 antibodies solely for the purpose of manufacturing BTT1023 or products containing BTT1023.

We have paid Medarex \$1 million in upfront license fees, \$1.08 million for research and development costs, as well as \$1.35 million for the supply of materials for a Phase 1 clinical trial. We are further obligated to pay Medarex up to an aggregate of \$8.6 million upon the occurrence of certain regulatory milestones for each product developed under the Medarex License Agreement, of which \$0.5 million has already been paid. We are also required to pay Medarex up to an aggregate of \$11.5 million if we achieve specified sales milestones, as well as a tiered mid-single digit royalty on net sales of products containing BTT1023 worldwide. Such royalties are payable on a country-by-country and product-by-product basis until the later of either the expiration of the last to expire of any patent or patent application controlled by Medarex that covers the applicable product in the applicable country, or 15 years from the first commercial sale of the applicable product in the applicable country.

We are required to use commercially reasonable efforts to develop, test, and manufacture products containing BTT1023. We must also use commercially reasonable efforts to obtain regulatory approvals for the sale of products containing BTT1023 worldwide, as well as to actively pursue commercial sales of such products in each country where all necessary regulatory approvals have been obtained. Medarex may terminate the exclusive license granted to us on a product-by-product and country-by-country basis, effective upon written notice to us, if we abandon or suspend development or commercialization of the applicable product in specified geographical regions under certain circumstances.

The term of the Medarex License Agreement will expire on a country-by-country and product-by-product basis when there are no remaining royalty obligations in a country. Upon the expiration of the Medarex License Agreement in a country, we will have a fully paid-up, royalty-free, perpetual license to use the licensed technology to commercialize the applicable product in such country. Either party may terminate the Medarex License Agreement for the other party's uncured material breach, subject to a specified cure period, or upon the occurrence of certain insolvency-related events involving the other party. We may also terminate our exclusive license from Medarex at any time upon written notice to Medarex.

Intellectual Property Rights

Our success depends in part on our ability to obtain and maintain proprietary protection for our products and product candidates, technology and know-how, to maintain our licenses to use intellectual property owned by third parties, to preserve the confidentiality of our trade secrets, to operate without infringing the proprietary rights of others and to prevent others from infringing our proprietary rights. We strive to protect the proprietary technologies that we believe are important to our business, including by seeking and maintaining patent protection intended to protect, for example, the composition of matter of our product candidates, their methods of use, the technology platforms used to generate them, related technologies and/or other aspects of the inventions that are important to our business. We also rely on know-how, continuing technological innovation and in-licensing opportunities to develop, strengthen, and maintain our proprietary positions. In addition, we rely on trade secrets to protect aspects of our business that are not amenable to, or that we do not consider appropriate for, patent protection, in order to develop and maintain our competitive position. We plan to continue to seek to expand our intellectual property

estate by filing patent applications directed to dosage forms, methods of treatment and additional compositions created or identified from our technology platforms and ongoing development of our product candidates, as and when we deem it appropriate to do so.

A third party may hold intellectual property, including patent rights, that are important or necessary to the development of our product candidates or use of our technology platforms. It may be necessary for us to use the patented or proprietary technology of third parties to commercialize our product candidates, in which case we would be required to obtain a license from these third parties. However such a license may not be available on commercially reasonable terms, or at all, and in such a situation our business could be harmed, possibly materially. For further discussion of the risks relating to intellectual property, see “Risk Factors — Risks Related to Our Intellectual Property.”

Patents

Our patent portfolio includes the following patents and patent applications, which we own or exclusively license:

Under the Roche License Agreement, we have exclusively licensed rights to issued composition of matter patents protecting tozadenant in the United States, Europe (including the United Kingdom, France, Germany, Italy and Spain), Japan and other jurisdictions which are currently expected to begin to expire in 2025. We have additional patent applications under prosecution that, if issued in their current form, would protect the use of tozadenant for enhancing cognition and motor function in Parkinson’s, and would be expected to expire in 2030.

Under the Roche License Agreement, we have also licensed rights to issued composition of matter patents protecting SYN120 in the United States, Europe (including the United Kingdom, France, Germany, Italy and Spain), Japan and other jurisdictions which are currently expected to expire in 2025.

We own issued composition of matter patents protecting BTT1023 in the United States, Australia, China, South Korea, Russia, New Zealand, Singapore, Ukraine and South Africa, which are currently expected to expire in 2028. Additional method of use patent applications are currently under prosecution, which, if issued in their current form, would protect the use of BTT1023 for the treatment or prevention of fibrotic conditions and would be expected to expire in 2030.

On approval, Selincro gained market exclusivity in the European Union via data protection for 10 years, which provides post-launch protection for the product to February 2023. The current marketed form of Selincro is protected by issued patents jointly owned by Lundbeck and us in multiple jurisdictions worldwide, including the United States, Canada, and Europe. Such patents are currently expected to expire in 2029.

The term of an individual patent depends upon the legal term for patents in the countries in which such patent is granted. In most countries, including the United States, the patent term is generally 20 years from the date on which the application for the patent was filed or, if the patent claims priority to an earlier filed application or applications, 20 years from the filing date of the earliest filed application where priority was claimed. In the United States, a patent’s term may, in certain cases, be lengthened by patent term adjustment, which compensates a patentee for administrative delays by the U.S. Patent and Trademark Office, or the USPTO, in examining and granting a patent, or may be shortened if a patent is terminally disclaimed over a commonly owned patent or a patent naming a common inventor and having an earlier expiration date. The Hatch-Waxman Act permits a patent term extension of up to five years beyond the expiration date of a U.S. patent as partial compensation for the length of time the drug is under regulatory review while the patent is in force. The length of the patent term extension is related to the length of time the drug is under regulatory review. Patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval and only one patent applicable to an approved

drug may be extended. Similar provisions are available in other jurisdictions to extend the term of a patent that covers an approved drug, or to offer similar protection for an extended period, as is the case in the European Union. In the future, if and when our product candidates receive approval from the FDA or other regulatory authorities, we expect to apply for patent term extensions on patents covering those products where such extensions are available; however there is no guarantee that the applicable authorities, including the FDA in the United States, will agree with our assessment of whether such extensions should be granted, and even if granted, the length of such extensions.

Trade Secrets

We also rely on trade secret protection for our confidential and proprietary information. Included in our trade secrets are various aspects of our manufacturing process that we conduct in cooperation with contract manufacturers. Although we take steps to protect our proprietary information and trade secrets, including through contractual means with our employees, contractors and consultants, third parties may independently develop substantially equivalent proprietary information and techniques or otherwise gain access to our trade secrets or disclose our technology. Thus, we may not be able to meaningfully protect our trade secrets.

Manufacturing and Facilities

We rely on and expect to continue to rely on third-party contract manufacturers to manufacture our drug substances and drug products for clinical trials of our product candidates, including tozadenant, SYN120 and BTT1023. For the foreseeable future, we expect to continue to rely on such contract manufacturers for the manufacture of any of our product candidates on a clinical or commercial scale, if any of our product candidates receives regulatory approval. In the course of clinical development we transfer the process to commercial manufacturers. The technology transfer generally includes, among others, the development and qualification of manufacturing processes, and the development and qualification of suitable analytical methods for test and release as well as stability testing. From our contract manufacturers we receive material meeting current Good Manufacturing Practice, or cGMP, standards for clinical supplies. Before and during the cooperation with a contract manufacturer we conduct technical and quality audits to control compliance with the mutually agreed process descriptions and to cGMP regulations. Our manufacturers themselves are controlled by their in-house quality assurance functions and inspected by regulatory agencies, including European national agencies, the FDA, and where applicable, local agencies. During the development of our drug candidates, our contract manufacturers scale the manufacturing process to suitable size. Such scaling up typically takes several steps and may involve modification of the process, in which case a renewed qualification of the manufacturing process with the relevant authorities is required.

Tozadenant is a small molecule. We have engaged a contract manufacturing service provider to develop a manufacturing process and supply material for clinical trials and potentially for future commercial use. The current manufacturing of tozadenant drug product (film coated tablets) has been outsourced to a contract manufacturer in North America. The manufacturing technology transfer included manufacture of feasibility batches of active and matching placebo at small scale, followed by scale-up of the selected formulation at scale suitable for our Phase 3 clinical program and preparation for manufacture of initial clinical supply material campaigns. Manufacturing of active and placebo campaigns have been successfully conducted at the Contract Manufacturing Organization, or CMO, meeting the current cGMP standards for clinical supplies. The formulation components comply with compendial requirements and the manufacturing process utilizes standard equipment and process for solid oral dosage forms. Our manufacturers purchase and stock raw materials, including excipients, at large scale from established sources.

The manufacture of tozadenant (SYN115 active pharmaceutical ingredient, or API, micronized) has been outsourced to a reputable API contract manufacturer in Taiwan. Regulatory starting materials and raw

materials are all provided by qualified vendors. All reagents and solvents comply with compendial requirements and the manufacturing process utilizes standard equipment for processing. We intend to work with the contracted CMO to prepare for registration and validation of the process at the CMO's facilities, in compliance with applicable regulations and guidelines from International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use, or ICH guidelines. Our manufacturers purchase and stock raw materials, including excipients, at large scale from established sources.

SYN120 is a small molecule. We have engaged a contract manufacturing service provider to develop a manufacturing process and supply material for clinical trials and potentially for future commercial use. The current formulation of SYN120 drug product is a tablet for oral administration. Our manufacturers typically purchase and stock excipients at large scale from multiple sources.

BTT1023 is a recombinant fully human monoclonal antibody. We have engaged a contract manufacturing service provider to develop manufacturing processes and supply drug substance, and also to supply drug product materials for clinical trials and potentially for future commercial use. The current formulation of BTT1023 drug product is for intravenous infusion. The technology transfer has included, among others, the development of a production cell line, the establishment of master and working cell banks, the development and qualification of upstream and downstream processes, the development of the drug product process and the development and qualification of suitable analytical methods for test and release as well as stability testing. From our contract manufacturers we receive process development-derived material for preclinical testing and material meeting current or cGMP, standards for clinical supplies. Our manufacturers usually purchase and stock fermentation materials or chromatography resins from multiple sources at large scale.

We rely on and will continue to rely on our contract manufacturers for drug substance and drug product. We generally have long-term quality and supply agreements with our manufacturers and seek to establish a good relationship in order to expeditiously solve problems should they arise. Our contract manufacturers have large capacities and, as they also serve other clients, have certain flexibility to adjust to demand. Our manufacturers typically purchase and stock raw materials at large scale from multiple and/or established sources and should therefore be less vulnerable to potential shortages. Generally, we need to commit to certain manufacturing slots and capacities in advance. We believe that our contract manufacturers operate to appropriate quality standards and have capacity to scale up for in-market supply.

Development and Commercialization Strategy

Development Portfolio

We have not yet established a sales, marketing or product distribution infrastructure because our lead product candidate is still at an early stage in clinical development. Prior to receiving marketing approvals, we plan to determine the most appropriate commercial strategy, which may involve setting up our own infrastructure, partnering with another commercial company or a combination of both. Outside the United States, we are more likely to enter into license, distribution or other marketing arrangements with third parties to commercialize any of our product candidates that obtain marketing approval.

We have exclusively licensed worldwide rights to develop and commercialize tozadenant products under the Roche License Agreement. Assuming that the pivotal Phase 3 clinical trial yields positive data, and long term safety is demonstrated in open-label treatment, we intend to file for registration, initially in the United States. Assuming that the Phase 3 clinical trial yields positive data, we would then evaluate the alternatives available for commercialization.

We have exclusively licensed worldwide rights to develop and commercialize SYN120 under the Roche License Agreement. We intend to continue with the Michael J. Fox Foundation-funded Phase 2a clinical trial in Parkinson's dementia and will continue to evaluate other strategic opportunities for this product candidate, including pursuing the previously planned Alzheimer's indication that is currently on hold pending obtaining requisite funding.

We currently retain global rights to BTT1023. We believe that the best way to maximize the value of the BTT1023 program is most likely through a partnership. If the Phase 2 clinical trial of BTT1023 in PSC is successful, we currently intend to monetize this asset by seeking a collaboration partner to develop this product through Phase 3 and commercialize it.

Selincro

Lundbeck is responsible for the commercialization of Selincro globally. The initial commercialization focus has been Europe, where Selincro is already on the market in 29 European countries. Lundbeck and Otsuka are jointly developing Selincro for the Japanese market, with the first Phase 3 clinical trial in Japan initiated in the first quarter of 2015. We understand that Lundbeck currently has no firm plans to develop Selincro for the United States.

Lundbeck has significant experience and a substantial track record with antidepressants, a therapeutic area with many parallels to alcohol use disorders. Lundbeck's strong marketing force and its long-established relationships with prescribers in the relevant therapeutic areas are expected to be very useful in maximizing the market potential for Selincro.

Competition

The central nervous system industry is highly competitive. We are currently developing product candidates that will compete with other drugs and therapies that currently exist or are being developed. Products we may develop in the future are also likely to face competition from other drugs and therapies, some of which we may not currently be aware. We have competitors both in the United States and internationally, including major multinational pharmaceutical companies, established biotechnology companies, specialty pharmaceutical companies, universities and other research institutions.

Tozadenant

Despite intense research over the last 50 years, there are no current treatments that offer a cure for Parkinson's. Physicians commonly treat the primary motor symptoms of the disease using a combination of compounds with diverse mechanisms of action, adding additional drugs to the patient's medication regime as the disease symptoms progress. In general, current therapies do not provide good long-term control of the disease and are associated with tolerability issues.

Adenosine A_{2a} antagonists represent a novel mechanism of action for the treatment of Parkinson's, with the potential for treating both motor and non-motor symptoms, and may have the potential for slowing disease progression. Istradefylline (approved in Japan; Phase 3 elsewhere), also an adenosine A_{2a} antagonist, potentially addresses the same patient population as tozadenant. Istradefylline was refused FDA approval in 2008, but was approved for sale in Japan (as Nourias) in 2013. Kyowa Hakko Kirin recently announced a new 600-patient Phase 3 development program of istradefylline in the United States, which is expected to be completed by the end of 2015 or early 2016. If both istradefylline and tozadenant were commercialized in the United States, they would be in direct competition. In addition, Vernalis plc has been developing an adenosine antagonist compound with potential application to Parkinson's and recently licensed it to an undisclosed private U.S. company.

More broadly, in the United States, tozadenant can be considered complementary to, rather than in competition with, currently approved treatments for Parkinson's that are adjunctive to levodopa, the current standard of care, because tozadenant is being developed to be used in combination with levodopa and such other adjunctive treatments. However, as most current adjunctive treatments to levodopa will be generic by the time tozadenant could be approved for marketing, it is probable that they would be used prior to tozadenant.

SYN120

Currently, there are no therapies that cure Parkinson's or Alzheimer's. Existing therapies for both Parkinson's dementia and Alzheimer's are targeted at improvement of symptoms.

Rivastigmine is the only product approved in the United States for the treatment of Parkinson's dementia. Existing therapies for cognitive deficits in patients with Alzheimer's are symptomatic and have limited efficacy and significant side effects. Five drugs have been approved by the FDA for symptomatic treatment of Alzheimer's: Aricept (donepezil) in 1996; Razadyne (galantamine) in 2001; Namenda (memantine) in 2003; and Exelon (rivastigmine) and Cognex (tacrin) in 1993.

There are several 5HT₆ antagonists currently in development. Pfizer's PF05212377 is in Phase 2, Lundbeck's LuAE58054 is in Phase 3 and GlaxoSmithKline reported results of a Phase 2 trial of SB742457 in mid-2011. SB742457 was acquired by Axovant Sciences, Inc. in December 2014 (referred to as RVT-101), which has announced plans to commence a Phase 3 program of RVT-101 for the treatment of mild-to-moderate Alzheimer's in the fourth quarter of 2015. Patients treated with SB742457 and LuAE58054, in addition to Aricept, the current standard treatment for Alzheimer's, have demonstrated improvement in cognition, validating the relevance of 5HT₆ receptors as a therapeutic target. These studies also suggest that 5HT₆ antagonists may be most effective when used in combination, rather than as alternatives, to cholinesterase inhibitors. These 5HT₆ antagonists are further advanced in development than SYN120. Although they appear to lack activity at the 5HT_{2a} receptor, and presumably will not improve neuropsychiatric symptoms, they may become treatment options prior to when SYN120 could reach the market. Differentiating SYN120 from these products will be necessary to effectively compete with them.

Other major development targets for symptomatic treatments of cognitive deficits are nicotinic acetylcholine receptor (nAChR) agonists or modulators and histamine H₃ receptor antagonists. Several nAChR compounds are in early stage development. Pimavanserin, a 5HT_{2a} inverse agonist, has recently shown promise in improving neuropsychiatric symptoms in Parkinson's psychosis and therefore has validated the importance of the 5HT_{2a} receptor as a target in this condition. It is expected that pimavanserin will be approved for treatment of Parkinson's dementia prior to when SYN120 could be launched and become the standard for treatment of the condition. Differentiation of SYN120 from pimavanserin will be necessary for it to compete effectively.

BTT1023

Despite the high prevalence of fibrosis and its enormous impact on human health, there are currently no FDA approved agents that can prevent, arrest or reverse fibrosis. No pharmacologic therapy has been proven effective for PSC, and there are no FDA or EMA approved treatments. In some EU countries, medicines containing ursodeoxycholic acid (bile acid) are authorized for treatment. We are aware of four competing clinical development programs in PSC, all of which are in Phase 2 development. Gilead's simtuzumab (GS-6624) anti-lysyl oxidase-like 2 antibody targets an enzyme important for fibrogenesis and, if efficacious, is expected to improve liver pathology. It is in a large, international, Phase 2 trial expected to be completed in July 2016 with a dosing period of 96 weeks and a biopsy endpoint. This trial could potentially be used for registration purposes. Simtuzumab is administered in a subcutaneous formulation by weekly injection, which patients may find more appealing than the monthly intravenous infusion currently envisaged for BTT1023.

The other three programs in development for PSC of which we are aware target bile acid transport in some way and we believe they are less likely to have an impact on the underlying disease process than BTT1023. Dr. Falk Pharma's norUrso is an ursodeoxycholic acid that may improve liver function. A Phase 2 trial of the compound has an estimated trial completion date of March 2014, but is still recruiting patients. Lumena Pharmaceuticals (recently acquired by Shire plc) is developing LUM001, a bile acid transport inhibitor currently in a small, open label, pilot trial in PSC with safety and tolerability as primary endpoints and an estimated trial completion date of December 2015. Like norUrso it may improve liver function. Intercept's obeticholic acid is another semi-synthetic bile acid analogue which could improve liver function and which may have anti-fibrotic effects, and is currently in a trial with an estimated completion date in June 2019.

Selincro

Other products for alcohol dependence currently available on the market are, according to their officially approved indications, mainly meant for the maintenance of total abstinence. Selincro is currently the only product specifically approved for the reduction of alcohol consumption in alcohol dependent individuals.

There are also certain products that could have potential to be used off-label against alcohol addiction (for example, serotonergics and certain anticonvulsants). Major off-label use of such drugs has not been reported to date. The following drug treatments used to support the maintenance of alcohol abstinence have been available in Europe for several years and include: Antabuse (disulfiram), which makes a person sick when he or she drinks; Revia/Vivitrol (naltrexone), which interferes with the pleasurable effects of drinking; and Campral (acamprosate), which reduces alcohol cravings. We believe that the therapeutic profile of Selincro is sufficiently distinct from these therapies, and in particular, from naltrexone, a competing opioid antagonist approved for the maintenance of alcohol abstinence in certain EU countries.

Government Regulation and Product Approval

Government authorities in the United States, at the federal, state and local level, and in other countries and jurisdictions, including the European Union, extensively regulate, among other things, the research, development, testing, manufacture, pricing, quality control, approval, packaging, storage, recordkeeping, labeling, advertising, promotion, distribution, marketing, post-approval monitoring and reporting, and import and export of pharmaceutical products. The processes for obtaining regulatory approvals in the United States and in foreign countries and jurisdictions, along with subsequent compliance with applicable statutes and regulations and other regulatory authorities, require the expenditure of substantial time and financial resources.

Review and Approval of Drugs and Biologics in the United States

In the United States, our small molecule products are regulated by the FDA as drugs under the Federal Food, Drug, and Cosmetic Act, or the FDCA, and regulations implemented by the agency. Our monoclonal products are regulated as biological products, or biologics, under the Public Health Service Act, or PHSA, and also the FDCA and its implementing regulations and guidance. The failure to comply with the applicable United States requirements at any time during the product development process, including non-clinical testing, clinical testing, the approval process or post-approval process, may subject an applicant to delays in the conduct of the trial, regulatory review and approval, and/or administrative or judicial sanctions. These sanctions may include, but are not limited to, the FDA's refusal to allow an applicant to proceed with clinical testing, refusal to approve pending applications, license suspension or revocation, withdrawal of an approval, warning letters, adverse publicity, product recalls, product seizures, total or

partial suspension of production or distribution, injunctions, fines, and civil or criminal investigations and penalties brought by the FDA or Department of Justice, or DOJ, or other governmental entities.

The process required by the FDA before a drug or biologic may be marketed in the United States generally involves satisfactorily completing each of the following steps:

- preclinical laboratory tests, animal studies and formulation studies all performed in accordance with the FDA's Good Laboratory Practice, or GLP, regulations;
- submission to the FDA of an investigational new drug, or IND, application for human clinical testing, which must become effective before human clinical trials may begin;
- approval by an independent institutional review board, or IRB, representing each clinical site before each clinical trial may be initiated;
- performance of adequate and well-controlled clinical trials to establish the safety and efficacy of the product candidate for each proposed indication and conducted in accordance with current Good Clinical Practices, or cGCP;
- submission of data supporting safety and efficacy as well as detailed information on the manufacture and composition of the product in clinical development and proposed labelling;
- preparation and submission to the FDA of an NDA for a drug product and a Biologic License Application, or BLA, for a biologic product;
- review of the product by an FDA advisory committee, where appropriate or if applicable;
- satisfactory completion of one or more FDA inspections of the manufacturing facility or facilities, including those of third parties, at which the product, or components thereof, are produced to assess compliance with cGMP, requirements and to assure that the facilities, methods and controls are adequate to preserve the product's identity, strength, quality and purity;
- satisfactory completion of any FDA audits of the non-clinical and clinical trial sites to assure compliance with cGCPs and the integrity of clinical data in support of the NDA or BLA;
- payment of user fees and securing FDA approval of the NDA and new drug product, or BLA and licensure of the new biologic product; and
- compliance with any post-approval requirements, including risk evaluation and mitigation strategies, or REMS, and any post-approval studies required by the FDA.

We filed investigational new drug applications with the FDA for tozadenant and SYN120 on March 17, 2008 and February 10, 2009, respectively.

Preclinical Studies and Investigational New Drug Application

Preclinical tests include laboratory evaluations of product chemistry, formulation and stability, as well as studies to evaluate the potential for efficacy and toxicity in animal studies. The conduct of the preclinical tests and formulation of the compounds for testing must comply with federal regulations and requirements. The results of the preclinical tests, together with manufacturing information and analytical data, are submitted to the FDA as part of an Investigational New Drug, or IND, application. The IND automatically becomes effective 30 days after receipt by the FDA, unless before that time the FDA raises concerns or questions about the product or conduct of the proposed clinical trial, including concerns that human research subjects will be exposed to unreasonable health risks. In that case, the IND sponsor and the FDA must resolve any outstanding FDA concerns before the clinical trials can begin.

As a result, submission of the IND may result in the FDA not allowing the trials to commence or allowing the trial to commence on the terms originally specified by the Sponsor in the IND. If the FDA raises concerns or questions either during this initial 30-day period, or at any time during the IND process, it may choose to impose a partial or complete clinical hold. This order issued by the FDA would delay either a proposed clinical trial or cause suspension of an ongoing trial, until all outstanding concerns have been adequately addressed and the FDA has notified the company that investigations may proceed. This could cause significant delays or difficulties in completing planned clinical trials in a timely manner.

Clinical Trials

Clinical trials involve the administration of the investigational product candidate to healthy volunteers or patients with the disease to be treated under the supervision of a qualified principal investigator in accordance with cGCP requirements. Clinical trials are conducted under trial protocols detailing, among other things, the objectives of the trial, inclusion and exclusion criteria, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated. A protocol for each clinical trial and any subsequent protocol amendments must be submitted to the FDA as part of the IND.

A sponsor who wishes to conduct a clinical trial outside the United States may, but need not, obtain FDA authorization to conduct the clinical trial under an IND. If a foreign clinical trial is not conducted under an IND, the sponsor may submit data from the clinical trial to the FDA in support of an NDA or BLA so long as the clinical trial is conducted consistent with the spirit of cGCP and in compliance with an international guideline for the ethical conduct of clinical research known as the Declaration of Helsinki and/or the laws and regulations of the country or countries in which the clinical trial is performed, whichever provides the greater protection to the participants in the clinical trial.

Further, each clinical trial must be reviewed and approved by an independent institutional review board, or IRB, either centrally or individually at each institution at which the clinical trial will be conducted. The IRB will consider, among other things, clinical trial design, patient informed consent, ethical factors, the safety of human subjects and the possible liability of the institution. An IRB must operate in compliance with the FDA regulations. The FDA, IRB or the clinical trial sponsor may suspend or discontinue a clinical trial at any time for various reasons, including a finding that the clinical trial is not being conducted in accordance with FDA requirements or the subjects or patients are being exposed to an unacceptable health risk. Clinical testing also must satisfy extensive Good Clinical Practice rules and the requirements for informed consent. Additionally, some clinical trials are overseen by an independent group of qualified experts organized by the clinical trial sponsor, known as a data safety monitoring board or committee. This group may recommend continuing the trial as planned, make changes in trial conduct, or cessation of the trial at designated check points based on access to certain data from the trial.

Clinical trials typically are conducted in three sequential phases, but the phases may overlap or be combined. Additional studies may be required after approval.

- *Phase 1* clinical trials are initially conducted in a limited population to test the product candidate for safety, including adverse effects, dose tolerance, absorption, metabolism, distribution, metabolism, excretion and pharmacodynamics in healthy humans or, on occasion, in patients, such as cancer patients.
- *Phase 2* clinical trials are generally conducted in a limited patient population to identify possible adverse effects and safety risks, evaluate the efficacy of the product candidate for specific targeted indications and determine dose tolerance and optimal dosage. Multiple Phase 2 clinical trials may be conducted by the sponsor to obtain information prior to beginning larger and more costly Phase 3 clinical trials.

- *Phase 3* clinical trials proceed if the Phase 2 clinical trials demonstrate that a dose range of the product candidate is potentially effective and has an acceptable safety profile. Phase 3 clinical trials are undertaken to further evaluate, in a larger number of patients, dosage, provide substantial evidence of clinical efficacy and further test for safety in an expanded and diverse patient population at multiple, geographically dispersed clinical trial sites. A well-controlled, statistically robust Phase 3 trial may be designed to deliver the data that regulatory authorities will use to decide whether or not to approve, and, if approved, how to appropriately label a drug: such Phase 3 studies are referred to as “pivotal.”

In some cases, the FDA may approve an NDA for a product candidate but require the sponsor to conduct additional clinical trials to further assess the drug’s safety and effectiveness after NDA approval. Such post-approval trials are typically referred to as Phase 4 clinical trials. These studies are used to gain additional experience from the treatment of patients in the intended therapeutic indication and to document a clinical benefit in the case of drugs approved under accelerated approval regulations. If the FDA approves a product while a company has ongoing clinical trials that were not necessary for approval, a company may be able to use the data from these clinical trials to meet all or part of any Phase 4 clinical trial requirement or to request a change in the product labeling. Failure to exhibit due diligence with regard to conducting Phase 4 clinical trials could result in withdrawal of approval for products.

Compliance with Current Good Manufacturing Practice Requirements

Before approving an NDA or BLA, the FDA typically will inspect the facility or facilities where the product is manufactured. The FDA will not approve an application unless it determines that the manufacturing processes and facilities are in full compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. The PHSA emphasizes the importance of manufacturing control for products like biologics whose attributes cannot be precisely defined.

Manufacturers and others involved in the manufacture and distribution of products must also register their establishments with the FDA and certain state agencies. Both domestic and foreign manufacturing establishments must register and provide additional information to the FDA upon their initial participation in the manufacturing process. Any product manufactured by or imported from a facility that has not registered, whether foreign or domestic, is deemed misbranded under the FDCA. Establishments may be subject to periodic unannounced inspections by government authorities to ensure compliance with cGMPs and other laws. Inspections must follow a “risk-based schedule” that may result in certain establishments being inspected more frequently. Manufacturers may also have to provide, on request, electronic or physical records regarding their establishments. Delaying, denying, limiting, or refusing inspection by the FDA may lead to a product being deemed to be adulterated.

Review and Approval of a New Drug Application or Biologic License Application

The results of product candidate development, preclinical testing and clinical trials, including negative or ambiguous results as well as positive findings, are submitted to the FDA as part of an NDA or BLA requesting approval to market the product. The NDA or BLA also must contain extensive manufacturing information and detailed information on the composition of the product and proposed labeling as well as payment of a user fee.

The FDA has 60 days after submission of the application to conduct an initial review to determine whether it is sufficient to accept for filing based on the agency’s threshold determination that it is sufficiently complete to permit substantive review. Once the submission has been accepted for filing, the FDA begins an in-depth review of the application. Under the goals and policies agreed to by the FDA under the Prescription Drug User Fee Act, or the PDUFA, the FDA has ten months in which to complete its initial review of a standard application and respond to the applicant, and six months for a priority review of the

application. The FDA does not always meet its PDUFA goal dates for standard and priority NDAs. The review process may often be significantly extended by FDA requests for additional information or clarification. The review process and the PDUFA goal date may be extended by three months if the FDA requests, or the applicant otherwise provides additional information or clarification regarding information already provided in the submission within the last three months before the PDUFA goal date.

Under the FDCA, the FDA may approve an NDA if it determines that the drug product is safe and effective for its intended use. Under the PHSA, the FDA may approve an BLA if it determines that the product is safe, pure and potent and the facility where the product will be manufactured meets standards designed to ensure that it continues to be safe, pure and potent.

On the basis of the FDA's evaluation of the application and accompanying information, including the results of the inspection of the manufacturing facilities, the FDA may issue an approval letter or a complete response letter. An approval letter authorizes commercial marketing of the product with specific prescribing information for specific indications. If the application is not approved, the FDA will issue a complete response letter, which will contain the conditions that must be met in order to secure final approval of the application, and when possible will outline recommended actions the sponsor might take to obtain approval of the application. Sponsors that receive a complete response letter may submit to the FDA information that represents a complete response to the issues identified by the FDA. Such resubmissions are classified under PDUFA as either Class 1 or Class 2. The classification of a resubmission is based on the information submitted by an applicant in response to an action letter. Under the goals and policies agreed to by the FDA under PDUFA, the FDA has two months to review a Class 1 resubmission and six months to review a Class 2 resubmission. The FDA will not approve an application until issues identified in the complete response letter have been addressed.

The FDA may also refer the application to an advisory committee for review, evaluation and recommendation as to whether the application should be approved. Typically, an advisory committee is a panel of independent experts, including clinicians and other scientific experts, that reviews, evaluates and provides a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions.

If the FDA approves a new product, it may limit the approved indications for use of the product. It may also require that contraindications, warnings or precautions be included in the product labeling. In addition, the FDA may call for post-approval studies, including Phase 4 clinical trials, to further assess the product's safety after approval. The agency may also require testing and surveillance programs to monitor the product after commercialization, or impose other conditions, including distribution restrictions or other risk management mechanisms, including REMS, to help ensure that the benefits of the product outweigh the potential risks. REMS can include medication guides, communication plans for healthcare professionals, and elements to assure safe use or ETASU. ETASU can include, but are not limited to, special training or certification for prescribing or dispensing, dispensing only under certain circumstances, special monitoring, and the use of patent registries. The FDA may prevent or limit further marketing of a product based on the results of post-market studies or surveillance programs. After approval, many types of changes to the approved product, such as adding new indications, manufacturing changes and additional labeling claims, are subject to further testing requirements and FDA review and approval.

Fast Track, Breakthrough Therapy and Priority Review Designations

The FDA is authorized to designate certain products for expedited review if they are intended to address an unmet medical need in the treatment of a serious or life-threatening disease or condition. These programs are fast track designation, breakthrough therapy designation and priority review designation.

Specifically, the FDA may designate a product for fast track review if it is intended, whether alone or in combination with one or more other products, for the treatment of a serious or life-threatening disease or condition, and it demonstrates the potential to address unmet medical needs for such a disease or condition. For fast track products, sponsors may have greater interactions with the FDA and the FDA may initiate review of sections of a fast track product's application before the application is complete. This rolling review may be available if the FDA determines, after preliminary evaluation of clinical data submitted by the sponsor, that a fast track product may be effective. The sponsor must also provide, and the FDA must approve, a schedule for the submission of the remaining information and the sponsor must pay applicable user fees. However, the FDA's time period goal for reviewing a fast track application does not begin until the last section of the application is submitted. In addition, the fast track designation may be withdrawn by the FDA if the FDA believes that the designation is no longer supported by data emerging in the clinical trial process.

Second, in 2012, Congress enacted the Food and Drug Administration Safety and Innovation Act, or FDASIA. This law established a new regulatory scheme allowing for expedited review of products designated as "breakthrough therapies." A product may be designated as a breakthrough therapy if it is intended, either alone or in combination with one or more other products, to treat a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the product may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. The FDA may take certain actions with respect to breakthrough therapies, including holding meetings with the sponsor throughout the development process; providing timely advice to the product sponsor regarding development and approval; involving more senior staff in the review process; assigning a cross-disciplinary project lead for the review team; and taking other steps to design the clinical trials in an efficient manner.

Third, the FDA may designate a product for priority review if it is a product that treats a serious condition and, if approved, would provide a significant improvement in safety or effectiveness. The FDA determines, on a case-by-case basis, whether the proposed product represents a significant improvement when compared with other available therapies. Significant improvement may be illustrated by evidence of increased effectiveness in the treatment of a condition, elimination or substantial reduction of a treatment-limiting product reaction, documented enhancement of patient compliance that may lead to improvement in serious outcomes, and evidence of safety and effectiveness in a new subpopulation. A priority designation is intended to direct overall attention and resources to the evaluation of such applications, and to shorten the FDA's goal for taking action on a marketing application from ten months to six months.

Accelerated Approval Pathway

The FDA may grant accelerated approval to a product for a serious or life-threatening condition that provides meaningful therapeutic advantage to patients over existing treatments based upon a determination that the product has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit. The FDA may also grant accelerated approval for such a condition when the product has an effect on an intermediate clinical endpoint that can be measured earlier than an effect on irreversible morbidity or mortality, or IMM, and that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments. Products granted accelerated approval must meet the same statutory standards for safety and effectiveness as those granted traditional approval.

For the purposes of accelerated approval, a surrogate endpoint is a marker, such as a laboratory measurement, radiographic image, physical sign, or other measure that is thought to predict clinical benefit,

but is not itself a measure of clinical benefit. Surrogate endpoints can often be measured more easily or more rapidly than clinical endpoints. An intermediate clinical endpoint is a measurement of a therapeutic effect that is considered reasonably likely to predict the clinical benefit of a product, such as an effect on IMM. The FDA has limited experience with accelerated approvals based on intermediate clinical endpoints, but has indicated that such endpoints generally may support accelerated approval where the therapeutic effect measured by the endpoint is not itself a clinical benefit and basis for traditional approval, if there is a basis for concluding that the therapeutic effect is reasonably likely to predict the ultimate clinical benefit of a product.

The accelerated approval pathway is most often used in settings in which the course of a disease is long and an extended period of time is required to measure the intended clinical benefit of a product, even if the effect on the surrogate or intermediate clinical endpoint occurs rapidly. Thus, accelerated approval has been used extensively in the development and approval of products for treatment of a variety of cancers in which the goal of therapy is generally to improve survival or decrease morbidity and the duration of the typical disease course requires lengthy and sometimes large trials to demonstrate a clinical or survival benefit.

The accelerated approval pathway is usually contingent on a sponsor's agreement to conduct, in a diligent manner, additional post-approval confirmatory studies to verify and describe the product's clinical benefit. As a result, a product candidate approved on this basis is subject to rigorous post-marketing compliance requirements, including the completion of Phase 4 or post-approval clinical trials to confirm the effect on the clinical endpoint. Failure to conduct required post-approval studies, or confirm a clinical benefit during post-marketing studies, would allow the FDA to withdraw the product from the market on an expedited basis. All promotional materials for product candidates approved under accelerated regulations are subject to prior review by the FDA.

Post-Approval Regulation

If regulatory approval for marketing of a product or new indication for an existing product is obtained, the sponsor will be required to comply with all regular post-approval regulatory requirements as well as any post-approval requirements that the FDA have imposed as part of the approval process. The sponsor will be required to report certain adverse reactions and production problems to the FDA, provide updated safety and efficacy information and comply with requirements concerning advertising and promotional labeling requirements. Drug manufacturers and certain of their subcontractors are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with ongoing regulatory requirements, including cGMP regulations, which impose certain procedural and documentation requirements upon drug manufacturers. Accordingly, the sponsor and its third-party manufacturers must continue to expend time, money and effort in the areas of production and quality control to maintain compliance with cGMP regulations and other regulatory requirements.

A product may also be subject to official lot release, meaning that the manufacturer is required to perform certain tests on each lot of the product before it is released for distribution. If the product is subject to official release, the manufacturer must submit samples of each lot, together with a release protocol showing a summary of the history of manufacture of the lot and the results of all of the manufacturer's tests performed on the lot, to the FDA. The FDA may in addition perform certain confirmatory tests on lots of some products before releasing the lots for distribution. Finally, the FDA will conduct laboratory research related to the safety, purity, potency, and effectiveness of pharmaceutical products.

Once an approval is granted, the FDA may withdraw the approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market.

Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information; imposition of post-market studies or clinical trials to assess new safety risks; or imposition of distribution or other restrictions under a Risk Evaluation and Mitigation Strategy, or REMS program. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of the product, complete withdrawal of the product from the market or product recalls;
- fines, warning letters or holds on post-approval clinical trials;
- refusal of the FDA to approve pending NDAs or supplements to approved NDAs, or suspension or revocation of product license approvals;
- product seizure or detention, or refusal to permit the import or export of products; or
- injunctions or the imposition of civil or criminal penalties.

The FDA strictly regulates marketing, labeling, advertising and promotion of products that are placed on the market. Drugs may be promoted only for the approved indications and in accordance with the provisions of the approved label. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant liability.

Orphan Drug Designation

Orphan drug designation in the United States is designed to encourage sponsors to develop drugs intended for rare diseases or conditions. In the United States, a rare disease or condition is statutorily defined as a condition that affects fewer than 200,000 individuals in the United States or that affects more than 200,000 individuals in the United States and for which there is no reasonable expectation that the cost of developing and making available the drug for the disease or condition will be recovered from sales of the drug in the United States.

Orphan drug designation qualifies a company for tax credits and market exclusivity for seven years following the date of the drug's marketing approval if granted by the FDA. An application for designation as an orphan product can be made any time prior to the filing of an application for approval to market the product. A product becomes an orphan when it receives orphan drug designation from the Office of Orphan Products Development, or OOPD, at the FDA based on acceptable confidential requests made under the regulatory provisions. The product must then go through the review and approval process like any other product. Orphan drug designations are decided solely by the OOPD staff, but the OOPD occasionally will request opinions from the Center for Drug Evaluation and Research, especially when dealing with issues such as the appropriateness of the requested indication or the scientific rationale described by the sponsor.

A sponsor may request orphan drug designation of a previously unapproved product or new orphan indication for an already marketed product. In addition, a sponsor of a product that is otherwise the same product as an already approved orphan drug may seek and obtain orphan drug designation for the subsequent product for the same rare disease or condition if it can present a plausible hypothesis that its product may be clinically superior to the first drug. More than one sponsor may receive orphan drug designation for the same product for the same rare disease or condition, but each sponsor seeking orphan drug designation must file a complete request for designation.

The period of exclusivity begins on the date that the marketing application is approved by the FDA and applies only to the indication for which the product has been designated. The FDA may approve a second

application for the same product for a different use or a second application for a clinically superior version of the product for the same use. The FDA cannot, however, approve the same product made by another manufacturer for the same indication during the market exclusivity period unless it has the consent of the sponsor or the sponsor is unable to provide sufficient quantities.

Abbreviated New Drug Applications for Generic Drugs

In 1984, with passage of the Hatch-Waxman Amendments to the FDCA, Congress authorized the FDA to approve generic drugs that are the same as drugs previously approved by the FDA under the NDA provisions of the statute. To obtain approval of a generic drug, an applicant must submit an abbreviated new drug application, or ANDA, to the agency. In support of such applications, a generic manufacturer may rely on the pre-clinical and clinical testing previously conducted for a drug product previously approved under an NDA, known as the reference listed drug, or RLD.

Specifically, in order for an ANDA to be approved, the FDA must find that the generic version is identical to the RLD with respect to the active ingredients, the route of administration, the dosage form, and the strength of the drug. At the same time, the FDA must also determine that the generic drug is “bioequivalent” to the innovator drug. Under the statute, a generic drug is bioequivalent to a RLD if the rate and extent of absorption of the drug do not show a significant difference from the rate and extent of absorption of the listed drug.

Upon approval of an ANDA, the FDA indicates whether the generic product is “therapeutically equivalent” to the RLD in its publication “Approved Drug Products with Therapeutic Equivalence Evaluations,” also referred to as the “Orange Book.” Physicians and pharmacists consider a therapeutic equivalent generic drug to be fully substitutable for the RLD. In addition, by operation of certain state laws and numerous health insurance programs, the FDA’s designation of therapeutic equivalence often results in substitution of the generic drug without the knowledge or consent of either the prescribing physician or patient.

Under the Hatch-Waxman Amendments, the FDA may not approve an ANDA until any applicable period of non-patent exclusivity for the RLD has expired. The FDCA provides a period of five years of non-patent data exclusivity for a new drug containing a new chemical entity. In cases where such exclusivity has been granted, an ANDA may not be filed with the FDA until the expiration of five years unless the submission is accompanied by a Paragraph IV certification, in which case the applicant may submit its application four years following the original product approval. The FDCA also provides for a period of three years of exclusivity if the NDA includes reports of one or more new clinical investigations, other than bioavailability or bioequivalence studies, that were conducted by or for the applicant and are essential to the approval of the application. This three-year exclusivity period often protects changes to a previously approved drug product, such as a new dosage form, route of administration, combination or indication.

Biosimilars and Exclusivity

The 2010 Patient Protection and Affordable Care Act, which was signed into law on March 23, 2010, included a subtitle called the Biologics Price Competition and Innovation Act of 2009 or BPCIA. That Act established a regulatory scheme authorizing the FDA to approve biosimilars and interchangeable biosimilars. To date, no biosimilar or interchangeable biosimilar has been licensed under the BPCIA, although biosimilars have been approved in Europe. The FDA has issued several draft guidance documents outlining an approach to review and approval of biosimilars. Those guidances are expected to be finalized sometime in 2014.

Under the Act, a manufacturer may submit an application for licensure of a biologic product that is “biosimilar to” or “interchangeable with” a previously approved biological product or “reference product.” In order for the FDA to approve a biosimilar product, it must find that there are no clinically important differences between the reference product and proposed biosimilar product in terms of safety, purity, and potency. For the FDA to approve a biosimilar product as interchangeable with a reference product, the agency must find that the biosimilar product can be expected to produce the same clinical results as the reference product, and (for products administered multiple times) that the biologic and the reference biologic may be switched after one has been previously administered without increasing safety risks or risks of diminished efficacy relative to exclusive use of the reference biologic.

Under the BPCIA, an application for a biosimilar product may not be submitted to the FDA until four years following the date of approval of the reference product. The FDA may not approve a biosimilar product until 12 years from the date on which the reference product was approved. Even if a product is considered to be a reference product eligible for exclusivity, another company could market a competing version of that product if the FDA approves a full BLA for such product containing the sponsor’s own preclinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity and potency of their product. The BPCIA also created certain exclusivity periods for biosimilars approved as interchangeable products. At this juncture, it is unclear whether products deemed “interchangeable” by the FDA will, in fact, be readily substituted by pharmacies, which are governed by state pharmacy law.

Patent Term Restoration and Extension

A patent claiming a new drug or biologic product may be eligible for a limited patent term extension under the Hatch-Waxman Act, which permits a patent restoration of up to five years for patent term lost during product development and the FDA regulatory review. The restoration period granted on a patent covering a product is typically one-half the time between the effective date of a clinical investigation involving human beings is begun and the submission date of an application, plus the time between the submission date of an application and the ultimate approval date. Patent term restoration cannot be used to extend the remaining term of a patent past a total of 14 years from the product’s approval date. Only one patent applicable to an approved product is eligible for the extension, and the application for the extension must be submitted prior to the expiration of the patent in question. A patent that covers multiple products for which approval is sought can only be extended in connection with one of the approvals. The USPTO reviews and approves the application for any patent term extension or restoration in consultation with the FDA.

Regulation Outside the United States

In order to market any product outside of the United States, a company must also comply with numerous and varying regulatory requirements of other countries and jurisdictions regarding quality, safety and efficacy and governing, among other things, clinical trials, marketing authorization, commercial sales and distribution of drug products. Whether or not it obtains FDA approval for a product, the company would need to obtain the necessary approvals by the comparable foreign regulatory authorities before it can commence clinical trials or marketing of the product in those countries or jurisdictions. The approval process ultimately varies between countries and jurisdictions and can involve additional product testing and additional administrative review periods. The time required to obtain approval in other countries and jurisdictions might differ from and be longer than that required to obtain FDA approval. Regulatory approval in one country or jurisdiction does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country or jurisdiction may negatively impact the regulatory process in others.

Regulation and Marketing Authorization in the European Union

The EMA is the scientific agency of the European Union that coordinates the evaluation and monitoring of new and approved medicinal products. It is responsible for the scientific evaluation of applications for EU marketing authorizations, as well as the development of technical guidance and the provision of scientific advice to sponsors. The EMA decentralizes its scientific assessment of medicines by working through a network of about 4,500 experts throughout the European Union, nominated by the member states. The EMA draws on resources of over 40 National Competent Authorities, or the NCAs, of EU member states.

The process regarding approval of medicinal products in the European Union follows roughly the same lines as in the United States and likewise generally involves satisfactorily completing each of the following:

- preclinical laboratory tests, animal studies and formulation studies all performed in accordance with the applicable EU Good Laboratory Practice regulations;
- submission to the relevant national authorities of a clinical trial application, or CTA, for each clinical trial, which must be approved before human clinical trials may begin;
- performance of adequate and well-controlled clinical trials to establish the safety and efficacy of the product for each proposed indication;
- submission to the relevant competent authorities of a marketing authorization application, or MAA, which includes the data supporting safety and efficacy as well as detailed information on the manufacture and composition of the product in clinical development and proposed labelling;
- satisfactory completion of an inspection by the relevant national authorities of the manufacturing facility or facilities, including those of third parties, at which the product is produced to assess compliance with strictly enforced cGMP;
- potential audits of the non-clinical and clinical trial sites that generated the data in support of the MAA; and
- review and approval by the relevant competent authority of the MAA before any commercial marketing, sale or shipment of the product.

We filed an MMA for Selincro and several CTAs for BTT1023 and tozadenant with European regulatory authorities, all of which are listed in the table below:

<u>Compound</u>	<u>Date of filing</u>	<u>Country</u>	<u>Indication</u>	<u>Original applicant</u>
Selincro	Dec. 21, 2011	Centralized (EU)	Reduction of alcohol consumption	H. Lundbeck A/S
BTT1023	Dec. 22, 2006	United Kingdom	First-in-man study	Biotie
BTT1023	Oct. 21, 2008	Bulgaria	Treatment of rheumatoid arthritis	Biotie
BTT1023	Oct. 9, 2008	Germany	Treatment of Psoriasis	Biotie
BTT1023	Nov. 14, 2014	United Kingdom	Treatment of primary sclerosing cholangitis (PSC)	University of Birmingham (UK)
SYN115 (tozadenant)	Oct. 25, 2011	Ukraine	Adjunctive treatment of Parkinson's disease	Biotie
SYN115 (tozadenant)	Nov. 23, 2011	Romania	Adjunctive treatment of Parkinson's disease	Biotie

Preclinical Studies

Preclinical tests include laboratory evaluations of product chemistry, formulation and stability, as well as studies to evaluate the potential efficacy and toxicity in animal studies. The conduct of the preclinical tests and formulation of the compounds for testing must comply with the relevant EU regulations and requirements. The results of the preclinical tests, together with relevant manufacturing information and analytical data, are submitted as part of the CTA when seeking approval to start a clinical trial, and with the MAA when seeking marketing authorization.

Clinical Trial Approval

Requirements for the conduct of clinical trials in the European Union including cGCP, are implemented in the currently Clinical Trials Directive 2001/20/EC and the GCP Directive 2005/28/EC. Pursuant to Directive 2001/20/EC and Directive 2005/28/EC, as amended, a system for the approval of clinical trials in the European Union has been implemented through national legislation of the EU member states. Under this system, approval must be obtained from the competent national authority of a EU member state in which a trial is planned to be conducted, or in multiple member states if the clinical trial is to be conducted in a number of member states. To this end, a CTA is submitted, which must be supported by an investigational medicinal product dossier, or IMPD, and further supporting information prescribed by Directive 2001/20/EC and Directive 2005/28/EC and other applicable guidance documents. Furthermore, a clinical trial may only be started after a competent ethics committee has issued a favorable opinion on the clinical trial application in that country.

In April 2014, the European Union legislator passed the new Clinical Trials Regulation (EU) No 536/2014 which is set to replace the current Clinical Trials Directive 2001/20/EC. To ensure that the rules for Clinical trials are identical throughout the EU, the new EU clinical trials legislation was passed as a regulation which is directly applicable in all EU member states. All clinical trials performed in the European Union are required to be conducted in accordance with the Clinical Trials Directive 2001/20/EC until the new Clinical Trials Regulation (EU) No 536/2014 will become applicable, which will be no earlier than 28 May 2016.

The new Regulation (EU) No 536/2014 aims to simplify and streamline the approval of clinical trial in the European Union. The main characteristics of the regulation include:

- A streamlined application procedure via a single entry point, the EU portal;
- A single set of documents to be prepared and submitted for the application as well as simplified reporting procedures which will spare sponsors from submitting broadly identical information separately to various bodies and different Member States;
- A harmonised procedure for the assessment of applications for clinical trials, which is divided in two parts. Part I is jointly assessed by all Member States concerned. Part II is assessed by each Member State concerned separately;
- Strictly defined deadlines for the assessment of clinical trial application; and
- The involvement of the ethics committees in the assessment procedure in accordance with the national law of the Member State concerned but within the overall timelines defined by the Regulation (EU) No 536/2014.

Marketing Authorization

Authorization to market a product in the member states of the European Union proceeds under one of four procedures: a centralized authorization procedure, a mutual recognition procedure, a decentralized procedure or a national procedure.

Centralized Authorization Procedure

The centralized procedure enables applicants to obtain a marketing authorization that is valid in all EU member states based on a single application. Certain medicinal products, including products developed by means of biotechnological processes must undergo the centralized authorization procedure for marketing authorization, which, if granted by the European Commission, is automatically valid in all – currently 28 – European Union member states. Sponsors may elect to file an MAA through the centralized procedures for other classes of products. The EMA and the European Commission administer this centralized authorization procedure pursuant to Regulation (EC) No 726/2004.

Pursuant to Regulation (EC) No 726/2004, this procedure is mandatory for:

- medicinal products developed by means of one of the following biotechnological processes:
 - recombinant DNA technology;
 - controlled expression of genes coding for biologically active proteins in prokaryotes and eukaryotes including transformed mammalian cells; and
 - hybridoma and monoclonal antibody methods;
- advanced therapy medicinal products as defined in Article 2 of Regulation (EC) No 1394/2007 on advanced therapy medicinal products;
- medicinal products for human use containing a new active substance which, on the date of entry into force of this Regulation, was not authorized in the European Union, for which the therapeutic indication is the treatment of any of the following diseases:
 - acquired immune deficiency syndrome;
 - cancer;
 - neurodegenerative disorder;
 - diabetes;
 - auto-immune diseases and other immune dysfunctions; and
 - viral diseases; and
- medicinal products that are designated as orphan medicinal products pursuant to Regulation (EC) No 141/2000.

The centralized authorization procedure is optional for other medicinal products if they contain a new active substance or if the applicant shows that the medicinal product concerned constitutes a significant therapeutic, scientific or technical innovation or that the granting of authorization is in the interest of patients in the European Union.

(i) Administrative Procedure

Under the centralized authorization procedure, the EMA's Committee for Human Medicinal Products, or CHMP serves as the scientific committee that renders opinions about the safety, efficacy and quality of medicinal products for human use on behalf of the EMA. The CHMP is composed of experts nominated by each member state's national authority for medicinal products, with one of them appointed to act as Rapporteur for the co-ordination of the evaluation with the possible assistance of a further member of the Committee acting as a Co-Rapporteur. After approval, the Rapporteur(s) continue to monitor the product throughout its life cycle. The CHMP has 210 days, to adopt an opinion as to whether a marketing authorization should be granted. The process usually takes longer in case additional information is

requested, which triggers clock-stops in the procedural timelines. The process is complex and involves extensive consultation with the regulatory authorities of member states and a number of experts. When an application is submitted for a marketing authorization in respect of a drug which is of major interest from the point of view of public health and in particular from the viewpoint of therapeutic innovation, the applicant may pursuant to Article 14(9) Regulation (EC) No 726/2004 request an accelerated assessment procedure. If the CHMP accepts such request, the time-limit of 210 days will be reduced to 150 days but it is possible that the CHMP can revert to the standard time-limit for the centralized procedure if it considers that it is no longer appropriate to conduct an accelerated assessment. Once the procedure is completed, a European Public Assessment Report, or EPAR, is produced. If the opinion is negative, information is given as to the grounds on which this conclusion was reached. After the adoption of the CHMP opinion, a decision on the MAA must be adopted by the European Commission, after consulting the European Union member states, which in total can take more than 60 days.

(ii) Conditional Approval

In specific circumstances, EU legislation (Article 14(7) Regulation (EC) No 726/2004 and Regulation (EC) No 507/2006 on Conditional Marketing Authorizations for Medicinal Products for Human Use) enables applicants to obtain a conditional marketing authorization prior to obtaining the comprehensive clinical data required for an application for a full marketing authorization. Such conditional approvals may be granted for products (including medicines designated as orphan medicinal products), if (1) the risk-benefit balance of the product is positive, (2) it is likely that the applicant will be in a position to provide the required comprehensive clinical trial data, (3) the product fulfills unmet medical needs, and (4) the benefit to public health of the immediate availability on the market of the medicinal product concerned outweighs the risk inherent in the fact that additional data are still required. A conditional marketing authorization may contain specific obligations to be fulfilled by the marketing authorization holder, including obligations with respect to the completion of ongoing or new studies, and with respect to the collection of pharmacovigilance data. Conditional marketing authorizations are valid for one year, and may be renewed annually, if the risk-benefit balance remains positive, and after an assessment of the need for additional or modified conditions and/or specific obligations. The timelines for the centralized procedure described above also apply with respect to the review by the CHMP of applications for a conditional marketing authorization.

(iii) Marketing Authorization Under Exceptional Circumstances

As per Art. 14(8) Regulation (EC) No 726/2004, products for which the applicant can demonstrate that comprehensive data (in line with the requirements laid down in Annex I of Directive 2001/83/EC, as amended) cannot be provided (due to specific reasons foreseen in the legislation) might be eligible for marketing authorization under exceptional circumstances. This type of authorization is reviewed annually to reassess the risk-benefit balance. The fulfillment of any specific procedures/obligations imposed as part of the marketing authorization under exceptional circumstances is aimed at the provision of information on the safe and effective use of the product and will normally not lead to the completion of a full dossier/approval.

Market Authorizations Granted by Authorities of EU Member States

In general, if the centralized procedure is not followed, there are three alternative procedures to obtain a marketing authorization in (one or several) EU member states as prescribed in Directive 2001/83/EC:

- The decentralized procedure allows applicants to file identical applications to several EU member states and receive simultaneous national approvals based on the recognition by EU member states of an assessment by a reference member state.
- The national procedure is only available for products intended to be authorized in a single EU member state.

- A mutual recognition procedure similar to the decentralized procedure is available when a marketing authorization has already been obtained in at least one European Union member state.

A marketing authorization may be granted only to an applicant established in the European Union.

Paediatric Studies

Prior to obtaining a marketing authorization in the European Union, applicants have to demonstrate compliance with all measures included in an EMA-approved Paediatric Investigation Plan, or PIP, covering all subsets of the paediatric population, unless the EMA has granted (1) a product-specific waiver, (2) a class waiver, or (3) a deferral for one or more of the measures included in the PIP. The respective requirements for all marketing authorization procedures are laid down in Regulation (EC) No 1901/2006, the so called Paediatric Regulation. This requirement also applies when a company wants to add a new indication, pharmaceutical form or route of administration for a medicine that is already authorized. The Paediatric Committee of the EMA, or PDCO, may grant deferrals for some medicines, allowing a company to delay development of the medicine in children until there is enough information to demonstrate its effectiveness and safety in adults. The PDCO may also grant waivers when development of a medicine in children is not needed or is not appropriate, such as for diseases that only affect the elderly population.

Before a marketing authorization application can be filed, or an existing marketing authorization can be amended, the EMA determines that companies actually comply with the agreed studies and measures listed in each relevant PIP.

Period of Authorization and Renewals

A marketing authorization shall be valid for five years in principle and the marketing authorization may be renewed after five years on the basis of a re-evaluation of the risk-benefit balance by the EMA or by the competent authority of the authorizing member state. To this end, the marketing authorization holder shall provide the EMA or the competent authority with a consolidated version of the file in respect of quality, safety and efficacy, including all variations introduced since the marketing authorization was granted, at least six months before the marketing authorization ceases to be valid. Once renewed, the marketing authorization shall be valid for an unlimited period, unless the Commission or the competent authority decides, on justified grounds relating to pharmacovigilance, to proceed with one additional five-year renewal. Any authorization which is not followed by the actual placing of the drug on the EU market (in case of centralized procedure) or on the market of the authorizing member state within three years after authorization shall cease to be valid (the so-called sunset clause).

Orphan Drug Designation and Exclusivity

Pursuant to Regulation (EC) No 141/2000 and Regulation (EC) No. 847/2000 the European Commission can grant such orphan medicinal product designation to products for which the sponsor can establish that it is intended for the diagnosis, prevention, or treatment of (1) a life-threatening or chronically debilitating condition affecting not more than five in 10,000 people in the European Union, or (2) a life threatening, seriously debilitating or serious and chronic condition in the European Union and that without incentives it is unlikely that sales of the drug in the European Union would generate a sufficient return to justify the necessary investment. In addition, the sponsor must establish that there is no other satisfactory method approved in the European Union of diagnosing, preventing or treating the condition, or if such a method exists, the proposed orphan drug will be of significant benefit to patients.

BTT1023 has received orphan drug designation for the treatment of PSC in Europe. We intend to pursue orphan drug designation for BTT1023 in the United States.

Orphan drug designation is not a marketing authorization. It is a designation that provides a number of benefits, including fee reductions, regulatory assistance, and the possibility to apply for a centralized EU marketing authorization (see “*Centralized Authorization Procedure*”), as well as 10 years of market exclusivity following a marketing authorization. During this market exclusivity period, neither the EMA, nor the European Commission nor the Member States can accept an application or grant a marketing authorization for a “similar medicinal product.” A “similar medicinal product” is defined as a medicinal product containing a similar active substance or substances as contained in an authorized orphan medicinal product, and which is intended for the same therapeutic indication. The market exclusivity period for the authorized therapeutic indication may be reduced to six years if, at the end of the fifth year, it is established that the orphan drug designation criteria are no longer met, including where it is shown that the product is sufficiently profitable not to justify maintenance of market exclusivity. In addition, a competing similar medicinal product may in limited circumstances be authorized prior to the expiration of the market exclusivity period, including if it is shown to be safer, more effective or otherwise clinically superior to the already approved orphan drug. Furthermore, a product can lose orphan drug designation, and the related benefits, prior to us obtaining a marketing authorization if it is demonstrated that the orphan drug designation criteria are no longer met.

Regulatory Data Protection

European Union legislation also provides for a system of regulatory data and market exclusivity. According to Article 14(11) of Regulation (EC) No 726/2004, as amended, and Article 10(1) of Directive 2001/83/EC, as amended, upon receiving marketing authorization, new chemical entities approved on the basis of complete independent data package benefit from eight years of data exclusivity and an additional two years of market exclusivity. Data exclusivity prevents regulatory authorities in the European Union from referencing the innovator’s data to assess a generic (abbreviated) application. During the additional two-year period of market exclusivity, a generic marketing authorization can be submitted, and the innovator’s data may be referenced, but no generic medicinal product can be marketed until the expiration of the market exclusivity. The overall ten-year period will be extended to a maximum of eleven years if, during the first eight years of those ten years, the marketing authorization holder, or MAH, obtains an authorization for one or more new therapeutic indications which, during the scientific evaluation prior to their authorization, are held to bring a significant clinical benefit in comparison with existing therapies. Even if a compound is considered to be a new chemical entity and the innovator is able to gain the period of data exclusivity, another company nevertheless could also market another version of the drug if such company obtained marketing authorization based on an MAA with a complete independent data package of pharmaceutical test, pre-clinical tests and clinical trials. However, products designated as orphan medicinal products enjoy, upon receiving marketing authorization, a period of 10 years of orphan market exclusivity — see also *Orphan Drug Designation and Exclusivity*. Depending upon the timing and duration of the EU marketing authorization process, products may be eligible for up to five years’ supplementary protection certificates, or SPCs pursuant to Regulation (EC) No 469/2009. Such SPCs extend the rights under the basic patent for the drug.

Regulatory Requirements After a Marketing Authorization Has Been Obtained

If we obtain authorization for a medicinal product in the European Union, we will be required to comply with a range of requirements applicable to the manufacturing, marketing, promotion and sale of medicinal products:

(i) Pharmacovigilance and Other Requirements

We will, for example, have to comply with the EU’s stringent pharmacovigilance or safety reporting rules, pursuant to which post-authorization studies and additional monitoring obligations can be imposed.

Other requirements relate to, for example, the manufacturing of products and active pharmaceutical ingredients in accordance with good manufacturing practice standards. EU regulators may conduct inspections to verify our compliance with applicable requirements, and we will have to continue to expend time, money and effort to remain compliant. Non-compliance with EU requirements regarding safety monitoring or pharmacovigilance, and with requirements related to the development of products for the pediatric population, can also result in significant financial penalties in the European Union. Similarly, failure to comply with the EU's requirements regarding the protection of individual personal data can also lead to significant penalties and sanctions. Individual European Union member states may also impose various sanctions and penalties in case we do not comply with locally applicable requirements.

(ii) Manufacturing

The manufacturing of authorized drugs, for which a separate manufacturer's license is mandatory, must be conducted in strict compliance with the EMA's cGMP requirements and comparable requirements of other regulatory bodies in the European Union, which mandate the methods, facilities and controls used in manufacturing, processing and packing of drugs to assure their safety and identity. The EMA enforces its cGMP requirements through mandatory registration of facilities and inspections of those facilities. The EMA may have a coordinating role for these inspections while the responsibility for carrying them out rests with the member states competent authority under whose responsibility the manufacturer falls. Failure to comply with these requirements could interrupt supply and result in delays, unanticipated costs and lost revenues, and could subject the applicant to potential legal or regulatory action, including but not limited to warning letters, suspension of manufacturing, seizure of product, injunctive action or possible civil and criminal penalties.

(iii) Marketing and Promotion

The marketing and promotion of authorized drugs, including industry-sponsored continuing medical education and advertising directed toward the prescribers of drugs and/or the general public, are strictly regulated in the European Union notably under Directive 2001/83EC, as amended. The applicable regulations aim to ensure that information provided by holders of marketing authorizations regarding their products is truthful, balanced and accurately reflects the safety and efficacy claims authorized by the EMA or by the competent authority of the authorizing member state. Failure to comply with these requirements can result in adverse publicity, warning letters, corrective advertising and potential civil and criminal penalties.

Other Healthcare Laws

Health care providers, physicians and third-party payors play a primary role in the recommendation and prescription of drug products that are granted marketing approval. Arrangements with third-party payors and customers are subject to broadly applicable fraud and abuse and other health care laws and regulations. In the United States, such restrictions under applicable federal and state healthcare laws and regulations, include the following:

- the federal Anti-Kickback Statute prohibits, among other things, persons from knowingly and wilfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made, in whole or in part, under a federal health care program such as Medicare and Medicaid;
- the federal False Claims Act imposes civil penalties, and provides for civil whistleblower or qui tam actions, against individuals or entities for knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government;

- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, imposes criminal and civil liability for executing a scheme to defraud any health care benefit program or making false statements relating to health care matters;
- the federal false statements statute prohibits knowingly and wilfully falsifying, concealing or covering up a material fact or making any materially false statement in connection with the delivery of or payment for health care benefits, items or services;
- the federal transparency requirements under the Health Care Reform Law will require manufacturers of drugs, devices, biologics and medical supplies to report to the Department of Health and Human Services information related to payments and other transfers of value to physicians and teaching hospitals and physician ownership and investment interests; and
- analogous state and foreign laws and regulations.

Efforts to ensure that our business arrangements with third parties will comply with applicable laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other health care laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, exclusion from government funded health care programs, such as Medicare and Medicaid, and the curtailment or restructuring of our operations. If any of the physicians or other providers or entities with whom we expect to do business are found to be not in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded health care programs.

Pharmaceutical Coverage, Pricing and Reimbursement

Significant uncertainty exists as to the coverage and reimbursement status of any products approved by the FDA and other government authorities. Sales of products will depend, in part, on the extent to which the costs of the products will be covered by third-party payors, including government health programs in the United States such as Medicare and Medicaid, commercial health insurers and managed care organizations. The process for determining whether a payor will provide coverage for a product may be separate from the process for setting the price or reimbursement rate that the payor will pay for the product once coverage is approved. Third party payors may limit coverage to specific drug products on an approved list, or formulary, which might not include all of the approved products for a particular indication.

In order to secure coverage and reimbursement for any product that might be approved for sale, a company may need to conduct expensive pharmacoeconomic studies in order to demonstrate the medical necessity and cost-effectiveness of the product, in addition to the costs required to obtain FDA or other comparable regulatory approvals. A payor's decision to provide coverage for a drug product does not imply that an adequate reimbursement rate will be approved. Third party reimbursement may not be sufficient to maintain price levels high enough to realize an appropriate return on our investment in product development.

The containment of healthcare costs has become a priority of governments, and the prices of drugs have been a focus in this effort. Third party payors are increasingly challenging the prices charged for medical products and services and examining the medical necessity and cost-effectiveness of medical products and services, in addition to their safety and efficacy. If these third-party payors do not consider our products to be cost-effective compared to other available therapies, they may not cover our products after approval as a benefit under their plans or, if they do, the level of payment may not be sufficient to allow us to sell our products at a profit. The U.S. government, state legislatures and non-U.S. governments have

shown significant interest in implementing cost containment programs to limit the growth of government-paid health care costs, including price controls, restrictions on reimbursement and requirements for substitution of generic products for branded prescription drugs. Adoption of such controls and measures, and tightening of restrictive policies in jurisdictions with existing controls and measures, could limit payments for pharmaceuticals such as the product candidates that we are developing and could adversely affect our net revenue and results.

In the European Union, pricing and reimbursement schemes vary widely from country to country. Some countries provide that drug products may be marketed only after a reimbursement price has been agreed. Some countries may require the completion of additional studies that compare the cost-effectiveness of our product candidate to currently available therapies (so called health technology assessment, or HTA) in order to obtain reimbursement or pricing approval. For example, the European Union provides options for its member states to restrict the range of drug products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. European Union member states may approve a specific price for a drug product or may instead adopt a system of direct or indirect controls on the profitability of the company placing the drug product on the market. Other member states allow companies to fix their own prices for drug products, but monitor and control prescription volumes and issue guidance to physicians to limit prescriptions. The downward pressure on health care costs in general, particularly prescription drugs, has become very intense. As a result, increasingly high barriers are being erected to the entry of new products. In addition, there can be considerably pressure by governments and other stakeholders on prices and reimbursement levels, including as part of cost containment measures. Political, economic and regulatory developments may further complicate pricing negotiations, and pricing negotiations may continue after reimbursement has been obtained. Reference pricing used by various EU member states, and parallel distribution (arbitrage between low-priced and high-priced member states), can further reduce prices. Any country that has price controls or reimbursement limitations for drug products may not allow favorable reimbursement and pricing arrangements for any of our products.

The marketability of any products for which we receive regulatory approval for commercial sale may suffer if the government and third-party payors fail to provide adequate coverage and reimbursement. In addition, emphasis on managed care in the United States has increased and we expect will continue to increase the pressure on drug pricing. Coverage policies, third-party reimbursement rates and drug pricing regulation may change at any time. In particular, the Patient Protection and Affordable Care Act was enacted in the United States in March 2010 and contains provisions that may reduce the profitability of drug products, including, for example, increased rebates for drugs sold to Medicaid programs, extension of Medicaid rebates to Medicaid managed care plans, mandatory discounts for certain Medicare Part D beneficiaries and annual fees based on pharmaceutical companies' share of sales to federal health care programs. Even if favorable coverage and reimbursement status is attained for one or more products for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

Organizational Structure and History

Our full name is Biotie Therapies Oyj, translated as Biotie Therapies Corp. in English. We are domiciled in Turku, Finland, and our address is Joukahaisenkatu 6, FI-20520 Turku, Finland. Our telephone number is +358 2 274 8900. We are a Finnish limited liability company and comply with Finnish legislation. We were incorporated in Finland in 1998. We listed our shares on the Finnish Stock Exchange on October 31, 2002, and our shares currently trade under the symbol "BTH1V." In February 2011, we acquired Synosia, a company that had been formed by certain former Roche executives and that had licensed a number of central nervous system focused assets that had previously been under development by

Roche, including tozadenant and SYN120. Our primary operating subsidiary is Biotie Therapies Inc., located in South San Francisco, California. As of March 31, 2015, our liquid assets totaled €27.8 million.

Facilities

Our headquarters are in Turku, Finland, where we occupy office space under a fixed term lease that after November 2016 will automatically continue with a mutual six-month termination period unless the lease is terminated on November 2016. Our primary operating subsidiary, Biotie Therapies, Inc., is based in South San Francisco, California, where we occupy office space under a five-year (sixty-month) lease period. The lease expires in December 2018.

Employees

As of March 31, 2015, we had 40 employees of which the majority is located in our office in South San Francisco, California, United States. Of these, 29 employees are engaged in research and development and 11 employees are engaged in finance, human resources, IT, investor relations, business development, facilities and business and general management. We have no collective bargaining agreements with our employees and we have not experienced any work stoppages. We consider our relations with our employees to be good.

Legal Proceedings

From time to time, we are subject to various legal proceedings and claims that arise in the ordinary course of our business activities. Although the results of litigation and claims cannot be predicted with certainty, as of the date of this prospectus, we do not believe we are party to any claim or litigation, the outcome of which, if determined adversely to us, would individually or in the aggregate be reasonably expected to have a material adverse effect on our business. Regardless of the outcome, litigation can have an adverse impact on us because of defense and settlement costs, diversion of management resources and other factors.

Within the past 12 months, we have not been party to any litigation, arbitration proceedings or administrative proceedings that may have a material effect on our financial condition or profitability, and we are not aware of any such proceedings being pending or threatened.

MANAGEMENT

General

Pursuant to the provisions of the Finnish Companies Act and our articles of association, our management and governance is divided among the shareholders through actions taken at general meetings of shareholders, the board of directors and our Managing Director, also referred to as our President and Chief Executive Officer, or CEO.

Our board of directors is responsible for the management and the proper organization of our activities. Our board of directors establishes the principles of our strategy, organization, accounting and financial control. Our President and CEO is responsible for our day-to-day management in accordance with the instructions and guidance from our board of directors. Our President and CEO is also responsible for ensuring that our accounting practices comply with the law and that our financial management has been arranged in a reliable manner. In addition, our senior management team assists the President and CEO in the day-to-day management.

Board of Directors

Under our articles of association, our board of directors must consist of at least three and at most ten members. We currently have seven directors. Our directors are elected by the annual general meeting of shareholders and their terms of office expire at the end of the subsequent annual general meeting. Our articles of association do not set limitations regarding the number of terms that directors may serve or restrict the decision-making power of the general meeting of shareholders in electing board members. The board of directors elects one of its members as the Chairman and may also elect a Vice Chairman. Our President and CEO cannot be elected as the Chairman of our board of directors and is not currently a member of the board of directors.

Our board of directors convenes as frequently as necessary to discharge its responsibilities. During 2014, our board of directors convened eleven times. A quorum of our board of directors exists when more than a half of the members are present. Our board of directors has established an audit committee and a nomination and remuneration committee to assist it in its operations.

The following table sets forth the name, position, age, initial year of appointment and expiration of current term for the current members of our board of directors:

<u>Name</u>	<u>Position</u>	<u>Age</u>	<u>Initial year of appointment</u>	<u>Expiration of current term(1)</u>
William M. Burns(2)	Chairman	67	2011	2016
Bernd Kastler(3)	Vice Chairman	65	2008	2016
Don M. Bailey(3)	Director	69	2015	2016
Merja Karhapää(3)	Director	53	2010	2016
Ismail Kola(2)	Director	58	2011	2016
Guido Magni(2)	Director	61	2011	2016
Mahendra G. Shah(2)	Director	70	2015	2016

(1) Pursuant to our articles of association, the members of our board of directors are elected by the annual general meeting of shareholders and the term of office of the board members expires at the end of the annual general meeting following their election.

(2) Member of nomination and remuneration committee.

(3) Member of audit committee.

The following is a brief summary of the business experience of our directors and director nominees. Unless otherwise indicated, the current business address for each of our directors is Biotie Therapies Corp., Joukahaisenkatu 6, FI-20520, Turku, Finland.

William M. Burns is the Chairman of our board of directors and has been a member of our board of directors since February 2011. He has had a long and distinguished career in the pharmaceutical industry and was employed by Roche from 1986 to 2010. He most recently served as chief executive officer of the Roche pharmaceuticals division. Prior to this, he held various senior positions with Roche, including as the head of the pharmaceuticals division, the head of Pharma Europe/International and the global head of strategic marketing and business development. Prior to joining Roche, Mr. Burns spent 17 years with Beecham Pharmaceuticals in the United Kingdom and Japan, where he held a variety of positions. Mr. Burns is a member of the board of directors of Mesoblast Ltd., Shire Plc and Vestergaard Frandsen SA; chairman of the board of directors of Masters Pharmaceuticals, Inc.; a member of the Chugai International Advisory Board; a member of the Technology Transfer Strategy Panel and chairman of the Health Innovation Challenge Fund in Wellcome Trust; and a member of the Scientific Advisory Board of the Center for Integrated Oncology at the University of Cologne/Bonn, Germany. Mr. Burns has a Bachelor of Arts (Honors Degree) from the University of Strathclyde, United Kingdom.

Bernd Kastler is the Vice Chairman of our board of directors and has been a member of our board of directors since November 2008. He is the cofounder of elbion NV and has previously served as a director and CEO of elbion NV from 2002 to 2008 and as a member of the executive board of ASTA Medica AG, the pharmaceutical subsidiary of Degussa AG, from 1989 to 2002. Prior to this he held various positions at Degussa AG. Mr. Kastler currently holds the position as managing director of his controlled company, Kastler GmbH. Mr. Kastler has a doctorate in law from the University of Giessen, Germany.

Don M. Bailey has been a member of our board since May 2015. Mr. Bailey was the chief executive officer of Questcor Pharmaceuticals, Inc. from 2007 to 2014 and chairman and/or chief executive officer of Comarco, Inc. between 1991 and 2007. He has served on the boards of Questcor, STAAR Surgical Company and Comarco in various capacities since 1991. Mr. Bailey is currently a board member of Mallinckrodt Plc and chairman of its portfolio committee. He earned his Master of Arts degree in operational research from the University of Southern California and also holds an MBA from Pepperdine University.

Merja Karhapää has been a member of our board of directors since April 2010. She has been the group general counsel and company secretary of Sanoma Corporation since 2008 and has worked as vice president of the legal affairs group of Sanoma Corporation since 2000. Prior to this, she held positions as vice president for intellectual capital at Danisco AS, trademark counsel and assistant general counsel of Cultor Corporation and Danisco AS and as corporate counsel of Sanoma Oyj (formerly, Sanoma News Oy) and Valmet Corporation. Mrs. Karhapää is a Market Court expert member (on intellectual property rights matters); chairman of the Finnish Intellectual Property Rights Forum; chairman of the Law Committee of the Confederation of Finnish Industries; and member of the Ministry of Education Copyright Commission. Mrs. Karhapää has an LL.M. from the University of Helsinki and a Postgraduate Intellectual Property Rights Diploma from Bristol University, United Kingdom.

Ismail Kola has been a member of our board of directors since February 2011. He has been an executive vice president of UCB S.A. and the president of New Medicines™ UCB since November 2009. From 2007 to 2009, he served as senior vice president, discovery research and early clinical research & experimental medicine at Schering-Plough Research Institute (pharmaceutical research arm) and chief scientific officer of Schering-Plough Corporation. He was senior vice president and site head, basic research at Merck & Co. and chaired its antibacterial and antifungal worldwide business strategy team from 2003 to 2007. Prior to that, he was vice president, research, and global head, genomics science and biotechnology,

with Pharmacia Corporation and served as a consultant to SmithKline Beecham Pharmaceuticals, where he was also a member of the Genomics Advisory Board. Prior to his move to the private industry, he worked as a professor of human molecular genetics and director of the research center for functional genomics and human disease at Monash University Medical School for 15 years. Dr. Kola is currently a member of the board of directors of Athersys, Inc. Dr. Kola also holds adjunct professorships of medicine at Washington University, St. Louis, United States and Monash University Medical School, Australia; a foreign adjunct professorship at the Karolinska Institute, Sweden; a visiting professor of medicine at the Nuffield Department of Medicine of the University of Oxford, United Kingdom; and is a William Pitt Fellow at Pembroke College, Cambridge University, United Kingdom. Dr. Kola holds a PhD in medicine from the University of Cape Town, South Africa.

Guido Magni has been a member of our board of directors since February 2011. He is an experienced drug developer who is currently a partner of Versant Ventures Management, LLC. Prior to that, he worked at Roche from 1993 to 2008, first as global head of central nervous system development and then as global head of medical science, global drug development, pharmaceuticals division from 1995 to 2008. While with Roche, he was a member of the research and development board, the life cycle committee and the business development board. Prior to that, he held the position of central nervous system senior project director in clinical development at Wyeth-Ayerst Laboratories Inc. Dr. Magni is a member of the board of directors of GenSight Biologics SA, PIQUR Therapeutics AG, AM Pharma BV and Mosaic Biomedicals SL. Dr. Magni holds a degree in medicine from the University of Padua, Italy and a PhD from the University of Rome, Italy in 1981.

Mahendra G. Shah has been a member of our board since May 2015. Dr. Shah is currently a venture partner at ViVo Capital. Previously, he founded NextWave Pharmaceuticals, Inc., a pediatric focused specialty pharmaceutical company, and acted as the company's chairman and chief executive officer from 2005 to 2009. He was also the chairman and chief executive officer of First Horizon Pharmaceuticals Corporation (1993-2003), vice president of EJ Financial Enterprises, Inc. (1991-1999) and a senior director at Fujisawa USA, Inc. (Astellas) (1987-1991). Previously, Dr. Shah worked in various scientific and management positions with Schering-Plough and Bristol Myers-Squibb. He has served on the boards of Unimed Pharmaceuticals, Inc., Introgen Therapeutics, Inc., Inpharmakon Corporation, Protomed Pharmaceuticals, Inc., Structural Bioinformatics Inc. and Zarix, Inc. Dr. Shah earned his Ph.D. in industrial pharmacy from St. John University.

Senior Management

The members of our senior management team manage their respective areas of our group under the guidance of our board of directors. We have a strong centralized senior management team led by Timo Veromaa, our President and CEO, who has broad experience in information technology, strategy, operations, finance, sales, communications and training. Our senior management team has many years of experience in drug development and business development, which was gained at a mix of large and small pharmaceutical companies, where they have all previously held senior positions. Our current senior management team members were appointed by our board of directors for an indefinite term.

The following table lists our senior management team:

<u>Name</u>	<u>Position</u>	<u>Age</u>	<u>Year of initial appointment</u>
Timo Veromaa	President and CEO	54	1998
David Cook	Chief Financial Officer	47	2013
Stephen Bandak	Chief Medical Officer	64	2007
Mehdi Paborji	Chief Operating Officer	60	2014

The following is a brief summary of the business experience of our senior management team. Unless otherwise indicated, the current business address for each member of our senior management team is Biotie Therapies Corp., Joukahaisenkatu 6, FI-20520, Turku, Finland.

Timo Veromaa was appointed as a member of the management team in December 1998 (serving as Vice President of research and product development from 1998 to 2005) and has served as our President and CEO since 2005. Prior to this, he was the medical director of Schering Oy from 1996 to 1998; research and program manager at Collagen Corporation (California, United States) from 1994 to 1996; postdoctoral fellow at Stanford University, (California, United States), from 1990 to 1993; and scientist at the University of Turku from 1985 to 1990. Dr. Veromaa currently serves as chairman of the board of Finnish Bioindustries FIB; and is a member of the board of directors of the Chemical Industry Federation of Finland and Herantis Pharma Plc, and member of the Advisory Board of the University of Eastern Finland. Dr. Veromaa holds an M.D. and a PhD from the University of Turku and has special competence in pharmaceutical medicine from the Finnish Medical Association.

David Cook was appointed as a member of the senior management team in February 2013, when he joined us as our Chief Financial Officer. Prior to this, he was the chief financial officer of Jazz Pharmaceuticals, International from 2012 to 2013; chief financial officer of EUSA Pharma Inc. from 2006 to 2012; group financial controller of Zeneus Pharma Limited from 2004 to 2006; and worked for PricewaterhouseCoopers in several countries from 1992 to 2004. He is also currently a nonexecutive director and chair of the audit committee of Alliance Pharma plc. Mr. Cook holds a Master of Arts degree from the University of Oxford, United Kingdom.

Stephen Bandak was appointed as a member of the senior management team in 2011 as our Chief Medical Officer. Prior to this, he was chief medical officer of Synosia Therapeutics Holding AG from 2007 to 2011; vice president of medical and regulatory at Novavax, Inc. from 2004 to 2006; and worked for Eli Lilly and Co. for over 26 years in a variety of leadership roles including as an executive director of the U.S. Medical Organization. He is currently a non-executive director of Hapten Sciences Inc. Dr. Bandak received training in medicine at Guys Hospital Medical School, University of London, United Kingdom and became a member of the Royal College of Physicians in 1977. Dr. Bandak's current business address is Biotie Therapies, Inc., located on 701 Gateway Boulevard — Suite 350, South San Francisco, CA 94080, United States.

Mehdi Paborji was appointed as a member of the senior management team in January 2014, when he joined us as Chief Operating Officer. Previously, he held a variety of senior roles in the pharmaceutical industry, including as the founder and chief operating officer of TheraVida, Inc. from 2005 to 2013; vice president, pharmaceutical development of Irvine Pharmaceutical Services, Inc. from 2004 to 2005; senior director, pharmaceutical research and development of Theravance Biopharma, Inc. from 2001 to 2004; and director, pharmaceuticals research and development at Bristol-Myers Squibb Company from 1986 to 2001. Mr. Paborji holds a PhD in bio-organic and physical organic chemistry from the University of Kansas, United States. Mr. Paborji's current business address is Biotie Therapies, Inc., located on 701 Gateway Boulevard — Suite 350, South San Francisco, CA 94080, United States.

Committees

Our board of directors has established an audit committee and a nomination and remuneration committee to support it in its decision-making process.

Audit Committee

The members of our audit committee are Don Bailey (Chairman), Bernd Kastler and Merja Karhapää.

The audit committee assists the board in overseeing our accounting, auditing and financial reporting processes. The responsibilities of the audit committee are to:

- monitor the reporting process of financial statements;
- supervise the financial reporting process;
- monitor the quality, adequacy and efficiency of our internal controls and risk management systems;
- initiate and oversee internal financial audits;
- review the description of the main features of the internal control and risk management systems pertaining to the financial reporting process;
- monitor the disclosure controls and procedures;
- review related party transactions in accordance with our related party transaction policy;
- evaluate and monitor the processes for the employees to raise concern, in confidence, about possible wrongdoing in financial reporting, accounting, internal accounting controls, auditing or other matters (whistle-blowing) and respond to any requests by employees and third parties in the context of our whistle-blowing policy;
- annually evaluate the independence of our statutory auditor or audit firm, particularly the provision of non-audit services provided to us;
- prepare the proposal for the resolution of the election of the auditor; and
- resolve any disagreements between management and the auditor regarding our financial reporting.

The audit committee meets as frequently as necessary to discharge its responsibilities, usually around the financial reporting calendar. During 2014 our audit committee met four times and reported to the board of directors after each meeting. It also meets with our auditors at least twice during the year and they are invited to attend all committee meetings.

Our board of directors has determined that all members of our audit committee are independent under Rule 10A-3 of the Exchange Act and the applicable rules of the NASDAQ. Our board of directors has determined that Don M. Bailey and Bernd Kastler each qualifies as an “audit committee financial expert,” as such term is defined in the rules of the SEC.

Nomination and Remuneration Committee

The members of our nomination and remuneration committee are William Burns (Chairman), Ismail Kola, Guido Magni and Mahendra Shah.

Our nomination and remuneration committee ensures the efficient oversight of nomination and remuneration matters.

The responsibilities of the nomination and remuneration committee are to:

- present recommendations to our board of directors for the proposal to the annual general meeting of shareholders concerning the composition and compensation of our board of directors;
- assist the board of directors in its determination of director independence;
- recommend to our board of directors the appointment of any members on our senior management team;
- prepare the framework for the compensation of our senior management team;
- assess the need for bonus or other incentive plans and review the design of, and targets for, any performance-related compensation plans;

- evaluate the performance of certain members of our senior executive team and propose an adequate level of compensation for each based on this evaluation;
- prepare expense reimbursement policies for our President and CEO and Chairman of board of directors;
- prepare and recommend to the board of directors our Code of Business Conduct and Ethics, review such Code annually and oversee compliance; and
- prepare the annual self-evaluation in accordance with the rules and procedures of our board of directors.

In 2014, our Nomination and Remuneration Committee held four meetings and reported to our board of directors after each meeting. Our nomination and remuneration committee is comprised solely of directors deemed by the board of directors to be independent and who meet requirements of Finnish law, the rules of the SEC and the applicable rules of the NASDAQ.

Corporate Governance

In addition to applicable laws, the rules of the Finnish Stock Exchange and our articles of association, we comply with the Finnish Corporate Governance Code issued in 2010 by the Finnish Securities Market Association, except that in deviation from recommendation 43 of the Finnish Corporate Governance Code, a member of our board of directors, Guido Magni, holds options entitling him to our shares. The options relate to the option program of Synosia (currently Biotie Therapies AG) and were granted prior to our acquisition of Synosia. For more information on the management's option plans, please refer to the section “— Share-Based Incentive Plans.” The Finnish Corporate Governance Code is based on the “comply or explain” principle, meaning that a company may deviate from an individual recommendation provided that it discloses the deviation and provides an explanation for it.

The NASDAQ Listing Rules include certain accommodations in the corporate governance requirements that allow foreign private issuers to follow “home country” corporate governance practices in lieu of the otherwise applicable corporate governance standards of NASDAQ. The application of such exceptions requires that we disclose the NASDAQ Listing Rules that we do not follow and describe the Finnish corporate governance practices we do follow in lieu of the relevant NASDAQ corporate governance standard. If and when the ADSs are listed on NASDAQ, we intend to continue to follow Finnish corporate governance practices in lieu of the corporate governance requirements of NASDAQ. In accordance with the Finnish Companies Act, our articles of association do not provide quorum requirements generally applicable to general meetings of shareholders. To this extent, our practice varies from the requirement of NASDAQ Listing Rule 5620(c), which requires an issuer to provide in its bylaws for a generally applicable quorum, and that such quorum may not be less than one-third of the outstanding voting stock. Although we must provide shareholders with an agenda and other relevant documents for the general meeting of shareholders, Finnish law does not have a regulatory regime for the solicitation of proxies and the solicitation of proxies is not a generally required in Finland, thus our practice will vary from the requirement of NASDAQ Listing Rule 5620(b). In addition, we have opted out of shareholder approval requirements for the issuance of securities in connection with certain events such as the acquisition of stock or assets of another company, the establishment of or amendments to equity-based compensation plans for employees, a change of control of us and certain private placements. To this extent, our practice varies from the requirements of NASDAQ Rule 5635, which generally requires an issuer to obtain shareholder approval for the issuance of securities in connection with such events. Finnish law does not require the implementation of a remuneration committee. Although we have a remuneration committee, our practice will vary from NASDAQ Listing Rule 5620(d) which sets forth certain requirements as to the responsibilities, composition and independence of a

compensation committee. For an overview of our corporate governance principles, see “Description of Share Capital and Articles of Association — Corporate governance.” Accordingly, our shareholders may not have the same protection afforded to shareholders of companies that are subject to these NASDAQ requirements.

As a foreign private issuer, under the listing requirements and rules of NASDAQ, we are not required to have independent directors on our board of directors, except that our audit committee is required to consist fully of independent directors, subject to certain phase-in schedules. Our board of directors has determined that, under current listing requirements and rules of NASDAQ, all of our directors are “independent directors.” In making such determination, our board of directors considered the relationships that each non-executive director has with us and all other facts and circumstances our board of directors deemed relevant in determining the director’s independence, including the number of shares beneficially owned by the director and his or her affiliated entities (if any). Moreover, based on the evaluation of independence by our board of directors, we consider all members of our board of directors to be independent of us and, with the exception of Mahendra G. Shah due to his affiliation with Vivo Capital and Guido Magni due to his affiliation with Versant Ventures, of our significant shareholders in accordance with the independence criteria set out in the Finnish Corporate Governance Code.

Code of Business Conduct and Ethics

We intend to adopt a Code of Business Conduct and Ethics applicable to the board of directors, the senior management team and all employees in connection with the consummation of this offering. Following the completion of this offering, the Code of Business Conduct and Ethics will be available on our website at www.biotie.com, where we will also disclose any amendments to the Code of Business Conduct and Ethics, or any waivers of its requirements.

Family Relationships

There are no family relationships among any of our senior management team members or directors.

Management Services Agreements

We have entered into management services agreements with our President and CEO and each member of the senior management team. None of the members of our board of directors has a service contract with us.

The employment contract with our President and CEO may be terminated by us with six months’ notice or by the President and CEO with three months’ notice. If we terminate the contract without grounds related to the President and CEO’s person, our President and CEO is entitled to a severance payment in the amount of 12 months’ salary, in addition to continued payment of his salary during the notice period.

The contracts for the other members of the senior management team generally provide that they may be terminated by us with six months’ notice or six months’ pay and benefits in lieu of notice.

Compensation of Members of the Board of Directors

Our shareholders determine the compensation payable to the members of our board of directors at our annual general meeting of shareholders. During the 2014 fiscal year, a total of €233,000 in fees was paid to the members of our board of directors.

At our annual general meeting of shareholders on May 26, 2015, our shareholders resolved that the remuneration payable to the Chairman of our board of directors would be €52,000 per year, to the Vice Chairman of our board of directors €46,000 per year and to other board members €36,000 per year. Further, annual remuneration for the members of the committees of our board of directors was set at: €10,000 for the

Chairman of the audit committee; €8,000 for the other audit committee members; €8,000 for the Chairman of the nomination and remuneration committee; and €4,000 for other nomination and remuneration committee members. Board members are also entitled to reimbursement for reasonable travel expenses incurred in connection with board and committee meetings.

The compensation paid to the current members of our board of directors in the year ended December 31, 2014 is presented in the following table:

	January 1 to December 31 2014 (audited) (€ thousands)
William M. Burns	54
Merja Karhapää	42
Bernd Kastler	44
Ismail Kola	39
Guido Magni	42

We do not currently grant shares, option rights or share units to the members of our board of directors. For information on the shareholdings of our board of directors, see “Principal and Selling Shareholders.”

The members of our board of directors do not receive any pension benefits. We do not have any service contracts with our directors, and none of our directors is entitled to any benefits following the termination of his or her service on the board.

Compensation of Members of the Senior Management Team

The following table sets forth the aggregate compensation and benefits provided to our President and CEO and the other members of our senior management team in the year ended December 31, 2014:

	January 1 to December 31 2014 (€ thousands)
Salaries and other short term employment benefits	1,995
Post-employment benefits (payments to defined contribution plans) . . .	79
Share-based payments	540
Total	2,614

The following table sets forth the compensation and benefits provided to our President and CEO on an individual basis:

	January 1 to December 31 2014 (€ thousands)
Salary and other short term employment benefits	527
Post-employment benefits (payments to defined contribution plan) . . .	42
Share-based payments	271
Total	840

Our board of directors allocated the following options, share units or similar equity rights to the current senior management team during the last two years:

- in 2013, 1,400,000 options and 350,000 share units;
- in 2014, 720,000 options, 1,440,000 senior management stock options, 420,000 stock units and 840,000 senior management stock units; the senior management stock options and the senior management stock units could result in between zero and three times the amount of shares being awarded, depending on the growth in our share price for the three years ending December 31, 2016; and
- in 2015 (as of March 31, 2015), 720,000 options and 480,000 stock units. For more information, see “— Share-Based Incentive Plans — Senior Management Team Program under the Share-Based Incentive Plans”.

The table below provides an overview, as of March 31, 2015, of the aggregate options, senior management stock options, share units and senior management share units held by the members of our senior management team under the Swiss option plan, stock option plan 2011, equity incentive plan 2011, stock option plan 2014 and equity incentive plan 2014. For more information on the terms of these awards, see “Share-Based Incentive Plans.”

<u>Name</u>	<u>Aggregate Number of Options and Share Units</u>	<u>Aggregate Number of Senior Management Stock Options and Senior Management Share Units</u>
Timo Veromaa	1,760,000	960,000
David Cook	1,080,000	480,000
Stephen Bandak	2,209,568	480,000
Mehdi Paborji	420,000	360,000

For information on the shareholdings of our senior management team, see “Principal and Selling Shareholders.”

We have committed, as a part of the terms of employment of our President and CEO and other executives, to make in addition to contributions to the strategy pension system certain contributions to voluntary, payment-based retirement insurance policies. In 2014, we made contributions totaling €79,000 to such retirement insurance policies. The senior management team members not residing in Finland are not covered by any Finnish statutory pension system.

Our board of directors appoints the President and CEO and decides on his annual base salary and benefits and the terms and conditions of his employment contract.

Our board of directors assesses annually the basis for bonus payments to our President and CEO and to the other members of our senior management team. Bonus payments under the annual bonus plan are discretionary, and bonuses are contingent on the participant being employed on the date that any bonus is paid. Bonuses under the plan are determined based on our achievement of corporate operational goals, which are set by our board of directors each year, as well as, for all participants other than the President and CEO, each participant’s achievement of personal goals. The target bonus for our President and CEO and our other senior management team members is 80% of their fixed annual compensation.

Our board of directors has resolved that all members of our senior management team must retain 25% of the net return from their stock options in the form of our shares, unless such 25% of net return is less than their 12-month gross salary, in which case the amount retained in the form of our shares will be equal in value to their 12-month gross salary. Such shares must be held as long as their service with us continues. Our board of directors may, in its discretion, permit exceptions to the ownership requirement in certain circumstances.

Share-Based Incentive Plans

Below is a summary of the five equity plans that are currently active, which form part of our incentive and commitment program for our key personnel. We do not grant any share-based incentive awards to our directors. However, Guido Magni, a member of our board of directors, holds options entitling him to purchase our shares. These options were granted under Synosia's option program, prior to our acquisition of Synosia.

Swiss Option Plan

The Swiss company Synosia, which we acquired in February 2011 and which is now operating as Biotie Therapies AG, has a stock option plan, which we refer to as the Swiss option plan, under which stock options have been granted to its employees, directors and consultants. In connection with the completion of the acquisition of Synosia, the Swiss option plan was amended so that instead of granting options with respect to Synosia shares, an aggregate maximum of 14,912,155 of our shares were made available for issuance under the plan.

The Swiss option plan is administered by our board of directors, which may make amendments to the terms of the stock options granted under the plan that are not adverse to the option holders, interpret the plan, settle all controversies relating to the plan and the awards granted thereunder and otherwise manage the plan.

The exercise prices for the options granted under the Swiss option plan range from CHF 0.09 to CHF 0.45 per share. The last day for exercise of options granted under the Swiss option plan is December 7, 2020.

Generally, should a participant's employment with, or service to, us terminate for reasons other than for cause, the participant will be entitled to exercise his or her option to the extent that the option was exercisable as of the date of termination, during a set period of time following such termination, or, if earlier, until the term of the option expires. If the participant is terminated by us for cause, the option will generally terminate at such time. In the event of our liquidation or dissolution, all outstanding options will generally be terminated and any outstanding options with respect to which we have a repurchase right may be repurchased by us. Alternatively, our board may, in its sole discretion, cause some or all options to become fully vested, exercisable and/or no longer subject to repurchase prior to the completion of the liquidation or dissolution, contingent on its completion. In the event of a corporate transaction (as defined in the Swiss option plan), options may generally be assumed by the surviving corporation or substituted for similar options, or our board may, in its discretion, provide that participants will receive payment for their outstanding options if such options would otherwise terminate if not exercised prior to the effective time of the corporate transaction. For participants whose service has not been terminated prior to the effective time and whose options are not assumed or substituted by the surviving corporation, we may accelerate the vesting of their options prior to the effective time, giving such participants an opportunity to exercise the options prior to such time. For participants whose service has terminated prior to the effective time and whose options are not assumed or substituted by the surviving corporation, their options will generally not be accelerated, and any options not exercised prior to the effective time will terminate. In the event of a change in control (as defined in the Swiss option plan), other than a takeover event as described below, our board may determine that all unvested options will become vested and fully exercisable; if our board does not so decide, and a participant experiences an involuntary termination without cause within 12 months following the change in control, each unvested option will become exercisable and may be exercised within 30 days following such termination. In the event of a takeover event (as defined in the Swiss option plan), each unvested option will automatically accelerate and become fully exercisable immediately following the effective date of the takeover event.

The Swiss option plan provides that equitable adjustments be made to outstanding options and the number of shares issuable under the plan in the event of a capitalization adjustment, including a stock split or a consolidation of shares.

As of March 31, 2015, an aggregate of 9,575,772 of our shares had been granted to the option holders upon the exercise of their respective options under the Swiss option plan. Options with respect to 2,824,772 of our shares remain outstanding under the Swiss option plan. As of March 31, 2015, 2,824,784 of our shares were held as treasury shares by our subsidiary, Biotie Therapies AG, for transfer upon the exercise of these options.

Stock Option Plan 2011

Our board of directors established the stock option plan 2011 on December 6, 2011. Our annual general meeting of shareholders had previously authorized the establishment of the stock option plan 2011 on May 6, 2011. This plan was established to grant stock options, mainly to our European employees, and 7,401,000 of our shares were authorized for issuance pursuant to stock option awards under the plan.

The stock option plan 2011 is administered by our board of directors, which may decide on the distribution of the stock options, make non-material amendments to the stock option plan 2011, interpret the terms and conditions of the plan and otherwise manage the plan.

The stock option plan 2011 provided that grants could be made in each of calendar years 2011, 2012 and 2013. The option exercise price for all stock options was €0.01 per share, which was determined with an intent to incentivize our employees and to align the objectives of our shareholders and employees. 2,467,000 of the shares available for issuance under the plan were available to be granted subject to option awards in 2011 and were marked as the 2011A tranche, 2,467,000 of the shares available for issuance were available to be granted subject to option awards in 2012 and were marked as the 2011B tranche and 2,467,000 of the shares available for issuance were available to be granted subject to option awards in 2013 and were marked as the 2011C tranche. According to the terms and conditions of the stock options, 50% of the maximum number of the stock options were granted to our employees subject to the fulfilment of strategic and operational targets, determined annually by our board of directors. The other 50% of the stock options were granted without reference to such targets. The share subscription period, during which awards may be exercised, is: for the 2011A tranche, January 1, 2014 to February 28, 2015; for the 2011B tranche, January 1, 2015 to February 29, 2016; and for the 2011C tranche, January 1, 2016 to February 28, 2017.

Generally, should a participant's employment with, or service to, us terminate (other than due to the participant's permanent disability, statutory retirement or death), the participant will forfeit, without compensation, all stock options for which the relevant share subscription period has not begun. However, our board of directors may, in its absolute discretion, permit a participant to retain some or all of the options following a termination of employment or service. In the event of our liquidation or deregistration, any stock options for which the performance targets have not yet been determined will vest at target, and option holders will be given an opportunity to exercise their stock options within a set period designated by our board of directors. If we are deregistered before the option holders have an opportunity to exercise their stock options, the option holders will have the same rights as our shareholders. In the event of a merger or spin-off transaction, any stock options for which the performance targets have not yet been determined will vest at target. Option holders will either, at the discretion of our board of directors, be given an opportunity to exercise their options prior to the consummation of the transaction, during a set period designated by our board of directors, or be given the right to sell their stock options prior to the consummation of the transaction, or the stock options may be converted into options to purchase shares in the surviving company. If a redemption right and obligation arises under the Finnish Limited Liability Companies Act, due to a shareholder acquiring shares representing over 90% of the voting rights in us, the option holders will have

the opportunity to exercise their stock options within a set period designated by our board of directors or will have the same rights and obligations as our shareholders. Our board of directors may make equitable adjustments to the number of shares underlying stock options and the number of shares available for issuance under the plan in response to changes in our share capital or certain other corporate events.

As of March 31, 2015, 6,779,750 options had been granted under the stock option plan 2011. Of these, 1,185,000 options have been forfeited and 2,916,750 have been exercised, so a maximum of 2,678,000 options remain outstanding under the stock option plan 2011.

Equity Incentive Plan 2011

Our board of directors established the equity incentive plan 2011 on December 6, 2011. Our annual general meeting of shareholders had previously authorized the establishment of the equity incentive plan 2011 on May 6, 2011. This plan is used to grant equity awards mainly to our employees in the United States. Share units representing an aggregate of a maximum of 4,599,000 of our shares may be delivered under the equity incentive plan 2011.

The equity incentive plan 2011 is administered by our board of directors, which may decide on the distribution of the share units, make non-material amendments to the equity incentive plan 2011, interpret the terms and conditions of the plan and otherwise manage the plan.

The equity incentive plan 2011 provided that grants could be made in each of calendar years 2011, 2012 and 2013. According to the terms and conditions of the equity incentive plan 2011, 50% of the maximum number of share units granted to our employees were subject to the fulfilment of strategic and operational targets, determined for each of 2011, 2012 and 2013 by our board of directors. The other 50% of the share units were to be granted without reference to such targets. Awards made in each of 2011, 2012 and 2013 vested (or will vest) on January 5, 2014, January 5, 2015 and January 5, 2016, respectively. Shares are delivered to participants following the expiration of the applicable vesting period.

Generally, should a participant's employment with, or service to, us end before the completion of a vesting period (other than due to the participant's permanent disability, statutory retirement or death), the participant's share units will be forfeited. However, our board of directors may, in its absolute discretion, permit a participant to retain some or all of the share units following a termination of employment or service. In the event of a merger or spin-off transaction, our board of directors may, in a fair and equitable manner, convert each share unit award into either a cash award or a right to acquire shares in the surviving company. If a redemption right and obligation arises under the Finnish Limited Liability Companies Act, due to a shareholder acquiring shares representing over 90% of the voting rights in us, the share unit awards will be converted into cash awards. Our board of directors may make equitable adjustments to the number of shares underlying stock options and the number of shares available for issuance under the plan in response to changes in our share capital or certain other corporate events.

As of March 31, 2015, 4,805,160 share units have been granted under the equity incentive plan 2011. 1,878,375 share units have been forfeited and 1,981,785 have been subscribed, so that the total outstanding share units under this plan are a maximum of 945,000.

Stock Option Plan 2014

Our board of directors established the stock option plan 2014 on January 2, 2014. Our annual general meeting of shareholders had previously authorized the establishment of the stock option plan 2014 on April 4, 2013. This plan is used to grant stock options to our European employees. The maximum total number of stock options that may be issued is 10,337,500, entitling the recipients to an aggregate of up to 10,337,500 of our shares. Our board of directors will decide on the distribution of the stock options.

The stock option plan 2014 is administered by our board of directors, which may decide on the distribution of the stock options, make non-material amendments to the stock option plan 2014, interpret the terms and conditions of the plan and otherwise manage the plan.

The stock option plan 2014 provides that awards may be made in each of 2014, 2015 and 2016. The option exercise price for all stock options under the stock option plan 2014 is €0.01 per share, which was determined with an intent to incentivize our employees and to align the objectives of our shareholders and employees. Under the stock option plan 2014, the stock options available for issuance are divided into seven tranches: 468,125 options were available for issuance in 2014 and are marked as the 2014A tranche, 1,404,375 options were available for issuance in 2014 and are marked as the 2014B tranche (we refer to the options in the 2014B tranche, together with the options in the 2014A tranche, as the 2014 options), 518,125 options are available for issuance in 2015 and are marked as the 2014C tranche, 1,554,375 options are available for issuance in 2015 and are marked as the 2014D tranche (we refer to the options in the 2014D tranche, together with the options in the 2014C tranche, as the 2015 options), 518,125 options are available for issuance in 2016 and are marked as the 2014E tranche, 1,554,375 options are available for issuance in 2016 and are marked as the 2014F tranche (we refer to the options in the 2014F tranche, together with the options in the 2014E tranche, as the 2016 options) and 4,320,000 options were available for issuance in 2014 and are marked as the 2014M tranche.

The share subscription periods, during which the options may be exercised, will be: (i) for the 2014A tranche, which represents approximately 25% of the 2014 options, January 1, 2016 to February 28, 2017; (ii) for the 2014B tranche, which represents approximately 75% of the 2014 options, January 1, 2017 to February 28, 2018; (iii) for the 2014C tranche, which represents approximately 25% of the 2015 options, January 1, 2017 to February 28, 2018; (iv) for the 2014D tranche, which represents approximately 75% of the 2015 options, January 1, 2018 to February 28, 2019; (v) for the 2014E tranche, which represents approximately 25% of the 2016 options, January 1, 2018 to February 28, 2019; (vi) for the 2014F tranche, which represents approximately 75% of the 2016 options, January 1, 2019 to February 29, 2020; and (vii) for the 2014M tranche, which represents the awards made to senior management during 2014, January 1, 2017 to February 28, 2018.

Generally, should a participant's employment with, or service to, us terminate (other than due to the participant's permanent disability, statutory retirement or death), the participant will forfeit, without compensation, all stock options for which the relevant share subscription period has not begun. However, our board of directors may, in its absolute discretion, permit a participant to retain some or all of the options following a termination of employment or service. In the event of our liquidation or deregistration, option holders will be given an opportunity to exercise their stock options within a set period designated by our board of directors. If we are deregistered before the option holders have an opportunity to exercise their stock options, the option holders will have the same rights as our shareholders. In the event of a merger or spin-off transaction, option holders will either, at the discretion of our board of directors, be given an opportunity to exercise their options prior to the consummation of the transaction, during a set period designated by our board of directors, or be given the right to sell their stock options prior to the consummation of the transaction, or the stock options may be converted into options to purchase shares in the surviving company. If a redemption right and obligation arises under the Finnish Limited Liability Companies Act, due to a shareholder acquiring shares representing over 90% of voting rights in us, the option holders will have the opportunity to exercise their stock options within a set period designated by our board of directors or will have the same rights and obligations as our shareholders. Our board of directors may make equitable adjustments to the number of shares underlying stock options and the number of shares available for issuance under the plan in response to changes in our share capital or certain other corporate events.

As of March 31, 2015, 3,429,500 options and 1,440,000 senior management stock options have been issued under the stock option plan 2014, of which 337,500 of the options have been forfeited. The senior management stock options relate to the additional senior management team program described below and are subject to additional market based performance criteria, which could result in a maximum of 4,320,000 options being issued. See “— Senior Management Team Program under the Share-Based Incentive Plans.”

Equity Incentive Plan 2014

Our board of directors established the equity incentive plan 2014 on January 2, 2014. Our annual general meeting of shareholders had previously authorized the establishment of the equity incentive plan 2014 on April 4, 2013. This plan is used to grant equity awards mainly to our employees in the United States. A maximum of 14,002,500 of our shares may be delivered under the equity incentive plan 2014. The share units are divided into seven tranches: the 2014A tranche, the 2014B tranche, the 2014C tranche, the 2014D tranche, the 2014E tranche, the 2014F tranche and 2014M tranche, in the proportions set forth below, with a maximum of 2,520,000 share units issuable under the 2014M tranche.

The equity incentive plan 2014 is administered by our board of directors, which may decide on the distribution of the share units, make non-material amendments to the equity incentive plan 2014, interpret the terms and conditions of the plan and otherwise manage the plan.

The equity incentive plan 2014 provides that awards may be made in each of 2014, 2015 and 2016. The exercise price for all share units will be the euro equivalent of \$0.01 per share, which was determined with an intent to incentivize our employees and align the objectives of our shareholders and employees. The exercise price must be paid prior to delivery. Awards granted in each of 2014, 2015 and 2016 may be exercised during the following applicable subscription periods: (i) for the 2014A tranche, which represents 25% of the share units awarded in 2014, January 5, 2016 to January 31, 2016; (ii) for the 2014B tranche, which represents the remaining share units awarded in 2014, January 5, 2017 to January 31, 2017; (iii) for the 2014C tranche, which represents 25% of the share units awarded in 2015, January 5, 2017 to January 31, 2017; (iv) for the 2014D tranche, which represents the remaining share units awarded in 2015, January 5, 2018 to January 31, 2018; (v) for the 2014E tranche, which represents 25% of the share units awarded in 2016, January 5, 2018 to January 31, 2018; (vi) for the 2014F tranche, which represents the remaining share units awarded in 2016, January 5, 2019 to January 31, 2019; and (vii) for the 2014M tranche, which represents the share units awarded to senior management in 2014, January 5, 2017 to January 31, 2017.

Generally, should a participant's employment with, or service to, us end before the completion of a vesting period (other than due to the participant's permanent disability, statutory retirement or death), the participant's share units will be forfeited. However, our board of directors may, in its absolute discretion, permit a participant to retain some or all of the share units following a termination of employment or service. In the event of our liquidation or deregistration, participants will be given an opportunity to exercise their share subscription rights within a set period designated by our board of directors. If we are deregistered before the participants have an opportunity to exercise their share subscription rights, the participants will have the same rights as our shareholders. In the event of a merger or spin-off transaction, participants will either, at the discretion of our board of directors, be given an opportunity to exercise their share subscription rights prior to the consummation of the transaction, during a set period designated by our board of directors, or be given the right to sell their share units prior to the consummation of the transaction, or the share units may be converted into rights to acquire shares of the surviving company. If a redemption right and obligation arises under the Finnish Limited Liability Companies Act, due to a shareholder acquiring shares representing over 90% of the voting rights in us, plan participants will have the opportunity to exercise their share subscription rights within a set period designated by our board of directors or will

have the same rights and obligations as our shareholders. Our board of directors may make equitable adjustments to the number of shares underlying stock options and the number of shares available for issuance under the plan in response to changes in our share capital or certain other corporate events.

As of March 31, 2015, 4,661,250 share units and 840,000 senior management share units have been granted under the equity incentive plan 2014, of which 852,500 share units have been forfeited. The senior management share units relate to the additional senior management team program (see below) and are subject to additional market based performance criteria, which could result in a maximum of 2,520,000 share units being issued.

Senior Management Team Program Under the Share-Based Incentive Plans

As part of the stock option plan 2014 and the equity incentive plan 2014, our board of directors resolved that part of the senior management team's long-term incentive compensation should be directly linked to achieving growth in our share price and, therefore, to shareholder returns. The senior management team comprises our President and CEO, Chief Financial Officer, Chief Medical Officer and Chief Operating Officer.

As such, 40% of the stock options or share units that would be expected to be issued to members of the senior management team over the three years of the stock option plan 2014 or the equity incentive plan 2014 were awarded in 2014. These senior management stock options and share units are subject to additional conditions that may result in the senior management team receiving greater or fewer awards than under the standard terms of the plans. The equity awards granted under the senior management team program will not vest unless the share price growth from January 1, 2014 to December 31, 2016 is greater than 35%. If the share price growth is greater than 35%, the members of the senior management team will receive a greater return, up to a maximum of three times the number of senior management stock options or share units granted. Maximum vesting will occur if the share price grows at least 100% over the three-year period.

The share subscription period for senior management team awards made under the stock option plan 2014 will be January 1, 2017 to February 28, 2018 and the share subscription period for senior management team awards made under the equity incentive plan 2014 will be January 5, 2017 to January 31, 2017. Grants under the management-specific program have been made with respect to 1,440,000 senior management stock options and 840,000 senior management share units.

In addition, the senior management team must keep at least 25% of the net return from each plan in the form of our shares, until a member of the senior management team's share ownership reaches the minimum share ownership level established by our board of directors. Such shares must be held as long as the executive's employment with or service to us continues. Our board of directors may, in its discretion, permit exceptions to these ownership obligations in certain circumstances.

Insurance and Indemnification

Our articles of association contain no provisions under which any member of our board of directors or senior management team members is indemnified in any manner against any liability which they may incur in their capacity as such. Article 12 of our articles of association, however, provides, amongst other matters, that in the annual general meeting of shareholders "the granting of discharge from liability of the members of the Board of Directors and the Managing Director" shall be resolved. We intend to enter into indemnification agreements with our directors and President and CEO and members of the management team upon consummation of this offering that give them the right, to the fullest extent permitted by law, to recover from us amounts, including but not limited to litigation expenses, and any damages they are ordered to pay, in relation to acts or omissions in the performance of their duties. However, there is generally no

entitlement to indemnification for acts or omissions that amount to willful, intentionally reckless or seriously culpable conduct. In addition to such indemnification, we provide our senior management team members and directors with customary directors' and officers' liability insurance.

At present, there is no pending material litigation or proceeding involving our directors or officers where indemnification will be required or permitted. In addition, we are not aware of any threatened material litigation or proceeding that may result in a claim for such indemnification.

Insofar as indemnification of liabilities arising under the Securities Act may be permitted to directors, management or persons controlling us pursuant to the foregoing provisions, we have been informed that, in the opinion of the SEC such indemnification is against public policy as expressed in the Securities Act and is therefore unenforceable.

PRINCIPAL AND SELLING SHAREHOLDERS

As of May 15, 2015, our outstanding share capital was €193.3 million, consisting of 455,968,174 outstanding shares, including 452,990,234 shares with voting rights and 2,977,940 are treasury shares held by us that and that we cannot vote.

The following table presents the beneficial ownership of our outstanding shares as of May 15, 2015, including:

- each person, or group of affiliated persons, known by us to beneficially own more than 5% of our outstanding shares;
- each of our directors;
- each of our senior management team members; and
- all directors and senior management team members as a group.

Beneficial ownership is determined in accordance with the rules of the SEC, and the information is not necessarily indicative of beneficial ownership for any other purpose. Under such rules, beneficial ownership includes any shares over which the individual has sole or shared voting power or investment power as well as any shares that the individual has the right to acquire within 60 days of May 15, 2015 through the exercise of any option, warrant or other right. Except as otherwise indicated, and subject to applicable community property laws, the persons named in the table have sole voting and investment power with respect to all shares held by that person.

The percentage of shares beneficially owned before this offering is computed on the basis of the 455,968,174 outstanding shares as of May 15, 2015. The percentage of shares beneficially owned on a pro forma basis before this offering is computed on the basis of 676,368,176 outstanding shares as of May 15, 2015 after giving effect to the automatic conversion of all outstanding convertible notes issued in connection with the Convertible Notes Financings to shares upon the completion of this offering. The percentage of shares beneficially owned on a pro forma basis after this offering is based on 977,281,615 shares to be outstanding after this offering after giving effect to the automatic conversion of all outstanding convertible notes issued in connection with the Convertible Notes Financings into shares upon the completion of this offering assuming no exercise of the underwriters' option to purchase additional ADSs, and 980,851,935 shares to be outstanding after this offering after giving effect to the automatic conversion of all outstanding convertible notes issued in connection with the Convertible Notes Financings into shares upon the completion of this offering and assuming full exercise of the underwriters' option to purchase additional ADSs from us and the selling shareholder. Shares that a person has the right to acquire within 60 days of May 15, 2015 are deemed outstanding for purposes of computing the percentage ownership of the person holding such rights, but are not deemed outstanding for purposes of computing the percentage ownership of any other person, except with respect to the percentage ownership of all directors and senior management as a group.

Certain of our existing investors and members of our board of directors have indicated an interest in purchasing up to an aggregate of \$17 million of the ADSs in this offering at the public offering price. However, because indications of interest are not binding agreements or commitments to purchase, these entities and persons may determine to not purchase any ADSs in this offering. It is also possible that these entities and persons and additional existing investors could indicate an interest in purchasing more of the ADSs. In addition, the underwriters could determine to sell fewer ADSs to any of these entities or persons than such entities or persons indicate an interest in purchasing or to not sell any ADSs to these entities and persons. The foregoing discussion and the table below do not reflect any potential purchases by these entities or persons.

Shareholder	Pro forma shares beneficially owned after this offering ⁽¹⁾							
	Shares beneficially owned before this offering		Pro forma shares beneficially owned before this offering ⁽¹⁾		Assuming underwriters' option to purchase additional shares is not exercised		Assuming underwriters' option to purchase additional shares is exercised in full	
	Number	Percent	Number	Percent	Number	Percent	Number	Percent
<i>5% Shareholders</i>								
Entities affiliated with Invesco Perpetual(2)	75,738,300	16.6%	75,738,300	11.2%	75,738,300	7.8%	75,738,300	7.7%
UCB S.A.(3)	41,566,710	9.1%	41,566,710	6.1%	41,566,710	4.2%	—	—
Entities affiliated with Versant Ventures(4)	34,268,341	7.5%	97,768,341	14.4%	97,768,341	10.0%	97,768,341	10.0%
Entities affiliated with Vivo Capital(5)	—	—	51,944,445	7.7%	51,944,445	5.3%	51,944,455	5.3%
OrbiMed Private Investments V, L.P.(6)	—	—	51,944,444	7.7%	51,944,444	5.3%	51,944,444	5.3%
<i>Directors and Senior Management</i>								
William M. Burns, Chairman	—	—	—	—	—	—	—	—
Bernd Kastler, Vice Chairman(7)	1,195,702	*	1,195,702	*	1,195,702	*	1,195,702	*
Don M. Bailey, Director(8)	—	—	3,055,556	*	3,055,556	*	3,055,556	*
Merja Karhapää, Director . . .	—	—	—	—	—	—	—	—
Ismail Kola, Director	—	—	—	—	—	—	—	—
Guido Magni, Director(9) . . .	134,592	*	134,592	*	134,592	—	134,592	—
Mahendra G. Shah, Director	—	—	—	—	—	—	—	—
Timo Veromaa, CEO & President(10)	1,250,000	*	1,250,000	*	1,250,000	*	1,250,000	*
David Cook, CFO(11)	200,000	*	200,000	*	200,000	*	200,000	*
Stephen Bandak, CMO(12)	2,296,021	*	5,629,354	*	5,629,354	*	5,629,354	*
Mehdi Paborji, COO	—	—	—	—	—	—	—	—
Directors and senior management as a group (11 persons)	5,076,315	1.1%	63,409,649	1.7%	63,409,649	1.2%	63,409,649	1.2%

* Indicates beneficial ownership of less than 1% of the total outstanding shares. The percentage of shares beneficially owned on a pro forma basis after this offering is based on 977,281,615 shares to be outstanding after this offering after giving effect to the automatic conversion of all outstanding convertible notes issued in connection with the Convertible Notes Financings into shares upon the completion of this offering assuming no exercise of the underwriters' option to purchase additional ADSs, and 980,851,935 shares to be outstanding after this offering after giving effect to the automatic conversion of all outstanding convertible notes issued in connection with the Convertible Notes Financings into shares upon the completion of this offering and assuming full exercise of the underwriters' option to purchase additional ADSs from us and the selling shareholder.

(1) The number of our shares outstanding on a pro forma basis includes the shares issuable upon the automatic conversion of the convertible notes issued in connection with the Convertible Notes Financings upon the completion of this offering.

- (2) Consists of (i) 37,678,364 shares held by Invesco Perpetual Income Fund; (ii) 28,883,861 shares held by Invesco Perpetual High Income Fund; (iii) 7,853,494 shares held by Invesco Perpetual UK Growth Fund; and (iv) 1,322,581 shares held by The BBC Pension Scheme. Each entity has delegated voting and dispositive powers with respect to its shares to Invesco Asset Management Limited. The address for each of Invesco Perpetual Income Fund, Invesco Perpetual UK Growth Fund and The BBC Pension Scheme is Perpetual Park Drive, Henley-on-Thames, Oxfordshire RG9 1HH, United Kingdom. The address of Invesco Asset Management Limited is 30 Finsbury Square, London EC2A 1AG, United Kingdom.
- (3) Consists of 41,566,710 shares held by UCB S.A., which has sole voting and dispositive power over the shares. The address for UCB S.A. is Allée de la Recherche 60, 1070 Brussels, Belgium.
- (4) Before this offering, consists of (i) 34,067,104 shares held by Versant Venture Capital III, L.P. (“VVC III”) and (ii) 201,237 shares held by Versant Side Fund III, L.P. (“VSF III”). Before this offering, pro forma for the issuance of the shares upon conversion of the convertible notes issued in the Convertible Notes Financings, consists of (i) 60,360,187 shares held by VVC III; (ii) 356,503 shares held by VSF III; (iii) 32,514,877 shares held by Versant Venture Capital V, L.P. (“VVC V”); (iv) 978,064 shares held by Versant Affiliates Fund V, L.P. (“VAF V”); (v) 2,474,542 shares held by Versant Venture Capital V (Canada) LP (“VVC CAN”); and (vi) 1,084,168 shares held by Versant Ophthalmic Affiliates Fund I, L.P. (“VOA”). Versant Ventures III, LLC (“VV III”) serves as the sole general partner of VVC III and VSF III and owns no shares directly. Brian G. Atwood, Samuel D. Colella, Ross A. Jaffe, William J. Link, Donald B. Milder, Rebecca B. Robertson, Bradley B. Bolzon, Charles M. Warden, Barbara N. Lubash and Robin L. Praeger are managing directors of VV III and share voting and dispositive power over the shares held by VVC III and VSF III; however, they each disclaim beneficial ownership of the shares held by VVC III and VSF III except to the extent of their pecuniary interests therein. Versant Ventures V, LLC (“VV V”) serves as the sole general partner of VOA, VAF V and VVC V and owns no shares directly. Versant Ventures V (Canada), L.P. (“VV V CAN”) serves as the sole general partner of VVC CAN and owns no shares directly. Samuel D. Colella, Ross A. Jaffe, William J. Link, Bradley J. Bolzon, Robin L. Praeger, Kirk G. Nielson and Thomas Woiwode are managing directors of VV V and VV V CAN and share voting and dispositive power over the shares held by VOA, VAF V, VVC V and VVC CAN; however, they each disclaim beneficial ownership of the shares held by VOA, VAF V, VVC V and VVC CAN except to the extent of their pecuniary interests therein. The address for each of the Versant Ventures entities is One Sansome Street, Suite 3630, San Francisco, CA 94104.
- (5) Consists of (i) 45,641,854 shares held by Vivo Capital Fund VIII, L.P. (Vivo Fund VIII) and (ii) 6,302,591 shares held by Vivo Capital Surplus Fund VIII, L.P. (Vivo Surplus VIII). Vivo Capital VIII, LLC, the sole general partner of both Vivo Fund VIII and Vivo Surplus VIII, has shared voting power and shared investment power over such securities, may be deemed to beneficially own such shares, and disclaims beneficial ownership of the shares except to the extent of its pecuniary interests therein. The address for each of these entities is 575 High Street, Suite 201, Palo Alto, CA 94301.
- (6) Consists of 51,944,444 shares held by OrbiMed Private Investments V, LP. OrbiMed Capital GP V LLC (“GP V”) is the general partner of OPI V, and OrbiMed Advisors LLC (“Advisors”) is the managing member of GP V. Samuel D. Isaly (“Isaly”) is the managing member of, and holder of a controlling interest in, Advisors. By virtue of such relationships, GP V, Advisors and Isaly may be deemed to have voting and investment power with respect to the securities held by OPI V noted above and as a result may be deemed to have beneficial ownership of such securities. Each of GP V, Advisors and Isaly disclaims beneficial ownership of such securities except to the extent of its or his pecuniary interest therein, if any. The address for these entities and persons is 601 Lexington Avenue, 54th floor, New York, New York 10022.

- (7) Consists of 1,195,702 shares held by Kastler GmbH. Mr. Bernd Kastler is sole shareholder and managing director of Kastler GmbH and has sole voting and dispositive power over the shares. The address for Kastler GmbH is Knollenweg 8, D-01445 Radebeul, Germany.
- (8) Consists of 3,055,556 shares held The Bailey 1995 Family Trust, for which Mr. Don M. Bailey serves as trustee.
- (9) Consists of 134,592 shares issuable upon the exercise of options exercisable within 60 days of May 15, 2015.
- (10) Consists of 1,250,000 shares.
- (11) Consists of 200,000 shares issuable upon the exercise of options exercisable within 60 days of May 15, 2015.
- (12) Before this offering, consists of (i) 916,453 shares and (ii) 1,379,568 shares issuable upon the exercise of options exercisable within 60 days of May 15, 2015. Before this offering, pro forma for the issuance of the shares upon conversion of the convertible notes issued in the Convertible Notes Financings, consists of (i) 4,249,786 shares and (ii) 1,379,568 shares issuable upon the exercise of options exercisable within 60 days of May 15, 2015.

Novo A/S, a former shareholder of ours, notified us in November 2013 that its holding of our shares had decreased below 5% of the total number of our shares and votes. We are not aware of any other significant changes in the percentage ownership held by any major shareholders during the past three years other than the changes that will result as a consequence of the automatic conversion of the convertible notes issued in connection with the Convertible Notes Financings into shares any purchases by shareholders who have indicated an interest in purchasing ADSs in this offering, and the sale by the selling shareholder of its shares if the underwriters exercise their option to purchase additional ADSs from the selling shareholder.

As of May 31, 2015, to our knowledge, we had 17 holders of record of our shares who are located in the United States. The aggregate number of shares held by these holders of record represents less than 1% of our outstanding shares. However, this is not representative of the number of beneficial holders of our shares who are located in the United States nor is it representative of the percentage of our shares held by beneficial holders who are located in the United States because a number of our shares are held of record by custodians for the account of brokers or other nominees.

RELATED-PARTY TRANSACTIONS

The following is a description of related-party transactions we have entered into since January 1, 2012 with any of members of our board of directors and senior management team and the holders of more than 10% of our shares.

Indemnification Agreements

We intend to enter into indemnification agreements with our directors and President and CEO and members of our senior management team upon the consummation of this offering. See “Management — Insurance and Indemnification” for a description of these indemnification agreements.

Employment Agreements

We have entered into service agreements with our senior management team, certain of which provide for pre-termination notice periods, severance and restrictive covenants. None of our directors have entered into service agreements with us. See “Management — Management Services Agreements” for a description of these service agreements.

Convertible Notes Financings

Pursuant to certain agreements entered into between us and the other parties identified therein in April and May 2015, certain new investors and existing shareholders, including our Chief Medical Officer, Stephen Bandak, a trust affiliated with one of our directors, Don M. Bailey, and entities affiliated with Versant Ventures, one of our 5% shareholders, subscribed for €9.5 million aggregate principal amount of our convertible promissory notes and received warrants exercisable for our shares on May 28, 2015, which we refer to as the Convertible Notes Financings. Dr. Bandak, the trust affiliated with Mr. Bailey and Versant Ventures subscribed for €0.5 million, €0.5 million and €9.5 million aggregate principal amount of our convertible notes, respectively. See “Management’s Discussion and Analysis of Financial Condition and Results of Operation—Subsequent Events—The Convertible Notes Financings” for a description of these agreements.

We have indemnification obligations to certain investors in connection with these financings. See “Risk Factors—Risks Related to Our Financial Position—In connection with the Convertible Notes Financings, we have indemnification obligations to certain investors pursuant to the subscription agreement with such investors. These obligations could subject us to substantial liabilities.”

Registration Rights Agreement

We and certain of the subscribers for our convertible notes issued in connection with the Convertible Notes Financings entered into a registration rights agreement. Pursuant to the registration rights agreement, we have agreed under certain circumstances to file a registration statement to register the resale of the shares or ADSs held by such security holders, as well as to cooperate in certain public offerings of such shares or ADSs. Registration of these shares or ADSs under the Securities Act would result in these shares or ADSs becoming freely tradable without restriction immediately upon the registered sale of such shares or ADSs. We have also agreed to reimburse the parties to the registration rights agreement for certain expenses incurred in connection with the filing of any registration statement and the marketing of any securities registered pursuant to the registration rights agreement.

Certain of our existing investors and certain members of our board of directors have indicated an interest in purchasing up to an aggregate of \$17 million of the ADSs in this offering at the public offering

price. However, because indications of interest are not binding agreements or commitments to purchase, these entities and persons may determine to not purchase any ADSs in this offering. It is also possible that these entities and persons and additional existing investors could indicate an interest in purchasing more of the ADSs. In addition, the underwriters could determine to sell fewer ADSs to any of these entities or persons than such entities or persons indicate an interest in purchasing or to not sell any ADSs to these entities and persons.

DESCRIPTION OF SHARE CAPITAL AND ARTICLES OF ASSOCIATION

General

Our legal and commercial name is Biotie Therapies Corp. (in Finnish: Biotie Therapies Oyj). We are a public limited liability company incorporated in Finland in 1998 and organized under the laws of Finland. We are registered in the Finnish Trade Register under the business identity code 1475830-6. Our principal executive offices are located on Joukahaisenkatu 6, FI-20520 Turku, Finland and our telephone number at this address is (+358) 2 274-8900. Our agent for service of process in the United States is Biotie Therapies, Inc. located on 701 Gateway Boulevard — Suite 350, South San Francisco, CA 94080 and the telephone number at this address is (650) 244-4850.

Share Capital

Share Capital and Shares

As of March 31, 2015, our total issued and outstanding share capital amounts to €193.3 million divided into 455,968,174 shares, of which 452,272,890 shares have voting rights and 3,695,284 are treasury shares held by us that we cannot vote. We have one series of shares, which entitles holders to equal rights in our company. Our shares have no nominal or par value and our share capital may be increased or reduced without amending our articles of association. Our share capital is denominated in euros.

On March 31, 2015, we held a total of 3,695,284 treasury shares, which represented approximately 0.8% of all of our shares. 2,824,784 of our treasury shares are held by our wholly owned subsidiary Biotie Therapies AG for the purpose of delivering shares under the Swiss option plan. No votes are conferred on our treasury shares. We expect that upon the completion of this offering, 220,400,001 shares will be issued upon the conversion of the convertible notes issued in the Convertible Notes Financings.

Upon completion of this offering and the automatic conversion of the convertible notes issued in connection with the Convertible Notes Financings upon the completion of this offering, our total as adjusted pro forma share capital will amount to €267.2 million (or €267.8 million if the underwriters exercise their option to purchase up to 44,629 additional ADSs from us in connection with this offering) and we will have 977,281,615 shares outstanding (or 980,851,935 shares if the underwriters exercise their option to purchase up to 44,629 additional ADSs from us in connection with the offering) in each case based on the assumptions set forth on the cover page of this prospectus. For changes in our share capital since December 31, 2012, see “Recent Sales of Unregistered Securities.”

Warrants

In connection with the Convertible Notes Financings, we issued to certain investors and existing shareholders an aggregate of 200,400,001 warrants. Each warrant entitles the holder to subscribe for one share at a subscription price of €0.17, adjustable in certain circumstances under the terms of the warrants. In certain circumstances, an acquirer of us may be required to pay an amount determined by reference to a Black-Scholes option pricing formula in satisfaction of the warrants. The warrants, irrespective of the consummation of this offering, entitle the holder to subscribe for our shares from November 1, 2015 until November 1, 2020.

Other Outstanding Securities

In addition to the shares already outstanding, we have granted options, senior management option units, share units and senior management share units, which upon vesting and exercise will lead to an increase in the number of our outstanding shares. A total of a maximum of 8,594,772 options (where each option entitles the holder to purchase one new share upon exercise), a maximum of 1,440,000 senior

management option units (where each senior management option unit entitles the holder to receive up to three options, depending on specified performance criteria, which would entitle the holder to purchase one new share on exercise), a maximum of 4,753,750 share units (where each share unit entitles the holder to one new share upon vesting) and a maximum of 840,000 senior management share units (where each senior management share unit entitles the holder to receive up to three share units, depending on specified performance criteria, which would entitle the holder to purchase one new share upon vesting) were outstanding and granted as of March 31, 2015. For further information, see “Management — Share-Based Incentive Schemes.”

Convertible Capital Loan

As of March 31, 2015, the aggregate amount of our issued convertible capital loan was €1.7 million. The original share subscription period was between June 1, 2000 and December 31, 2005. As the loan capital was not repaid during the original subscription period, the exchange right continues until the loan capital has been paid or the loans have been converted into our shares. If the exchange right of the convertible loan is exercised, the holders of the convertible capital loan would receive in the aggregate 828,000 new shares.

By virtue of the terms and conditions of the convertible capital loan we issued, the holders of this loan have under certain circumstances an equal right with the shareholders to subscribe for new shares. We do not have any other convertible loans besides the aforementioned convertible capital loan.

Authorization on the Issue of Shares and on the Issue of Options and Other Rights Entitling to Shares

The annual general meeting held on May 26, 2015 authorized our board of directors to resolve to issue shares in one or more share issues. The authorization includes the right to issue new shares or dispose of the shares in our possession and to issue options or other special rights that create share entitlements pursuant to Chapter 10 of the Finnish Companies Act. The authorization consists of up to 95,000,000 shares in the aggregate.

The authorization does not exclude our board of directors’ right to resolve on a directed issue. The authorization may be used for material arrangements from our point of view, such as financing or implementing business arrangements or investments or for other such purposes where our board of directors has determined that there is a considerable financial reason that would justify issuing shares, options or other special rights that create share entitlements or a directed share issue.

Our board of directors is authorized to resolve on all other conditions of a share issue, options and other special right entitlements as referred to in Chapter 10 of the Finnish Companies Act, including the payment period, determination grounds for the subscription price and subscription price or issuance of shares, option rights or special rights free of charge or the means of payment of the subscription price (for example, partial or entire payment in cash or other assets).

The authorization is effective until June 30, 2015 and supersedes earlier authorizations.

Standby Equity Distribution Agreement

We renewed a Standby Equity Distribution Agreement in August 2012 which provides that we may at any time during the commitment period ending in November 2015, subject to certain pre-agreed terms and conditions, require YA Global to subscribe for our newly issued shares or purchase treasury shares in our possession by delivering an advance notice to YA Global.

Listing

Our shares have been entered into the Euroclear book-entry securities system and are admitted to trading on Finnish Stock Exchange under the trading code “BTH1V.” The ADSs have been approved for listing on the NASDAQ Global Select Market under the symbol “BITI.”

Transfer Agent and Registrar

Upon the closing of this offering, the transfer agent and depositary for the ADSs will be The Bank of New York Mellon.

Articles of Association and Finnish Law

Set forth below is a summary of relevant information concerning our share capital and material provisions of our articles of association and applicable Finnish law. This summary does not contain all the information relating to ADSs that may be important to you, and we urge you to read this summary in conjunction with the “Description of American Depositary Shares” included elsewhere in this prospectus, before deciding to invest in the ADSs. This summary does not constitute legal advice regarding those matters and should not be regarded as such. Because such statements are summaries, they do not address all aspects of Finnish law that may be relevant to us and our shareholders or all aspects of Delaware law which may differ from Finnish law, and they are not intended to be a complete discussion of the respective rights. For a description of matters related to our board of directors and their indemnification, see “Management — Board of Directors” and “Management — Insurance and Indemnification.”

Amendment of Articles of Association

The general meeting of shareholders may generally resolve to amend our articles of association with a majority of two-thirds of the votes cast and of the shares represented at the general meeting of shareholders. However, subject to the nature of the matter to be resolved, the provisions of the Finnish Companies Act regarding a qualified majority apply to certain resolutions. For example, resolutions involving amendments to the articles of association that change the respective rights of shareholders holding the same class of shares or increase the redemption rights of a company or its shareholders, would require the consent of all shareholders and if only certain shareholders are affected, would require the consent of all shareholders affected by the amendment in addition to the applicable majority requirement. For further information relating to ADSs holders, see “Description of American Depositary Shares.”

Our Shareholders’ Register

Our shares have been entered in dematerialized form into the Finnish book-entry securities system maintained by Euroclear Finland Ltd, or Euroclear. Companies whose shares are listed on the Finnish Stock Exchange are required to use the Finnish book-entry securities system.

Corporate Objectives

Pursuant to Article 3 of our articles of association, our line of business consists of the development, manufacture and sale of products and equipment used in the biotechnology, pharmaceutical industries and laboratory environment, diagnostics, the production of medical and psychotherapy services and consultancy related thereto, research and educational services, as well as the publication of books, magazines and other publications in the field. We may purchase and sell, as well as lease and rent real estate for our operations and own, sell and possess shares and securities provided that we do not engage in the professional trading of securities or investment.

Shareholders' Meeting and Consents

General Meeting

Under the Finnish Companies Act, our shareholders exercise their decision-making power concerning company matters at the general meetings of shareholders. Pursuant to the Finnish Companies Act, our annual general meeting of shareholders shall be held annually within six months of the end of the financial year.

Pursuant to the Finnish Companies Act, our annual general meeting of shareholders shall resolve on matters including, among others, the following:

- adoption of the financial statements and consolidated financial statements;
- granting discharge from liability to the members of our board of directors and the managing director;
- use of profit shown in the statement of financial position;
- election of members of our board of directors; and
- election of auditors.

Furthermore, an authorization for our board of directors to resolve on a share issue or issue of other specific rights entitled to shares and amendments to our articles of association requires the resolution of a general meeting of shareholders. In addition to annual general meetings, extraordinary general meetings of shareholders may also be held if required.

The general meeting of shareholders handles the matters required by the Finnish Companies Act, our articles of association and as presented to it by our board of directors. As a general rule, the general meeting of shareholders is convened by our board of directors. If a shareholder or shareholders controlling at least 10% of our shares or our auditor request in writing that a certain matter be handled at a general meeting of shareholders, our board of directors must convene a general meeting of shareholders within one month from the receipt of the request. Under the Finnish Companies Act, a shareholder may submit a written request to our board of directors to include on the agenda for the next general meeting of shareholders any matter falling within the competence of the general meeting of shareholders, provided that the request is submitted in a sufficiently timely manner as would allow it to be included in the notice to the meeting. As we are a public company, a request submitted at least four weeks prior to giving notice of a meeting is sufficiently timely.

Under our articles of association, our shareholders are convened to a general meeting of shareholders by publishing the convening notices on our website. The convening notices shall be published no earlier than two months before the last registration date mentioned in the notice convening and not later than three weeks prior to the date of the meeting. In addition, our board of directors shall publish a summary notice of the general meeting of shareholders in one or several national daily newspapers, or by sending the notice of the general meeting of shareholders as a registered letter or other verifiable way to the shareholders' addresses, which are registered in our share register. According to our articles of association, a shareholder must notify us of their intention to attend the meeting no later than on the date mentioned in the notice to the meeting, which may be no earlier than ten days prior to the meeting. For further information relating to ADSs holders, see "Description of American Depositary Shares."

Quorum and Voting Rights

Under Finnish law, a shareholder may attend and vote at a general meeting of shareholders in person or by way of proxy representation. Each of our shares confers the right to cast one vote at a general meeting of shareholders. Shareholders who have been entered in our shareholders' register maintained by Euroclear

eight business days before a general meeting of shareholders (the record date) have the right to attend the general meeting of shareholders. In addition each shareholder or proxy representative may have an assistant present at the general meeting of shareholders. For further information relating to ADSs holders, see “Description of American Depositary Shares.”

A proxy representative shall produce a dated proxy document or otherwise in a reliable manner demonstrate his/her right to represent a shareholder at a general meeting of shareholders. When a shareholder participates in the general meeting of shareholders by means of several proxy representatives representing the shareholder based on shares at different securities accounts, the proxy will identify which shares are represented in connection with the registration for the general meeting of shareholders. It is not customary in Finland for a company to issue forms of proxy to its shareholders. Accordingly, we do not do so.

Nominee registered shareholders can attend and vote at the general meeting of shareholders by instructing their broker or other custodian to register the shareholder in our temporary register of shareholders and give the voting instructions in accordance with the broker’s or custodian’s instructions.

At a general meeting of shareholders, resolutions generally require the approval of the majority of the votes cast. However, subject to the nature of the matter to be resolved, the provisions of the Finnish Companies Act regarding a qualified majority apply to certain resolutions. For example, resolutions involving amendments to the articles of association, share issues without shareholders’ preemptive subscription rights and decisions on mergers or demergers require a qualified majority of at least two-thirds of the votes cast and of the shares represented at the general meeting of shareholders. In addition, certain resolutions, such as those involving amendments to the articles of association that change the respective rights of shareholders holding the same class of shares or increase the redemption rights of a company or its shareholders, would require the consent of all shareholders and if only certain shareholders are affected, would require the consent of all shareholders affected by the amendment in addition to the applicable majority requirement.

In accordance with Finnish law and generally accepted business practices, our articles of association do not provide quorum requirements generally applicable to general meetings of shareholders. To this extent, our practice varies from the requirement of NASDAQ Listing Rule 5620(c), which requires an issuer to provide in its bylaws for a generally applicable quorum, and that such quorum may not be less than one-third of the outstanding voting stock.

Dividends and Other Distributions of Funds

Each of our shares confers equal rights to share in the distribution of our funds. Under the Finnish Companies Act, the annual general meeting of shareholders decides on the distribution of dividends, if any, on the basis of the proposal of our board of directors in connection with the adoption of our audited financial statements. Any material changes in a company’s financial situation after the preparation of the financial statements shall be taken into account in the distribution of dividends. Pursuant to the Finnish Companies Act, the distribution of dividends shall be based on the latest adopted and audited financial statements and a company may also pay interim dividends based on the earnings of the current financial year in accordance with the audited financial statements adopted by an extraordinary general meeting of shareholders. A company may distribute only the unrestricted equity less the funds to be left undistributed according to the articles of association, if any. No funds may be distributed if at the time of deciding on the distribution it is known or it should be known that the company is insolvent or that the distribution will result in insolvency. A dividend or other distribution of assets may not exceed the amount proposed or approved by our board of directors. However, if shareholders holding a minimum of one-tenth of all shares so demand at an annual general meeting of shareholders prior to a decision regarding the use of the profit, and sufficient distributable funds are available, the profit to be distributed shall equal at least half of the

profit of the financial year after deduction of items to be left undistributed under the articles of association, if any. According to the Finnish Companies Act, shareholders may not, however, request a distribution of profit exceeding 8% of shareholders' equity. The dividend for the financial year potentially distributed prior to the annual general meeting shall be deducted from the distributable amount. The payment of dividend requires the approval of the majority of the votes cast at the annual general meeting of shareholders. According to the Finnish Companies Act, the annual general meeting of shareholders may also authorize our board of directors to resolve on the distribution of dividends.

Dividend and other distributions are paid to shareholders or their nominees that are included in our shareholders' register on the relevant record date. Such register is maintained by Euroclear through the relevant book-entry account operators. Under the Finnish book-entry securities system, dividends are paid by account transfers to the accounts of the shareholders appearing in the register. Dividend entitlement lapses after three years if a dividend remains unclaimed for that period, in which case the unclaimed dividend will be retained by us.

Under the Finnish Companies Act, we may acquire or redeem treasury shares. Decisions on the acquisition or redemption of treasury shares must be made by the general meeting of shareholders and require at least two-thirds of the votes cast as well as of the shares represented at the meeting. The general meeting of shareholders may also authorize our board of directors to decide on acquisition of treasury shares using the unrestricted equity for a specific period of time, which cannot exceed 18 months. Treasury shares may be acquired in a proportion other than that of the shares held by the shareholders only if there is a weighty financial reason for a company to do so. As a general rule, treasury shares may be redeemed in a proportion other than that of the shares held by the shareholders only by the consent of all shareholders. In a public company, the decision to buy back or redeem shares or to accept them as a pledge shall not be made so that the treasury shares in the possession of, or held as pledges by, a company and its subsidiaries would exceed 10% of all shares. Shares held by us or our subsidiaries, if any, are not entitled to participate in the general meeting or to dividend distributions.

Foreign Exchange Control

Shares in a Finnish company may be purchased by nonresidents of Finland without any separate Finnish exchange control consent. Nonresidents may also receive dividends without separate Finnish exchange control consent, the transfer of assets out of Finland being subject to payment by us of withholding taxes in the absence of an applicable taxation treaty. Non-Finnish residents having acquired shares in a Finnish limited liability company may receive shares pursuant to a bonus issue or through participation in a rights issue without separate Finnish exchange control consent. Shares in a Finnish company may be sold in Finland to Non-Finnish residents, and the proceeds of such sale may be transferred out of Finland in any convertible currency. There are no Finnish exchange control regulations restricting the sale of shares in a Finnish company by nonresidents to other nonresidents.

Mandatory Tender Offer and Redemption Obligation

Under the Finnish Securities Markets Act (746/2012) as amended, or the Finnish Securities Markets Act, a shareholder whose voting power increases so as to exceed certain triggering thresholds (initially 30% and again at 50%) of the total voting rights in a company is required, subject to certain conditions, to offer to purchase the remaining shares of the company, as well as any other rights entitled to shares issued by the company within one month, such as subscription rights, convertible bonds or stock options issued by the company. The purchase price shall be the fair price of the securities in question. The fair price is determined on the basis of the highest price paid for the security during the preceding six months by the shareholder or any party in close connection to the shareholder. This price can be deviated from for a specific reason. If the

shareholder or any related party has not during the six months preceding the offer acquired any securities that are the target for the offer, the fair price is determined based on the average of the prices paid for the security in public trading during the preceding three months weighted by the volume of trade. This price can be deviated from for a specific reason.

Under the Finnish Companies Act a shareholder whose holding exceeds 90% of the total number of shares or voting rights in a company has both the right and, upon a request from the minority shareholders, the obligation to purchase all the shares of the minority shareholders for the current market price. The market price is determined, among other things, on the basis of the recent market price of the shares. The purchase procedure under the Finnish Companies Act differs, and the purchase price may differ, from the purchase procedure and price under the Finnish Securities Markets Act, as discussed above. However, if the threshold of 90% has been exceeded through either a mandatory or a voluntary public tender offer pursuant to the Finnish Securities Markets Act, the fair price under the Finnish Companies Act is deemed to be the price offered in the public offer, unless there are specific reasons to deviate from it.

Disclosure of Shareholder Ownership or Voting Power

According to the Finnish Securities Market Act, a shareholder is required to promptly notify the company and the Finnish Financial Supervisory Authority, or Finnish FSA, when its ownership or voting power reaches, exceeds or falls below 5%, 10%, 15%, 20%, 25%, 30%, 50% or 90% or two-thirds of all the shares or the voting rights outstanding. The term “ownership” includes ownership by the shareholder, as well as selected related parties, and calculating the ownership or voting power covers agreements or other arrangements that when concluded would cause the proportion of voting rights or number of shares to reach, exceed or fall below the above-mentioned limits. Upon receiving such notice, the company is required to promptly disclose it by a publication on the Finnish Stock Exchange.

Pursuant to the Regulation (EU) No. 236/2012 of the European Parliament and the Council on short selling and certain aspects of credit default swaps, any person that acquires or disposes of a net short position relating to our issued share capital, or by a transaction creating or relating to any financial instrument where the effect or one of the effects of the transaction is to confer a financial advantage on the person entering into that transaction in the event of a decrease in the price of such shares is required to notify the Finnish FSA if, as a result of which such acquisition or disposal his net short position reaches, exceeds or falls below 0.2% of our issued share capital and each 0.1% above that. If the net short position reaches 0.5%, and also at every 0.1% above that, the Finnish FSA will disclose the net short position to the public.

In accordance with U.S. federal securities laws, holders of our shares and holders of ADSs will be required to comply with disclosure requirements relating to their ownership of our securities. Any person that, after acquiring beneficial ownership of our shares or the ADSs, is the beneficial owners of more than 5% of our outstanding shares or shares underlying ADSs must file with the SEC a Schedule 13D or Schedule 13G, as applicable, disclosing the information required by such schedules, including the number of our shares or shares underlying ADSs that such person has acquired (whether alone or jointly with one or more other persons). In addition, if any material change occurs in the facts set forth in the report filed on Schedule 13D (including a more than 1% increase or decrease in the percentage of the total shares beneficially owned), the beneficial owner must promptly file an amendment disclosing such change.

Prohibition of Nominee Registered Holdings for the Benefit of Finnish Citizens and Entities

According to Finnish law, Finnish citizens and entities may not hold securities in a Finnish publicly listed company through a nominee, such as a custodian bank. Accordingly, holding of ADSs may not be allowed for Finnish citizens and entities if this would be deemed in effect to constitute prohibited holding of the Company’s shares through a nominee.

Comparison of Finnish Corporate Law and Our Articles of Association and United States Corporate Law

The following comparison between Finnish corporation law, which applies to us, and Delaware corporation law, the law under which many publicly listed corporations in the United States are incorporated, discusses additional matters not otherwise described in this prospectus. Although we believe this summary is materially accurate, the summary is subject to Finnish law and Delaware corporation law, including the Delaware General Corporation Law, or the DGCL.

Corporate Governance

We rely on a provision in the NASDAQ Listing Rules that allows us to follow Finnish corporate law with respect to certain aspects of corporate governance. This allows us to continue following certain corporate governance practices that differ in significant respects from the corporate governance requirements applicable to U.S. companies listed on the Nasdaq. For further information, see “Management — Corporate Governance.”

Duties of Directors

Finland. As a general rule, Finnish listed companies use a so-called one-tier governance model, which, in addition to the general meeting, comprises the board of directors and the managing director. According to the Finnish Companies Act, a company may also have a supervisory board. Very few listed companies have supervisory boards and neither do we. The boards of Finnish listed companies mainly consist of non-executive directors. Our board of directors is responsible for the administration and the proper organization of the operations of the company. The board of directors supervises and controls the operative management of the company, appoints and dismisses our president and CEO, approves our strategic goals and principles of risk management and ensures the proper operation of the management system. Our president and CEO is responsible for our day-to-day management in accordance with the instructions and guidance given by our board of directors and ensuring that our accounting practices comply with the law and that our financial management has been arranged in a reliable manner. The duty of the board of directors is to promote the best interest of the company and all of our shareholders. A director does not represent the interests of the parties who have proposed his or her election as director. Our directors are under no obligation to hold a specific number of shares under our articles of association.

Delaware. The board of directors bears the ultimate responsibility for managing the business and affairs of a corporation. In discharging this function, directors of a Delaware corporation owe fiduciary duties of care and loyalty to the corporation and to its stockholders. Delaware courts have decided that the directors of a Delaware corporation are required to exercise informed business judgment in the performance of their duties. Informed business judgment means that the directors have informed themselves of all material information reasonably available to them. Delaware courts have also imposed a heightened standard of conduct upon directors of a Delaware corporation who take any action designed to defeat a threatened change in control of the corporation. In addition, under Delaware law, when the board of directors of a Delaware corporation approves the sale or break-up of a corporation, the board of directors may, in certain circumstances, have a duty to obtain the highest value reasonably available to the stockholders.

Directors’ Terms

Finland. Pursuant to our articles of association, the members of our board of directors are elected by the annual general meeting of shareholders and the term of office of the board members expires at the end of the annual general meeting following their election. Our articles of association set no limitations

regarding the number of terms that directors may serve, nor do they in any other way restrict the decision-making power of the general meeting of shareholders in electing board members. However, the Finnish Corporate Governance Code contains several recommendations regarding the composition of our board of directors, especially with regard to meeting the independence and other requirements applicable to publicly listed companies in Finland. Moreover, a board member is typically not considered independent under the Finnish Corporate Governance Code if he has served as a non-executive director for more than 12 consecutive years. Our directors do not have a mandatory retirement age requirement under our articles of association.

Delaware. The DGCL generally provides for a one-year term for directors, but permits directorships to be divided into up to three classes with up to three-year terms, with the years for each class expiring in different years, if permitted by the certificate of incorporation, an initial bylaw or a bylaw adopted by the stockholders. A director elected to serve a term on a “classified” board may not be removed by stockholders without cause. There is no limit in the number of terms a director may serve.

Directors’ Vacancies

Finland. The proposal of the nomination and remuneration committee of our board of directors for the composition of our board of directors shall be included in the notice of the general meeting of shareholders. The same applies to a proposal for the composition of our board of directors made by a shareholder or shareholders with at least 10% of the votes carried by our shares, provided that the candidates have given their consent to the election and we have received information on the proposal sufficiently in advance so that it may be included in the notice of the general meeting. The candidates proposed in corresponding order thereafter are required to be disclosed to the public separately. The Finnish Corporate Governance Code recommends that the company report the biographical details of the candidates for the board on its website.

Delaware. The DGCL provides that vacancies and newly created directorships may be filled by a majority of the directors then in office (even though less than a quorum) unless (i) otherwise provided in the certificate of incorporation or bylaws of the corporation or (ii) the certificate of incorporation directs that a particular class of stock is to elect such director, in which case any other directors elected by such class, or a sole remaining director elected by such class, will fill such vacancy.

Conflict-of-Interest Transactions

Finland. The board of directors is always obliged to act in the company’s interests and in such a way that its acts or measures are not likely to produce unjustified benefit to any shareholder or other third party at the cost of the company or another shareholder. Pursuant to the Finnish Companies Act, a member of the board of directors is disqualified from participating in the handling of a matter pertaining to a contract between himself and the company. In addition, a member of the board of directors may not participate in the handling of a contract between the company and a third party, if he or she may receive a material benefit that may be in conflict with the interests of the company. The above provisions on a contract apply equally to other transactions, court proceedings and other rights of action. In principle, a board member may not participate in the handling of a matter if the board member has interests in the matter in another capacity. In order to avoid conflicts of interest, it is recommended in the Finnish Corporate Governance Code that the majority of the directors should not have interdependent relationship with the company and of this majority at least two directors shall also be independent of significant shareholders of the company. When votes are cast, the majority opinion will be the board’s decision and, in the case of a tie, the chairman will have the casting vote.

Delaware. The DGCL generally permits transactions involving a Delaware corporation and an interested director of that corporation if:

- the material facts as to the director's relationship or interest are disclosed and a majority of disinterested directors consent;
- the material facts are disclosed as to the director's relationship or interest and a majority of shares entitled to vote thereon consent; or
- the transaction is fair to the corporation at the time it is authorized by the board of directors, a committee of the board of directors or the stockholders.

Proxy Voting by Directors

Finland. A director of a Finnish company may not issue a proxy representing the director's voting rights as a director.

Delaware. A director of a Delaware corporation may not issue a proxy representing the director's voting rights as a director.

Shareholder Rights

Quorum and Voting Rights

Finland. Under Finnish law, a shareholder may attend and vote at a general meeting of shareholders in person or by way of proxy representation. Each of our shares confers the right to cast one vote at a general meeting of shareholders. Shareholders who have been entered in our shareholders' register maintained by Euroclear eight working days before a general meeting of shareholders, or the record date, have the right to attend the general meeting of shareholders. In addition each shareholder or proxy representative may have an assistant present at the general meeting of shareholders.

A proxy representative shall produce a dated proxy document or otherwise in a reliable manner demonstrate his/her right to represent a shareholder at a general meeting of shareholders. When a shareholder participates in the general meeting of shareholders by means of several proxy representatives representing the shareholder based on shares at different securities accounts, the proxy will identify which shares are represented in connection with the registration for the general meeting of shareholders. It is not customary in Finland for a company to issue forms of proxy to its shareholders. Accordingly, we do not do so.

Other nominee registered shareholders can attend and vote at the general meeting of shareholder by instructing their broker or other custodian to register the shareholder in our temporary register of shareholders and give the voting instructions in accordance with the broker's or custodian's instructions.

At a general meeting of shareholders, resolutions generally require the approval of the majority of the votes cast. Subject to the nature of the matter to be resolved, the provisions of the Finnish Companies Act regarding qualified majority or unanimity shall apply.

In accordance with Finnish law and generally accepted business practices, our articles of association do not provide quorum requirements generally applicable to general meetings of shareholders. To this extent, our practice varies from the requirement of NASDAQ Listing Rule 5620(c), which requires an issuer to provide in its bylaws for a generally applicable quorum, and that such quorum may not be less than one-third of the outstanding voting stock.

Delaware. Under the DGCL, each stockholder is entitled to one vote per share of stock, unless the certificate of incorporation provides otherwise. In addition, the certificate of incorporation may provide for cumulative voting at all elections of directors of the corporation, or at elections held under specified

circumstances. Either the certificate of incorporation or the bylaws may specify the number of shares and/or the amount of other securities that must be represented at a meeting in order to constitute a quorum, but in no event will a quorum consist of less than one-third of the shares entitled to vote at a meeting.

Stockholders as of the record date for the meeting are entitled to vote at the meeting, and the board of directors may fix a record date that is no more than 60 nor less than 10 days before the date of the meeting, and if no record date is set then the record date is the close of business on the day next preceding the day on which notice is given, or if notice is waived then the record date is the close of business on the day next preceding the day on which the meeting is held. The determination of the stockholders of record entitled to notice or to vote at a meeting of stockholders shall apply to any adjournment of the meeting, but the board of directors may fix a new record date for the adjourned meeting.

Shareholder Proposals

Finland. The general meeting of shareholders handles the matters required by the Finnish Companies Act, our articles of association and as presented to it by our board of directors. As a general rule, the general meeting of shareholders is convened by our board of directors. If a shareholder or shareholders controlling at least 10% of our shares or our auditor request in writing that a certain matter be handled at a general meeting of shareholders, our board of directors must convene a general meeting of shareholders within one month from the receipt of the request. Under the Finnish Companies Act, a shareholder may submit a written request to our board of directors to include on the agenda for the next general meeting of shareholders any matter falling within the competence of the general meeting of shareholders, provided that the request is submitted in a sufficiently timely manner as would allow it to be included in the notice to the meeting. As we are a public company, a request submitted at least four weeks prior to giving notice of a meeting is sufficiently timely.

Delaware. Delaware law does not specifically grant stockholders the right to bring business before an annual or special meeting. However, if a Delaware corporation is subject to the SEC's proxy rules, a stockholder who owns at least \$2,000 in market value, or 1% of the corporation's securities entitled to vote, may propose a matter for a vote at an annual or special meeting in accordance with those rules.

Action by Written Consent

Finland. Under Finnish law, shareholders' resolutions may be adopted in writing without holding a meeting of shareholders, provided that (i) all shareholders agree on this practice for decision making and, (ii) the resolution is adopted unanimously by all shareholders, which makes a written shareholder's resolution in a publicly listed company such as ours unlikely.

Delaware. Although permitted by Delaware law, publicly listed companies do not typically permit stockholders of a corporation to take action by written consent.

Appraisal Rights

Finland. The concept of appraisal rights is not known as such under Finnish law. However, the Finnish Companies Act provides that a shareholder of a merged Finnish company who has voted against a merger may demand that the surviving company redeem the consideration to be paid to the shareholder in the merger at a fair price. If the fair price is not agreed upon with the surviving company, the price shall be determined in statutory arbitration proceedings.

Under the Finnish Securities Markets Act, a shareholder whose voting power exceeds certain triggering thresholds, (initially 30% and again at 50%) of the total voting rights in a company shall, within one month, offer to purchase the remaining shares of the company, as well as any other rights entitling to the shares issued by the company, such as subscription rights, convertible bonds or stock options issued by

the company. The purchase price shall be the fair price of the securities in question. The fair price is determined on the basis of the highest price paid for the security during the preceding six months by the shareholder or any party in close connection to the shareholder. This price can be deviated from for a specific reason. If the shareholder or any related party has not during the six months preceding the offer acquired any securities that are the target for the offer, the market price is determined based on the average of the prices paid for the security in public trading during the preceding three months weighted by the volume of trade. This price can be deviated from for a specific reason.

Under the Finnish Companies Act a shareholder whose holding exceeds 90% of the total number of shares or voting rights in a company has both the right and, upon a request from the minority shareholders, the obligation to purchase all the shares of the minority shareholders at a fair price. The purchase procedure under the Finnish Companies Act differs, and the purchase price may differ, from the purchase procedure and price under the Securities Market Act, as discussed above. However, if the threshold of 90% has been exceeded through either a mandatory or a voluntary public tender offer pursuant to the Finnish Securities Market Act, the market price under the Finnish Companies Act is deemed to be the price offered in the public offer, unless there are specific reasons to deviate from it.

Delaware. The DGCL provides for stockholder appraisal rights, or the right to demand payment in cash of the judicially determined fair value of the stockholder's shares, in connection with certain mergers and consolidations.

Shareholder Suits

Finland. Under Finnish law, a limited liability company, its shareholders, and third parties have the right of action against certain parties, including board members and the management for breach of the Finnish Companies Act or the articles of association. In addition, one or several shareholders may under certain circumstances bring an action in their own name for the purpose of collecting damages to the company, provided it is probable at the time of commencing the action that the company itself will not claim such damages. It is not possible to commence a class action suit based on a breach of the Finnish Companies Act.

Delaware. Under the DGCL, a stockholder may bring a derivative action on behalf of the corporation to enforce the rights of the corporation. An individual may also commence a class action suit on behalf of himself or herself and other similarly situated stockholders where the requirements for maintaining a class action under Delaware law have been met. A person may institute and maintain such a suit only if that person was a stockholder at the time of the transaction which is the subject of the suit. In addition, under Delaware case law, the plaintiff normally must be a stockholder at the time of the transaction that is the subject of the suit and throughout the duration of the derivative suit. Delaware law also requires that the derivative plaintiff make a demand on the directors of the corporation to assert the corporate claim before the suit may be prosecuted by the derivative plaintiff in court, unless such a demand would be futile.

Repurchase of Shares

Finland. Under the Finnish Companies Act, we may acquire or redeem treasury shares. Decisions on the acquisition or redemption of treasury shares must be made by the general meeting of shareholders and require at least two-thirds of the votes cast as well as of the shares represented at the meeting. The general meeting of shareholders may also authorize our board of directors to decide on acquisition of treasury shares using the unrestricted equity for a specific period of time, which cannot exceed 18 months. Treasury shares may be acquired in a proportion other than that of the shares held by the shareholders only if there is a weighty financial reason for a company to do so. As a general rule, treasury shares may be redeemed in a proportion other than that of the shares held by the shareholders only by the consent of all shareholders. In a

public company, the decision to acquire or redeem own shares or to accept them as pledge shall not be made so that the treasury shares in the possession of, or held as pledges by, a company and its subsidiaries would exceed 10% of all shares. Shares held by us or a subsidiary of ours shall not entitle to participation in the general meeting or to dividend distribution.

Delaware. Under the DGCL, a corporation may purchase or redeem its own shares unless the capital of the corporation is impaired or the purchase or redemption would cause an impairment of the capital of the corporation. A Delaware corporation may, however, purchase or redeem out of capital any of its preferred shares or, if no preferred shares are outstanding, any of its own shares if such shares will be retired upon acquisition and the capital of the corporation will be reduced in accordance with specified limitations.

Anti-Takeover Provisions

Finland. Under Finnish law, certain ex ante measures are possible and permissible that may reduce the likelihood of a company becoming subject to a public tender offer. These may include provisions in the articles of association concerning, for example, the maximum number of votes that a shareholder can cast at a shareholders' meeting, increased majority voting requirements for certain types of shareholder decisions, or a duty to make an offer to purchase outstanding shares at a price specified in the articles of association to all other shareholders upon exceeding a certain ownership threshold. We have not adopted any specific provisions in our articles of association that may have the effect of making a takeover of us more difficult or less attractive. In addition to the application of the general fiduciary duties of our board of directors under the Finnish Companies Act, certain key aspects of the conduct of the parties in a takeover situation are governed by the Finnish Securities Markets Act as well as by the Helsinki Takeover Code that operates on the comply or explain principle.

Delaware. In addition to other aspects of Delaware law governing fiduciary duties of directors during a potential takeover, the DGCL also contains a business combination statute that protects Delaware companies from hostile takeovers and from actions following the takeover by prohibiting some transactions once an acquirer has gained a significant holding in the corporation.

Section 203 of the DGCL prohibits "business combinations," including mergers, sales and leases of assets, issuances of securities and similar transactions by a corporation or a subsidiary with an interested stockholder that beneficially owns 15% or more of a corporation's voting stock, within three years after the person becomes an interested stockholder, unless:

- the transaction that will cause the person to become an interested stockholder is approved by the board of directors of the target prior to the transactions;
- after the completion of the transaction in which the person becomes an interested stockholder, the interested stockholder holds at least 85% of the voting stock of the corporation not including shares owned by persons who are directors and officers of interested stockholders and shares owned by specified employee benefit plans; or
- after the person becomes an interested stockholder, the business combination is approved by the board of directors of the corporation and holders of at least 66.67% of the outstanding voting stock, excluding shares held by the interested stockholder.

A Delaware corporation may elect not to be governed by Section 203 by a provision contained in the original certificate of incorporation of the corporation or an amendment to the original certificate of incorporation or to the bylaws of the company, which amendment must be approved by a majority of the shares entitled to vote and may not be further amended by the board of directors of the corporation. Such an amendment is not effective until twelve months following its adoption.

Inspection of Books and Records

Finland. Finnish law does not provide a right for a shareholder to inspect any books or records of a company apart from the share and shareholder's register, which is required to be made publically available in a company's principal office. Under Finnish law, sufficient information on the items to be dealt with at a general meeting of shareholders shall be made available to the shareholders before a general meeting of shareholders. The notice of the general meeting and the following information shall be made available on the company website at least three weeks before the general meeting: (a) the documents to be submitted to the general meeting and (b) draft resolutions to the general meeting. The documents presented to the annual general meeting, which are placed on the website, include, for example, the financial statements, the report by the board of directors and the auditors' report. The company is required to disclose on its website, in a timely manner, the date by which a shareholder shall notify the board of directors of an issue that he or she demands to be included in the agenda of the annual general meeting. A shareholder who is present at a general meeting of shareholders also has the right to request information with respect to the matters to be considered at the meeting. In addition, the minutes of the general meeting including the voting results and the appendices of the minutes that are part of a decision made by the meeting, shall be posted on the company website within two weeks of the general meeting. The documents related to the general meeting, which are placed on the website, shall be available on the company website for at least three months after the general meeting.

Delaware. Under the DGCL, any stockholder may inspect for any proper purpose certain of the corporation's books and records during the corporation's usual hours of business.

Removal of Directors

Finland. Under Finnish law, the general meeting of shareholders is at all times entitled to elect the number and composition of the board of directors within the framework set out in a company's articles of association at the annual general meeting or an extraordinary general meeting. The proposal of the nomination and remuneration committee of our board of directors for the composition of our board of directors shall be included in the notice of the general meeting of shareholders. The same applies to a proposal for the composition of our board of directors made by a shareholder or shareholders with at least 10% of the votes carried by our shares, provided that the candidates give their consent to the election and we receive information on the proposal sufficiently in advance so that it may be included in the notice of the general meeting. The candidates proposed in corresponding order thereafter are disclosed to the public separately.

Delaware. Under the DGCL, any director or the entire board of directors may be removed, with or without cause, by the holders of a majority of the shares then entitled to vote at an election of directors, except (i) unless the certificate of incorporation provides otherwise, in the case of a corporation whose board is classified, stockholders may effect such removal only for cause or (ii) in the case of a corporation having cumulative voting, if less than the entire board is to be removed, no director may be removed without cause if the votes cast against his or her removal would be sufficient to elect him if then cumulatively voted at an election of the entire board of directors, or, if there are classes of directors, at an election of the class of directors of which he or she is a part.

Preemptive Rights

Finland. Under the Finnish Companies Act, the existing shareholders have a preemptive right to subscribe for shares offered in proportion to the amount of shares in their possession in connection with any offering of shares. However, a general meeting of shareholders may vote, by a majority which represents at least two-thirds of the votes cast and two-thirds of the shares represented at the meeting, to waive this

preemptive right, provided that, from the company's perspective, there is a weighty financial reason for the waiver. Certain non-Finnish shareholders may not necessarily be able to exercise their preemptive subscription rights in our future offerings due to the legislation and regulations of their home country.

Delaware. Under the DGCL, stockholders have no preemptive rights to subscribe for additional issues of stock or to any security convertible into such stock unless, and to the extent that, such rights are expressly provided for in the certificate of incorporation.

Dividends

Finland. Each of our shares confers equal rights to share in the distribution of our funds. Under the Finnish Companies Act, the annual general meeting of shareholders decides on the distribution of dividends, if any, on the basis of the proposal of our board of directors in connection with the adoption of our audited financial statements. Any material changes in a company's financial situation after the preparation of the financial statements shall be taken into account in the distribution of dividends. Pursuant to the Finnish Companies Act, the distribution of dividends shall be based on the latest adopted and audited financial statements and a company may also pay interim dividends based on the earnings of the current financial year in accordance with the audited financial statements adopted by an extraordinary general meeting of shareholders. A company may distribute only the unrestricted equity less the funds to be left undistributed according to the articles of association, if any. No funds may be distributed if at the time of deciding on the distribution it is known or it should be known that the company is insolvent or that the distribution will result in insolvency. A dividend or other distribution of assets may not exceed the amount proposed or approved by our board of directors. However, if shareholders holding a minimum of one-tenth of all shares so demand at an annual general meeting of shareholders prior to a decision regarding the use of the profit, and sufficient distributable funds are available, the profit to be distributed shall equal at least half of the profit of the financial year after deduction of items to be left undistributed under the articles of association, if any. According to the Finnish Companies Act, shareholders may not, however, request a distribution of profit exceeding 8% of shareholders' equity. The dividend for the financial year potentially distributed prior to the annual general meeting shall be deducted from the distributable amount. The payment of dividend requires the approval of the majority of the votes cast at the annual general meeting of shareholders. According to the Finnish Companies Act, the annual general meeting of shareholders may also authorize our board of directors to resolve on the distribution of dividends on the basis of adopted financial statements. Such authorization shall define the maximum amount of dividends to be distributed thereunder and may not remain in effect after the following annual general meeting.

Dividend and other distributions are paid to shareholders or their nominees that are included in our shareholders' register on the relevant record date. Such register is maintained by Euroclear through the relevant book-entry account operators. Under the Finnish book-entry securities system, dividends are paid by account transfers to the accounts of the shareholders appearing in the register. Dividend entitlement lapses after three years if a dividend remains unclaimed for that period, in which case the unclaimed dividend will be retained by us.

Delaware. Under the DGCL, a Delaware corporation may pay dividends out of its surplus (the excess of net assets over capital), or in case there is no surplus, out of its net profits for the fiscal year in which the dividend is declared and/or the preceding fiscal year (provided that the amount of the capital of the corporation is not less than the aggregate amount of the capital represented by the issued and outstanding stock of all classes having a preference upon the distribution of assets). In determining the amount of surplus of a Delaware corporation, the assets of the corporation, including stock of subsidiaries owned by the corporation, must be valued at their fair market value as determined by the board of directors, without regard to their historical book value. Dividends may be paid in the form of common stock, property or cash.

Shareholder Vote on Certain Reorganizations

Finland. Under the Finnish Companies Act, a resolution approved by at least a two-thirds majority of the votes cast and shares represented at a general meeting of shareholders is generally necessary to approve a merger or a demerger. However, in the surviving company, the board of directors can make a decision on a merger unless (i) the surviving company holds less than nine-tenths of the shares in the merger and (ii) shareholders with at least one-twentieth of the shares in the surviving company request that the decision is taken by the general meeting of shareholders.

There is no specific requirement in the Finnish Companies Act which provide for a shareholder vote on a sale of all or substantially all of the assets of a company. However, a company may include a provision in its articles of association relating to any corporate action under which a higher majority of any class of shares is required than would otherwise be the case for.

Delaware. Under the DGCL, the vote of a majority of the outstanding shares of capital stock entitled to vote thereon generally is necessary to approve a merger or consolidation or the sale of all or substantially all of the assets of a corporation. The DGCL permits a corporation to include in its certificate of incorporation a provision requiring for any corporate action the vote of a larger portion of the stock or of any class or series of stock than would otherwise be required.

Under the DGCL, no vote of the stockholders of a surviving corporation to a merger is needed, however, unless required by the certificate of incorporation, if (i) the agreement of merger does not amend in any respect the certificate of incorporation of the surviving corporation, (ii) the shares of stock of the surviving corporation are not changed in the merger and (iii) the number of shares of common stock of the surviving corporation into which any other shares, securities or obligations to be issued in the merger may be converted does not exceed 20% of the surviving corporation's common stock outstanding immediately prior to the effective date of the merger. In addition, stockholders may not be entitled to vote in certain mergers with other corporations that own 90% or more of the outstanding shares of each class of stock of such corporation, but the stockholders will be entitled to appraisal rights.

DESCRIPTION OF AMERICAN DEPOSITARY SHARES

American Depositary Shares

The Bank of New York Mellon, as depositary, will register and deliver American Depositary Shares, also referred to as ADSs. Each ADS will represent 80 shares (or a right to receive 80 shares) deposited with Nordea Bank Finland plc, as custodian for the depositary in Finland. Each ADS will also represent any other securities, cash or other property which may be held by the depositary. The depositary's office at which the ADSs will be administered is located at 101 Barclay Street, New York, New York 10286. The principal executive office of The Bank of New York Mellon is located at One Wall Street, New York, New York 10286.

You may hold ADSs either (A) directly (i) by having an American Depositary Receipt, also referred to as an ADR, which is a certificate evidencing a specific number of ADSs, registered in your name, or (ii) by having uncertificated ADSs registered in your name, or (B) indirectly by holding a security entitlement in ADSs through your broker or other financial institution that is a direct or indirect participant in The Depositary Trust Company, or DTC. If you hold ADSs directly, you are a registered ADS holder, also referred to as an ADS holder. This description assumes you are an ADS holder. If you hold the ADSs indirectly, you must rely on the procedures of your broker or other financial institution to assert the rights of ADS holders described in this section. You should consult with your broker or financial institution to find out what those procedures are.

As an ADS holder, we will not treat you as one of our shareholders and you will not have shareholder rights. Finnish law governs shareholder rights. The depositary will be the holder of the shares underlying your ADSs. As a registered holder of ADSs, you will have ADS holder rights. A deposit agreement among us, the depositary, ADS holders and all other persons indirectly or beneficially holding ADSs sets out ADS holder rights as well as the rights and obligations of the depositary. New York law governs the deposit agreement and the ADSs. In the event of any discrepancy between the ADRs and the deposit agreement, the deposit agreement governs.

The ADSs will be registered with the SEC on Form F-6 (File no. 333-204707) and the form deposit agreement will be filed as an exhibit to such registration statement and to this registration statement.

Registered holders of uncertificated ADSs will receive statements from the depositary confirming their holdings.

The following is a summary of the material provisions of the deposit agreement. For more complete information, you should read the entire deposit agreement and the form of ADR. See "Where You Can Find More Information" for directions on how to obtain copies of those documents.

Dividends and Other Distributions

How will you receive dividends and other distributions on the shares?

The depositary has agreed to pay or distribute to ADS holders the cash dividends or other distributions it or the custodian receives on shares or other deposited securities, after deducting its fees and expenses. You will receive these distributions in proportion to the number of shares your ADSs represent.

Cash. The depositary will convert any cash dividend or other cash distribution we pay on the shares into U.S. dollars, if it can do so on a reasonable basis and can transfer the U.S. dollars to the United States. If that is not possible or if any government approval is needed and cannot be obtained, the deposit agreement allows the depositary to distribute the foreign currency only to those ADS holders to whom it is possible to do so. It will hold the foreign currency it cannot convert for the account of the ADS holders who have not been paid. It will not invest the foreign currency and it will not be liable for any interest.

Before making a distribution, any withholding taxes, or other governmental charges that must be paid will be deducted. See “Taxation.” It will distribute only whole U.S. dollars and cents and will round fractional cents to the nearest whole cent. *If the exchange rates fluctuate during a time when the depositary cannot convert the foreign currency, you may lose some or all of the value of the distribution.*

Shares. The depositary may distribute additional ADSs representing any shares we distribute as a dividend or free distribution. It may sell shares which would require it to deliver a fraction of an ADS (or ADSs representing those shares) and distribute the net proceeds in the same way as it does with cash. If the depositary does not distribute additional ADSs, the outstanding ADSs will also represent the new shares. The depositary may sell a portion of the distributed shares (or ADSs representing those shares) sufficient to pay its fees and expenses in connection with that distribution. The depositary may withhold any distribution of ADSs if it has not received satisfactory assurances from us that the distribution does not require registration under the Securities Act.

Rights to purchase additional shares. If we offer holders of our securities any rights to subscribe for additional shares or any other rights, the depositary may (i) exercise those rights on behalf of ADS holders, (ii) distribute those rights to ADS holders or (iii) sell those rights and distribute the net proceeds to ADS holders, in each case after deduction or upon payment of its fees and expenses. To the extent the depositary does not do any of those things, it will allow the rights to lapse. *In that case, you will receive no value for them.* The depositary will exercise or distribute rights only if we ask it to and if satisfactory assurances are provided to the depositary that it is legal to do so. If the depositary will exercise rights, it will purchase the securities to which the rights relate and distribute those securities or, in the case of shares, new ADSs representing the new shares, to subscribing ADS holders, but only if ADS holders have paid the exercise price to the depositary. U.S. securities laws may restrict the ability of the depositary to distribute rights or ADSs or other securities issued on exercise of rights to all or certain ADS holders, and the securities distributed may be subject to restrictions on transfer. For example, you may not be able to trade these ADSs freely in the United States. In this case, the depositary may deliver restricted depositary shares that have the same terms as the ADSs described in this section except for changes needed to put the necessary restrictions in place.

Other Distributions. The depositary will send to ADS holders anything else we distribute on deposited securities by any means it thinks is legal, fair and practical. If it cannot make the distribution in that way, the depositary has a choice. It may decide to sell what we distributed and distribute the net proceeds, in the same way as it does with cash. Or, it may decide to hold what we distributed, in which case ADSs will also represent the newly distributed property. However, the depositary is not required to distribute any securities (other than ADSs) to ADS holders unless it receives satisfactory evidence from us that it is legal to make that distribution under the Securities Act. The depositary may sell a portion of the distributed securities or property sufficient to pay its fees and expenses in connection with that distribution. U.S. securities laws may restrict the ability of the depositary to distribute securities to all or certain ADS holders, and the securities distributed may be subject to restrictions on transfer.

The depositary is not responsible if it decides that it is unlawful or impractical to make a distribution available to any ADS holders. We have no obligation to register ADSs, shares, rights or other securities under the Securities Act. We also have no obligation to take any other action to permit the distribution of ADSs, shares, rights or anything else to ADS holders. *This means that you may not receive the distributions we make on our shares or any value for them if it is illegal or impractical for us to make them available to you.*

Deposit, Withdrawal and Cancellation

How are ADSs issued?

The depositary will deliver ADSs if you or your broker deposits shares or evidence of rights to receive shares with the custodian and upon notification by the custodian to the depositary of such deposit and the person or persons to whom or upon whose written order ADSs are deliverable in respect thereof. Upon payment of its fees and expenses and of any taxes or charges, such as stamp taxes or share transfer taxes or fees, the depositary will register the appropriate number of ADSs in the names you request and will deliver the ADSs to or upon the order of the person or persons that made the deposit.

How can ADS holders withdraw the deposited securities?

You may surrender your ADSs for the purpose of withdrawal at the depositary's office. Upon payment of its fees and expenses and of any taxes or charges, such as stamp taxes or share transfer taxes or fees, the depositary will deliver the shares and any other deposited securities underlying the ADSs to the ADS owner or a person the ADS holder designates at the office of the custodian. Or, at your request, risk and expense, the depositary will deliver the deposited securities at its office, if feasible may charge you a fee and its expenses for instructing the custodian regarding delivery of deposited securities.

How do ADS holders interchange between certificated ADSs and uncertificated ADSs?

You may surrender your ADR to the depositary for the purpose of exchanging your ADR for uncertificated ADSs. The depositary will cancel that ADR and will send to the ADS holder a statement confirming that the ADS holder is the registered holder of the uncertificated ADSs. Alternatively, upon receipt by the depositary of a proper instruction from a registered holder of uncertificated ADSs requesting the exchange of uncertificated ADSs for certificated ADSs, the depositary will execute and deliver to the ADS holder an ADR evidencing those ADSs.

Voting Rights

How do you vote?

ADS holders may instruct the depositary how to vote the number of deposited shares their ADSs represent. If we request the depositary to solicit voting instructions (and we are not required to do so), the depositary will notify ADS holders of a shareholders' meeting and send or make voting materials available to such holder. Those materials will describe the matters to be voted on and explain how ADS holders may instruct the depositary how to vote. For instructions to be valid, they must reach the depositary by a date set by the depositary. The depositary will try, as far as practical, subject to the laws of Finland and the provisions of our articles of association or similar documents, to vote or to have its agents vote the shares or other deposited securities as instructed by ADS holders. If we do not request that the depositary solicit voting instructions, ADS holders can still send voting instructions, and, in that case, the depositary may try to vote as instructed, but it is not required to do so.

Except by instructing the depositary as described above, you won't be able to exercise voting rights unless you surrender your ADSs and withdraw the shares. However, you may not know about the meeting enough in advance to withdraw the shares. In any event, the depositary will not exercise any discretion in voting deposited securities and it will only vote or attempt to vote as instructed or as described in the following sentence. If we asked the depositary to solicit your instructions at least 30 days before the meeting date but the depositary does not receive voting instructions from you by the specified date, it will consider you to have authorized and directed it to give a discretionary proxy to a person designated by us to

vote the number of deposited securities represented by your ADSs. The depositary will give a discretionary proxy in those circumstances to vote on all questions at to be voted upon unless we notify the depositary that:

- we do not wish to receive a discretionary proxy;
- there is substantial shareholder opposition to the particular question; or
- the particular question would have an adverse impact on our shareholders.

We are required to notify the depositary if one of the conditions specified above exists.

We cannot assure you that you will receive the voting materials in time to ensure that you can instruct the depositary to vote your shares. In addition, the depositary and its agents are not responsible for failing to carry out voting instructions or for the manner of carrying out voting instructions. *This means that you may not be able to exercise voting rights and there may be nothing you can do if your shares are not voted as you requested.*

If we request the depositary to act, we agree to give the depositary notice of any such meeting and details concerning the matters to be voted upon as far in advance of the meeting date as practical.

Fees and Expenses

Persons depositing or withdrawing shares or ADS holders must pay:

\$5.00 (or less) per 100 ADSs (or portion of 100 ADSs)

\$0.05 (or less) per ADS

A fee equivalent to the fee that would be payable if securities distributed to you had been shares and the shares had been deposited for issuance of ADSs

\$0.05 (or less) per ADS per calendar year

Registration or transfer fees

Expenses of the depositary

For:

- Issuance of ADSs, including issuances resulting from a distribution of shares or rights or other property
- Cancellation of ADSs for the purpose of withdrawal, including if the deposit agreement terminates
- Any cash distribution to ADS holders
- Distribution of securities distributed to holders of deposited securities (including rights) that are distributed by the depositary to ADS holders
- Depositary services
- Transfer and registration of shares on our share register to or from the name of the depositary or its agent when you deposit or withdraw shares
- Cable, telex and facsimile transmissions (when expressly provided in the deposit agreement)
- Converting foreign currency to U.S. dollars

Taxes and other governmental charges the depositary or the custodian has to pay on any ADSs or shares underlying ADSs, such as share transfer taxes, stamp duty or withholding taxes	As necessary
Any charges incurred by the depositary or its agents for servicing the deposited securities	As necessary

The depositary collects its fees for delivery and surrender of ADSs directly from investors depositing shares or surrendering ADSs for the purpose of withdrawal or from intermediaries acting for them. The depositary collects fees for making distributions to investors by deducting those fees from the amounts distributed or by selling a portion of distributable property to pay the fees. The depositary may collect its annual fee for depositary services by deduction from cash distributions or by directly billing investors or by charging the book-entry system accounts of participants acting for them. The depositary may collect any of its fees by deduction from any cash distribution payable (or by selling a portion of securities or other property distributable) to ADS holders that are obligated to pay those fees. The depositary may generally refuse to provide fee-attracting services until its fees for those services are paid.

From time to time, the depositary may make payments to us to reimburse us for costs and expenses generally arising out of the establishment or maintenance of the ADS program, waive fees and expenses for services provided to us by the depositary or share revenue from the fees collected from ADS holders. In performing its duties under the deposit agreement, the depositary may use brokers, dealers or other service providers that are affiliates of the depositary and that may earn or share fees or commissions.

The depositary may convert foreign currency itself or through any of its affiliates and, in those cases, acts as principal for its own account and not as an agent, fiduciary or broker on behalf of any other person and earns revenue, including, without limitation, fees and spreads that it will retain for its own account. The depositary makes no representation that the exchange rate used or obtained in any currency conversion will be the most favorable rate that could be obtained at the time or as to the method by which that rate will be determined, subject to its obligations under the deposit agreement.

Payment of Taxes

You will be responsible for any taxes or other governmental charges payable on your ADSs or on the deposited securities represented by any of your ADSs. The depositary may refuse to register any transfer of your ADSs or allow you to withdraw the deposited securities represented by your ADSs until those taxes or other charges are paid. It may apply payments owed to you or sell deposited securities represented by your ADSs to pay any taxes owed and you will remain liable for any deficiency. If the depositary sells deposited securities, it will, if appropriate, reduce the number of ADSs to reflect the sale and pay to ADS holders any proceeds, or send to ADS holders any property, remaining after it has paid the taxes.

Tender and Exchange Offers; Redemption, Replacement or Cancellation of Deposited Securities

The depositary will not tender deposited securities in any voluntary tender or exchange offer unless instructed to do so by an ADS holder surrendering ADSs and subject to any condition or procedures the depositary may establish.

If deposited securities are redeemed for cash in a transaction that is mandatory for the depositary as a holder of deposited securities, the depositary will call for surrender of a corresponding number of ADSs and distribute the net redemption money to the holders of called ADSs upon surrender of those ADSs.

If there is any change in the deposited securities such as a sub-division, combination or other reclassification, or any merger, consolidation, recapitalization or reorganization affecting the issuer of deposited securities in which the depositary receives new securities in exchange for or in lieu of the old deposited securities, the depositary will hold those replacement securities as deposited securities under the deposit agreement. However, if the depositary decides it would not be lawful and practical to hold the replacement securities because those securities could not be distributed to ADS holders or for any other reason, the depositary may instead sell the replacement securities and distribute the net proceeds upon surrender of the ADSs.

If there is a replacement of the deposited securities and the depositary will continue to hold the replacement securities, the depositary may distribute new ADSs representing the new deposited securities or ask you to surrender your outstanding ADRs in exchange for new ADRs identifying the new deposited securities.

If there are no deposited securities underlying ADSs, including if the deposited securities are cancelled, or if the deposited securities underlying ADSs have become apparently worthless, the depositary may call for surrender of those ADSs or cancel those ADSs upon notice to the ADS holders.

Amendment and Termination

How may the deposit agreement be amended?

We may agree with the depositary to amend the deposit agreement and the ADRs without your consent for any reason. If an amendment adds or increases fees or charges, except for taxes and other governmental charges or expenses of the depositary for registration fees, facsimile costs, delivery charges or similar items, or prejudices a substantial right of ADS holders, it will not become effective for outstanding ADSs until 30 days after the depositary notifies ADS holders of the amendment. *At the time an amendment becomes effective, you are considered, by continuing to hold your ADSs, to agree to the amendment and to be bound by the ADRs and the deposit agreement as amended.*

How may the deposit agreement be terminated?

The depositary will initiate termination of the deposit agreement if we instruct it to do so. The depositary may initiate termination of the deposit agreement if:

- 60 days have passed since the depositary told us it wants to resign but a successor depositary has not been appointed and accepted its appointment;
- we delist the ADSs from an exchange on which they were listed and do not list the ADSs on another exchange;
- we appear to be insolvent or enter insolvency proceedings;
- all or nearly all the value of the deposited securities has been distributed either in cash or in the form of securities;
- there are no deposited securities underlying the ADSs or the underlying deposited securities have become apparently worthless; or
- there has been a replacement of deposited securities.

If the deposit agreement will terminate, the depositary will notify ADS holders at least 90 days before the termination date. At any time after the termination date, the depositary may sell the deposited securities. After that, the depositary will hold the money it received on the sale, as well as any other cash it is holding

under the deposit agreement, unsegregated and without liability for interest, for the pro rata benefit of the ADS holders that have not surrendered their ADSs. Normally, the depositary will sell as soon as practicable after the termination date.

After the termination date and before the depositary sells, ADS holders can still surrender their ADSs and receive delivery of deposited securities, except that the depositary may refuse to accept a surrender for the purpose of withdrawing deposited securities if it would interfere with the selling process. The depositary may refuse to accept a surrender for the purpose of withdrawing sale proceeds until all the deposited securities have been sold. The depositary will continue to collect distributions on deposited securities, but, after the termination date, the depositary is not required to register any transfer of ADSs or distribute any dividends or other distributions on deposited securities to the ADSs holder (until they surrender their ADSs) or give any notices or perform any other duties under the deposit agreement except as described in this paragraph.

Limitations on Obligations and Liability

Limits on our Obligations and the Obligations of the Depositary; Limits on Liability to Holders of ADSs

The deposit agreement expressly limits our obligations and the obligations of the depositary. It also limits our liability and the liability of the depositary. We and the depositary:

- are only obligated to take the actions specifically set forth in the deposit agreement without negligence or bad faith;
- are not liable if we are or it is prevented or delayed by law or circumstances beyond our or its control from performing our or its obligations under the deposit agreement;
- are not liable if we or it exercises discretion permitted under the deposit agreement;
- are not liable for the inability of any holder of ADSs to benefit from any distribution on deposited securities that is not made available to holders of ADSs under the terms of the deposit agreement, or for any special, consequential or punitive damages for any breach of the terms of the deposit agreement;
- have no obligation to become involved in a lawsuit or other proceeding related to the ADSs or the deposit agreement on your behalf or on behalf of any other person;
- are not liable for the acts or omissions of any securities depositary, clearing agency or settlement system; and
- may rely upon any documents we believe or it believes in good faith to be genuine and to have been signed or presented by the proper person.

In the deposit agreement, we and the depositary agree to indemnify each other under certain circumstances.

Requirements for Depositary Actions

Before the depositary will deliver or register a transfer of ADSs, make a distribution on ADSs, or permit withdrawal of shares, the depositary may require:

- payment of share transfer or other taxes or other governmental charges and transfer or registration fees charged by third parties for the transfer of any shares or other deposited securities;

- satisfactory proof of the identity and genuineness of any signature or other information it deems necessary; and
- compliance with regulations it may establish, from time to time, consistent with the deposit agreement, including presentation of transfer documents.

The depositary may refuse to deliver ADSs or register transfers of ADSs when the transfer books of the depositary or our transfer books are closed or at any time if the depositary or we think it advisable to do so.

Your Right to Receive the Shares Underlying Your ADSs

ADS holders have the right to cancel their ADSs and withdraw the underlying shares at any time except:

- when temporary delays arise because: (i) the depositary has closed its transfer books or we have closed our transfer books; (ii) the transfer of shares is blocked to permit voting at a shareholders' meeting; or (iii) we are paying a dividend on our shares;
- when you owe money to pay fees, taxes and similar charges; or
- when it is necessary to prohibit withdrawals in order to comply with any laws or governmental regulations that apply to ADSs or to the withdrawal of shares or other deposited securities.

This right of withdrawal may not be limited by any other provision of the deposit agreement.

Pre-release of ADSs

The deposit agreement permits the depositary to deliver ADSs before deposit of the underlying shares. This is called a pre-release of the ADSs. The depositary may also deliver shares upon cancellation of pre-released ADSs (even if the ADSs are canceled before the pre-release transaction has been closed out). A pre-release is closed out as soon as the underlying shares are delivered to the depositary. The depositary may receive ADSs instead of shares to close out a pre-release. The depositary may pre-release ADSs only under the following conditions: (1) before or at the time of the pre-release, the person to whom the pre-release is being made (i) represents to the depositary in writing that it or its customer beneficially owns the shares or ADSs to be deposited, (ii) assigns all beneficial rights, title and interest in the ADSs to the depositary and (iii) will not take any action with respect to the ADSs that is inconsistent with the transfer of beneficial ownership; (2) the pre-release is fully collateralized with cash or other collateral that the depositary considers appropriate; and (3) the depositary must be able to close out the pre-release on not more than five business days' notice. In addition, the depositary will limit the number of ADSs that may be outstanding at any time as a result of pre-release, although the depositary may disregard the limit from time to time if it thinks it is appropriate to do so.

Direct Registration System

In the deposit agreement, all parties to the deposit agreement acknowledge that the Direct Registration System, also referred to as DRS, and Profile Modification System, also referred to as Profile, will apply to the ADSs. DRS is a system administered by DTC that facilitates interchange between registered holding of uncertificated ADSs and holding of security entitlements in ADSs through DTC and a DTC participant. Profile is feature of DRSs that allows a DTC participant, claiming to act on behalf of a registered holder of uncertificated ADSs, to direct the depositary to register a transfer of those ADSs to DTC or its nominee and to deliver those ADSs to the DTC account of that DTC participant without receipt by the depositary of prior authorization from the ADS holder to register that transfer.

In connection with and in accordance with the arrangements and procedures relating to DRS/Profile, the parties to the deposit agreement understand that the depositary will not determine whether the DTC participant that is claiming to be acting on behalf of an ADS holder in requesting registration of transfer and delivery as described in the paragraph above has the actual authority to act on behalf of the ADS holder (notwithstanding any requirements under the Uniform Commercial Code). In the deposit agreement, the parties agree that the depositary's reliance on and compliance with instructions received by the depositary through the DRS/Profile System and in accordance with the deposit agreement will not constitute negligence or bad faith on the part of the depositary.

Shareholder Communications; Inspection of Register of Holders of ADSs

The depositary will make available for your inspection at its office all communications that it receives from us as a holder of deposited securities that we make generally available to holders of deposited securities. The depositary will send you copies of those communications or otherwise make those communications available to you if we ask it to. You have a right to inspect the register of holders of ADSs, but not for the purpose of contacting those holders about a matter unrelated to our business or the ADSs.

SHARES AND AMERICAN DEPOSITARY SHARES ELIGIBLE FOR FUTURE SALE

Prior to this offering, no public market existed in the United States for our shares or the ADSs and we cannot assure you that a significant public market for the ADSs will be sustained after this offering. Future sales of the ADSs in the public market after this offering and the availability of the ADSs for future sale could adversely affect the market price of the ADSs prevailing from time to time. As described below, certain of our shares currently outstanding will not be available for sale shortly after this offering due to contractual restrictions on transfers of shares. However, sales of substantial numbers of ADSs or shares, or the perception that these sales could occur, could adversely affect prevailing market prices for the ADSs and could impair our future ability to raise equity capital.

Upon completion of this offering, we will have 977,281,615 shares outstanding, including 220,400,001 shares to be issued by us upon the automatic conversion of all outstanding convertible notes issued in connection with the Convertible Notes Financings upon the completion of this offering (or 980,851,935 shares if the underwriters exercise in full their option to purchase up to 44,629 additional ADSs in connection with the offering).

All of the ADSs sold in this offering will be freely tradable without restrictions or further registration under the Securities Act, except for any ADSs sold to our “affiliates,” as that term is defined under Rule 144 under the Securities Act. Restricted securities may be sold in the United States on the NASDAQ only if registered or if their resale qualifies for exemption from registration described below under Rule 144 or 701 promulgated under the Securities Act. The restricted shares may also be sold outside of the United States in accordance with Regulation S of the Securities Act.

Taking into account the lock-up agreements described below, and assuming the underwriters do not release any shareholders from these agreements earlier than scheduled, our shares (including shares represented by ADSs) will be available for sale in the public market as follows:

- 3,761,418 ADSs representing 300,913,440 shares will be eligible for immediate sale on the public market to the extent they are not purchased by our affiliates; and
- approximately 278,130,843 shares that are held by current shareholders may be deposited for ADSs that will be eligible for immediate sale on the public market, as well as 41,566,710 shares held by the selling shareholder, to the extent the underwriters do not exercise their option to purchase additional shares within 30 days of the date of this prospectus.

Lock-up Agreements

All of our directors and officers and certain of our shareholders and security-holders who own over 29.3% of the outstanding shares existing prior to this offering (52.4% after giving effect to the automatic conversion of all outstanding convertible notes issued in connection with the Convertible Notes Financings into shares upon the completion of this offering) are subject to lock-up restrictions pursuant to which they may not offer, sell, contract to sell (including any short sale), pledge, hypothecate, establish an open “put equivalent position” within the meaning of Rule 16a-1(h) under the Exchange Act, grant any option, right or warrant for the sale of, purchase any option or contract to sell, sell any option or contract to purchase or otherwise encumber, dispose of or transfer, grant any rights with respect to, directly or indirectly, any shares, ADSs or other share capital or securities convertible into or exchangeable for shares, ADSs or other

share capital, enter into a transaction which would have the same effect or other arrangement that transfers, in whole or in part, any of the economic consequences of ownership of the shares, ADSs or other share capital, whether such aforementioned transaction is to be settled by delivery of the shares or ADSs or such other securities, in cash or otherwise, or publicly disclose the intention to make any such offer, sale, pledge or disposition, or to enter into any such transaction, swap hedge or other arrangement without, in each case, the prior written consent of RBC Capital Markets, LLC and Stifel, Nicolaus & Company, Incorporated for a period of 180 days after the date of this prospectus, subject to specified limited exceptions. The selling shareholder shares are subject to the same restrictions for 30 days after the date of this prospectus, except to the extent that such shares are sold to the underwriters in connection with this offering. RBC Capital Markets, LLC and Stifel, Nicolaus & Company, Incorporated, in their sole discretion, may release any of the securities subject to these restrictions at any time, which, in the case of officers and directors, shall be with notice. For more information, see “Underwriting.”

Rule 144

Affiliate Resales of Restricted Securities

In general, beginning 90 days after the effective date of the registration statement of which this prospectus is a part, a person who is an affiliate of ours, or who was an affiliate at any time during the 90 days before a sale, who has beneficially owned part of our shares for at least six months would be entitled to sell in “broker’s transactions” or certain “riskless principal transactions” or to market makers, a number of shares within any three-month period that does not exceed the greater of:

- 1% of the number of our shares then outstanding, which will equal approximately 9,772,816 shares immediately after this offering; or
- the average weekly trading volume in the ADSs on the NASDAQ during the four calendar weeks preceding the filing of a notice on Form 144 with respect to such sale.

Affiliate resales under Rule 144 also are subject to the availability of current public information about us. In addition, if the number of securities being sold under Rule 144 by an affiliate during any three-month period exceeds 5,000 securities or has an aggregate sale price in excess of \$50,000, the seller must file a notice on Form 144 with the SEC and the NASDAQ concurrently with either the placing of a sale order with the broker or the execution directly with a market maker.

Nonaffiliate Resales of Restricted Securities

In general, beginning 90 days after the effective date of the registration statement of which this prospectus is a part, a person who is not an affiliate of ours at the time of sale, and has not been an affiliate at any time during the three months preceding a sale, and who has beneficially owned our shares for at least six months but less than a year, is entitled to sell such securities subject only to the availability of current public information about us. If such person has held our shares for at least one year, such person can resell under Rule 144(b)(1) without regard to any Rule 144 restrictions, including the 90-day public company requirement and the current public information requirement.

Nonaffiliate resales are not subject to the manner of sale, volume limitation or notice filing provisions of Rule 144.

Rule 701

In general, under Rule 701, any of our employees, directors, officers, consultants or advisors who purchases shares from us in connection with a compensatory stock or option plan or other written agreement

before the effective date of a registration statement under the Securities Act is entitled to sell such shares 90 days after such effective date in reliance on Rule 144. A person who is an affiliate of ours can resell shares in reliance on Rule 144 without having to comply with the holding period requirement, and a person who is not an affiliate of ours can resell shares in reliance on Rule 144 without having to comply with the current public information and holding period requirements.

The SEC has indicated that Rule 701 will apply to typical stock options granted by an issuer before it becomes subject to the reporting requirements of the Exchange Act, along with the shares acquired upon exercise of such options, including exercises after an issuer becomes subject to the reporting requirements of the Exchange Act.

Form S-8 Registration Statement

After the completion of this offering, we intend to file one or more registration statements on Form S-8 under the Securities Act covering our shares subject to outstanding options and shares issuable under our share-based incentive schemes. We expect to file the registration statement covering shares offered pursuant to our share-based incentive schemes on or shortly after the date of this prospectus, permitting the resale of such shares by nonaffiliates in the public market without restriction under the Securities Act and the sale by affiliates in the public market, subject to compliance with the resale provisions of Rule 144. Accordingly, our shares registered under any such registration statement will be available for sale in the open market upon exercise by the holders, subject to vesting and holding restrictions, as applicable, Rule 144 limitations applicable to our affiliates and the contractual lock-up provisions described above.

Registration Rights Agreement

We and certain of the subscribers for our convertible notes and recipients of warrants issued in connection with the Convertible Notes Financings have entered into a registration rights agreement. Pursuant to the registration rights agreement, we have agreed under certain circumstances to file a registration statement to register the resale of the shares or ADS held by such security-holders, including shares issuable upon exercise of the warrants, as well as to cooperate in certain public offerings of such shares or ADSs. Registration of these shares or ADSs under the Securities Act would result in these shares or ADSs becoming freely tradable without restriction immediately upon the registered sale of such shares or ADSs. We have also agreed to reimburse the parties to the registration rights agreement for certain expenses incurred in connection with the filing of any registration statement and the marketing of any securities registered pursuant to the registration rights agreement.

Regulation S

Regulation S provides generally that sales made in offshore transactions are not subject to the registration or prospectus delivery requirements of the Securities Act. Accordingly, restricted securities may be sold in offshore transactions in compliance with Regulation S.

TAXATION

The following summary contains a description of certain Finnish and United States federal income tax consequences of the acquisition, ownership and disposition of ADSs, but it does not purport to be a comprehensive description of all the tax considerations that may be relevant to a decision to purchase ADSs. The summary is based upon the tax laws of Finnish and regulations thereunder and on the tax laws of the United States and regulations thereunder as of the date hereof, which are subject to change.

Finnish Tax Considerations

The following is a description of Finnish income and transfer tax consequences. The description below only addresses Finnish tax legislation and does not take into account the tax laws of any other countries. The following does not address tax consequences applicable to shareholders that may be subject to special tax rules. Such shareholders include, among others, business entities exempt from income tax and general or limited partnerships. Furthermore, this description does not address the tax consequences of Finnish resident shareholders in controlled foreign corporations in Finland or Finnish inheritance tax nor gift tax consequences.

This description is based on:

- The Finnish Income Tax Act (1535/1992, as amended);
- The Finnish Business Income Tax Act (360/1968, as amended);
- The Finnish Act on the Taxation of Nonresidents' Income (627/1978, as amended); and
- The Finnish Transfer Tax Act (931/1996, as amended).

In addition, case law and any decisions and statements made by the tax authorities in effect and available on the date of this prospectus have also been taken into account. Tax legislation, case law and statements given by the tax authorities are subject to change, which could also have retroactive effects.

General

The scope of taxation in Finland is defined by the tax liability position of a taxpayer. The worldwide income of persons resident in Finland is subject to taxation in Finland. Nonresidents are taxed only on Finnish-source income. In addition, all income of nonresidents derived from a permanent establishment located in Finland will be taxed in Finland. Tax treaties binding on Finland may restrict the applicability of the Finnish internal tax legislation and prevent the Finnish taxation of income derived by a nonresident.

Generally, a natural person is deemed a resident in Finland for tax purposes if the person stays in Finland for more than six consecutive months or if the permanent home and domicile of the person is in Finland. A Finnish citizen is deemed a resident in Finland for tax purposes during the year he or she has emigrated from Finland and three subsequent years unless he or she proves that no essential ties to Finland existed during the relevant tax year. Earned income is taxed at progressive tax rates, while capital income up to €30,000 is taxed at a rate of 30% and capital income exceeding €30,000 at a rate of 33%. Corporate entities established under the laws of Finland are regarded as residents of Finland and thus subject to corporate income tax on their worldwide income. The current corporate income tax rate in Finland is 20%.

The following is a summary of certain Finnish tax consequences relating to the subscription, ownership and disposition of our shares and ADSs by Finnish resident and nonresident shareholders.

Taxation of Finnish Corporations

Dividends

The tax treatment of dividends distributed by a company listed on the Finnish Stock Exchange or on another regulated market according to Section 33a (2) of the Income Tax Act, or the listed company, varies depending on whether the Finnish company receiving the dividend is a listed company or a nonlisted company.

Dividends received by a listed company from another listed company resident in a member state of the European Economic Area are generally exempt from tax. However, in the event that the underlying Finnish shares belong to the investment assets of such a shareholder, 75% of the dividend received by the listed company is taxable income and 25% is tax exempt income. Only financial, insurance and pension institutions may have investment assets. The effective tax rate in these situations is 15%.

If the recipient is a nonlisted company, the dividends it receives are fully taxable income if such a shareholder does not directly own at least 10% of the share capital of the distributing company. If the direct ownership is at least 10% when the dividend is distributed, the dividend received on such shares is tax exempt. However, if a nonlisted company receives a dividend from the shares of a Finnish company included in its investment assets, 75% of the dividend is taxable income and 25% is tax exempt regardless of the ownership threshold.

Capital Gains or Losses

Finnish corporations are subject to national corporate income tax on their worldwide income. Any capital gains from the sale of shares are generally regarded as taxable income arising from business activities or other activities of a Finnish resident corporation. The taxable income of a Finnish corporation is determined separately for business activities and for other activities. Income from both sources is taxed according to a fixed rate which currently is 20%.

The capital gain (as well as capital loss) is calculated by deducting the total sum of the actual acquisition cost and selling cost from the transfer price. The acquisition cost of shares sold is thus deductible from the income of the source to which the shares sold belonged.

Any capital loss arising from the sale of shares attributable to business activities is initially deductible from income in the business income source. Confirmed losses from business activities can be carried forward from the taxable income from business activities for ten years following the loss-making year. Capital losses attributable to other income can only be offset against capital gains arising from the same income source and can be carried forward only for the subsequent five tax years.

Despite the above, capital gains based on the disposal of shares in a limited liability company may be tax exempt for ordinary corporate entities provided, among other things, that the seller company has held the shares for at least one year continuously and that the seller company has owned at least 10% of our share capital and that the shares belong to the seller's fixed assets attributable to business activities. Capital losses relating to the disposals of shares entitled to this tax exemption will not be tax deductible. Capital losses arising from the disposal of shares, which belong to the seller's fixed assets, but do not qualify for tax exemption, are deductible only from capital gains arising from the disposal of shares in the same tax year and the subsequent five years.

Taxation of Finnish Resident Individuals

Dividends

Eighty-five percent of dividends received by a natural person resident in Finland from a listed company is taxable as capital income, whereas 15% is tax exempt income, provided that the shares do not belong to the assets of the individual's business activities. The current applicable tax rate is 30% for capital income of up to €30,000 and 33% for capital income exceeding €30,000.

When a listed company distributes dividends to individuals, the listed company is obligated to withhold advance tax on the dividend payments. On the date of this prospectus, the tax withholding is 25.5% of the amount of the dividend. The advance tax withheld by the distributing company is credited against the final tax payable for the tax year by the recipient of the dividend. Individuals must check from their pre-completed tax return that the dividend information is correct, and, when necessary, correct the right amount of dividends and tax withholding with the tax authorities.

Capital Gains and Losses

Capital gains arising from the sale of the shares are initially taxed as capital income for persons. Correspondingly, any loss arising from the sale of shares is deductible from capital gains. The current tax rate applied to such capital gains is 30% for capital income of up to €30,000 and 33% for capital income exceeding €30,000. However, capital gains are exempted from tax if the total amount of the transfer prices of the person's sold assets does not exceed €1,000 in a tax year. Capital losses arising from the sale of shares that do not belong to the business activities of the individual are only deductible only from capital gains arising in the same year or during the subsequent five years. Capital losses will not, however, be tax deductible if the total amount of the acquisition costs of the assets sold by the individual does not exceed €1,000 in a tax year.

Capital gains and losses are calculated as the difference between the transfer price and the aggregate of the actual acquisition cost and sales-related expenses. Alternatively, individuals may choose to apply the presumptive acquisition cost instead of the actual acquisition cost for the shares. As the presumptive acquisition cost, 20% is deducted from the transfer price but, if the shareholder has held the shares for at least ten years, the presumptive acquisition cost is 40% of the transfer price. If the presumptive acquisition cost is applied instead of the actual acquisition cost, all expenses arising from acquiring the gains are deemed to be included in the presumptive acquisition cost and, therefore, cannot be deducted separately from the transfer price.

Natural persons resident in Finland must enter information about the disposal of the shares during the tax year in their precompleted tax return.

Taxation of Nonresident Investors

Dividend

In connection with the payment of dividends from a Finnish company to a nonresident investor, the Finnish dividend payer is obliged to withhold withholding tax in connection with the payment of the dividend.

The current withholding tax rate applicable to dividends paid to nonresident natural persons of Finland is 30% and that applicable to dividends paid to nonresident corporate entities of Finland is currently 20%. The withholding tax may be reduced or removed pursuant to applicable tax treaty provisions.

Under the tax treaty in force between Finland and the U.S., or the Tax Treaty, dividends paid by a Finnish company to a U.S. tax resident recipient entitled to the benefits under the Tax Treaty are in general

subject to a withholding tax at a rate of 15%. For a qualifying shareholder that is a company owning directly at least 10% of the voting stock of the company paying the dividends, the applicable tax rate is 5%. Furthermore, dividends may under certain conditions be exempted from Finnish withholding taxation in case the U.S. resident recipient is a company that has owned shares representing 80% or more of the voting power in the company paying the dividends for a 12-month period ending on the date on which the entitlement to dividends is determined, or if the recipient is a U.S. resident pension fund fulfilling the criteria set in the Tax Treaty.

Furthermore, no withholding tax shall be levied on dividends paid to such corporate entities residing within the European Union, as defined in Article 2 of the Parent-Subsidiary Directive (90/435/EEC), if the recipient company directly holds at least 10% of the share capital of the dividend distributing Finnish company.

Nor is withholding tax levied in Finland from dividends to a nonresident entity distributed by a Finnish company, if (i) the entity receiving dividend resides in the European Economic Area; (ii) the Mutual Assistance Directive 2011/16/EU or an agreement on mutual assistance and information exchange in tax matters applies to the home state of the receiver of the dividend; and (iii) the company receiving a dividend is equivalent to a Finnish entity defined in the Finnish Income Tax Act, Section 33d, Subsection 4, or in Section 6a of the Finnish Business Income Tax Act; (iv) the dividend would be fully tax exempt if paid to a Finnish limited liability company; and (v) the entity establishes (with a certificate from the home member state's tax authority) that in accordance with the agreements on avoiding double taxation applicable in the home state of the recipient of dividends, the withholding tax cannot be reimbursed in full.

Notwithstanding the statements in the preceding paragraph, the dividend is only partly tax exempt if the shares in the distributing company belong to the investment assets of the recipient corporate entity, and that corporate entity does not directly hold at least 10% of the capital of the distributing company. In this case, the applicable withholding tax rate is currently 15%. A prerequisite for this tax treatment is that the recipient corporate entity has its registered office within the EEA and that mutual assistance between Finland and the country, in which the recipient corporate entity is registered, shall be organized in mutual assistance on tax matters in accordance with the Mutual Assistance Directive or a tax treaty.

Withholding tax is always levied on dividends paid on shares that are nominee-registered at a rate of at least 15%, or a higher percentage provided for in the applicable tax treaty, provided that, pursuant to the information duly ascertained by the payer, the recipient qualifies under the tax treaty provisions applicable to dividends. The recipient of dividends may, prior to the payment, provide the payer with an explanation of his or her domicile and the other requirements for the application of the tax treaty, in which case he or she may receive the dividend on the nominee- registered share at a lower tax rate pursuant to the applicable tax treaty.

If the recipient of the dividends is a nonresident natural person residing in the EEA, she or he can claim, provided that certain preconditions are met, that the taxation of dividends paid by a Finnish company is executed in accordance with the Finnish Tax Procedure Act (1558/1995, as amended) instead of withholding tax. A precondition is that the mutual assistance in tax matters between Finland and the recipient's country of residence is organized in accordance with the Mutual Assistance Directive or a tax treaty concerning executive and mutual assistance and, furthermore, that the Finnish withholding tax cannot, by virtue of provisions in the applicable tax treaty, be credited in its entirety in the country in which the recipient is residing.

Capital Gains and Losses

Investors that are not resident in Finland for tax purposes are not generally subject to Finnish tax on capital gains arising from the transfer of shares, unless the transfer of the shares relates to business activities carried out in Finland (through a permanent establishment) or more than 50% of the total assets of the transferred company consists of one or more real estate properties located in Finland.

Transfer Tax

Transfer tax is generally not payable on the transfer of shares subject to public trading on a regulated market or multilateral trading facility against fixed cash consideration on the condition that the broker or other party to the transaction is an investment firm, a foreign investment firm or other investment services provider as defined in the Finnish Act on Investment Services (747/2012, as amended) or the transferee has been approved as a trading party in the market where the transfer is executed. If the intermediary or other trading party is not a securities broker as defined in the Transfer Tax Act (i.e., the intermediary is a foreign broker that does not have a branch or office in Finland), the precondition for the tax exemption is that the transferee notifies the Finnish tax authorities of the transfer within two months of the transfer or that the intermediary submits an annual notification to the tax authorities pursuant to the Tax Procedure Act.

If the shares are to be transferred through a transaction other than that described above and either the seller or the buyer or both are resident in Finland, a transfer tax at the rate of 1.6% of the transfer price (2% on transfers of shares in a company qualified as a real estate company) is payable by the buyer. However, transfer tax of less than €10 does not have to be paid under Section 27 of the Transfer Tax Act. If the buyer is neither a resident of Finland nor a Finnish branch or office of a foreign credit institution, investment firm or fund company, the seller must collect the tax from the buyer. If neither of the parties to the transaction are resident in Finland or a Finnish branch or office of a foreign credit institution, investment firm or fund company, the transfer of shares will in general be exempt from Finnish transfer tax (transfers of qualified real estate companies are, however, subject to transfer tax).

Where a Finnish investment firm or credit institution or the Finnish branch or office of a foreign investment firm or credit institution is a party to or is used as a broker in the transaction, it is obliged to collect the possible transfer tax on behalf of the buyer and account the tax to the state.

No Finnish transfer tax is payable in connection with the issuance and subscription of new shares or ADSs.

It should be noted that the initial public offering of the ADSs is expected to be carried out as a sale of existing ADSs by the underwriters and not as an issue of new ADSs. Therefore, as no Finnish intermediary will be involved in the sale of the ADSs, any investors resident in Finland for tax purposes will have an obligation to file to the Finnish tax authorities the transfer tax notification referred to above. Such filing obligation does not exist with respect to investors not resident in Finland for tax purposes. Should an investor resident in Finland for tax purposes not comply with this filing obligation, the sale of ADSs will not qualify for the transfer tax exemption and Finnish transfer tax will be payable by the investor at a rate of 1.6%.

Material U.S. Federal Income Tax Considerations for U.S. Holders

In the opinion of Davis Polk & Wardwell LLP, the following is a description of the material U.S. federal income tax consequences to the U.S. Holders described below of owning and disposing of ADSs. It does not describe all tax considerations that may be relevant to a particular person's decision to acquire the ADSs. This discussion applies only to a U.S. Holder that holds ADSs as capital assets for tax purposes. In addition, it does not describe all of the tax consequences that may be relevant in light of the U.S. Holder's

particular circumstances, including federal, estate, gift or alternative minimum tax consequences, any state, local or non-U.S. tax consequences, the potential application of the provisions of the Code known as the Medicare contribution tax, and tax consequences applicable to U.S. Holders subject to special rules, such as:

- certain financial institutions;
- insurance companies;
- real estate investment trusts or regulated investment companies;
- dealers in securities;
- traders in securities who use a mark-to-market method of tax accounting;
- persons holding ADSs as part of a hedging transaction, straddle, wash sale, conversion transaction or integrated transaction or persons entering into a constructive sale with respect to the ADSs;
- persons whose functional currency for U.S. federal income tax purposes is not the U.S. dollar;
- entities classified as partnerships for U.S. federal income tax purposes or other pass-through entities;
- tax exempt entities, including an “individual retirement account” or “Roth IRA”;
- persons that own or are deemed to own 10% or more of our voting stock;
- persons holding ADSs in connection with a trade or business conducted outside of the United States;
- certain former citizens or long-term residents of the United States; or
- persons that receive our shares as compensation for the performance of services.

If an entity that is classified as a partnership for U.S. federal income tax purposes holds ADSs, the U.S. federal income tax treatment of a partner will generally depend on the status of the partner and the activities of the partnership. Partnerships holding ADSs and partners in such partnerships should consult their tax advisers as to the particular U.S. federal income tax consequences of owning and disposing of the ADSs.

This discussion is based on the Code, administrative pronouncements, judicial decisions, final, temporary and proposed Treasury regulations, and the income tax treaty between Finland and the United States, or the Tax Treaty, all as of the date hereof, any of which is subject to change or differing interpretations, possibly with retroactive effect. It is also based in part on representations by the depositary and assumes that each obligation under the deposit agreement and any related agreement will be performed in accordance with its terms.

For purposes of this discussion, “U.S. Holder” is a holder who, for U.S. federal income tax purposes, is a beneficial owner of ADSs who is eligible for the benefits of the Tax Treaty and is:

- a citizen or individual resident of the United States;
- a corporation, or other entity taxable as a corporation for U.S. federal income tax purposes, created or organized in or under the laws of the United States, any state therein or the District of Columbia; or
- an estate or trust the income of which is subject to U.S. federal income taxation regardless of its source.

In general, a U.S. Holder who owns ADSs will be treated as the owner of the underlying shares represented by those ADSs for U.S. federal income tax purposes. Accordingly, no gain or loss will be recognized if a U.S. Holder exchanges ADSs for the underlying shares represented by those ADSs.

The U.S. Treasury has expressed concern that parties to whom ADSs are released before shares are delivered to the depository, or pre-release, or intermediaries in the chain of ownership between holders and the issuer of the security underlying the ADSs, may be taking actions that are inconsistent with the claiming of foreign tax credits by U.S. Holders of ADSs. These actions would also be inconsistent with the claiming of the reduced rate of tax, described below, applicable to dividends received by certain noncorporate U.S. Holders. Accordingly, the creditability of Finnish withholding taxes, and the availability of the reduced tax rate for dividends received by certain noncorporate U.S. Holders, each described below, could be affected by actions taken by such parties or intermediaries.

U.S. Holders should consult their tax advisers concerning the U.S. federal, state, local and non-U.S. tax consequences of owning and disposing of ADSs in their particular circumstances.

Taxation of Distributions

Subject to the passive foreign investment company rules described below, distributions paid on ADSs, other than certain pro rata distributions of shares, will generally be treated as dividends to the extent paid out of our current or accumulated earnings and profits (as determined under U.S. federal income tax principles). For so long as the ADSs are readily tradable on an established securities market in the United States (such as the NASDAQ) or we are eligible for benefits under the Tax Treaty, dividends paid to certain noncorporate U.S. Holders will be eligible for taxation as “qualified dividend income” and therefore, subject to applicable limitations, will be taxable at rates not in excess of the long-term capital gain rate applicable to such U.S. Holder. U.S. Holders should consult their tax advisers regarding the availability of the reduced tax rate on dividends in their particular circumstances. The amount of a dividend will include any amounts withheld in respect of Finnish withholding taxes. The amount of the dividend will be treated as foreign-source dividend income to U.S. Holders and will not be eligible for the dividends-received deduction generally available to U.S. corporations under the Code. Dividends will be included in a U.S. Holder’s income on the date of the depository’s receipt of the dividend. The amount of any dividend income paid in euros will be the U.S. dollar amount calculated by reference to the exchange rate in effect on the date of actual or constructive receipt, regardless of whether the payment is in fact converted into U.S. dollars. If the dividend is converted into U.S. dollars on the date of receipt, a U.S. Holder should not be required to recognize foreign currency gain or loss in respect of the dividend income. A U.S. Holder may have foreign currency gain or loss if the dividend is converted into U.S. dollars after the date of receipt.

Subject to applicable limitations, some of which vary depending upon the U.S. Holder’s particular circumstances, and subject to the discussion above regarding concerns expressed by the U.S. Treasury, Finnish taxes withheld from dividends on ADSs at a rate not exceeding the rate provided by the Tax Treaty may be creditable against the U.S. Holder’s U.S. federal income tax liability. The rules governing foreign tax credits are complex and U.S. Holders should consult their tax advisers regarding the creditability of foreign taxes in their particular circumstances. In lieu of claiming a foreign tax credit, U.S. Holders may, at their election, deduct foreign taxes, including any Finnish withholding tax, in computing their taxable income, subject to generally applicable limitations under U.S. law. An election to deduct foreign taxes instead of claiming foreign tax credits applies to all foreign taxes paid or accrued in the taxable year.

Sale or Other Disposition of ADSs

Subject to the passive foreign investment company rules described below, gain or loss realized on the sale or other disposition of ADSs will be capital gain or loss, and will be long-term capital gain or loss if the U.S. Holder held the ADSs for more than one year. The amount of the gain or loss will equal the difference between the U.S. Holder’s tax basis in the ADSs disposed of and the amount realized on the disposition, in each case as determined in U.S. dollars. This gain or loss will generally be U.S.-source income or loss for foreign tax credit purposes. The deductibility of capital losses for U.S. federal income tax purposes is subject to various limitations under the Code.

Passive Foreign Investment Company (“PFIC”) Rules

Under the Code, we will be a PFIC for any taxable year in which, after the application of certain “look-through” rules with respect to subsidiaries, either (i) 75% or more of our gross income consists of “passive income” or (ii) 50% or more of the average quarterly value of our assets consist of assets that produce, or are held for the production of, “passive income.” Passive income generally includes interest, dividends, rents and royalties (except to the extent derived in the active conduct of a trade or business) and the excess of gain over losses from disposition of assets which produce passive income. Whether we will be a PFIC in 2015 or any future year depends on the composition of our income and assets, and the relative fair market value of our assets from time to time, which has varied, and we expect will continue to vary, substantially over time. Because (i) we currently own, and will own after the completion of this offering, a substantial amount of passive assets, including cash, and (ii) the valuation of our assets that generate non-passive income for PFIC purposes, including our intangible assets, is uncertain and may vary substantially over time, it is uncertain whether we will be, and there can be no assurance that we will not be, a PFIC in 2015 or any future years. In addition, we may, directly or indirectly, hold equity interests in Lower-tier PFICs. If we were a PFIC for any year during which a U.S. Holder holds ADSs, we generally would continue to be treated as a PFIC with respect to that U.S. Holder for all succeeding years during which the U.S. Holder holds ADSs, even if we ceased to meet the threshold requirements for PFIC status.

If we were a PFIC for any taxable year during which a U.S. Holder held ADSs (assuming such U.S. Holder has not made a timely mark-to-market election, or a QEF election, each as described below), gain recognized by a U.S. Holder on a sale or other disposition (including certain pledges) of the ADSs would be allocated ratably over the U.S. Holder’s holding period for the ADSs, or on an indirect disposition of shares of a Lower-tier PFIC. The amounts allocated to the taxable year of the sale or other disposition and to any year before we became a PFIC would be taxed as ordinary income. The amount allocated to each other taxable year would be subject to tax at the highest rate in effect for individuals or corporations, as appropriate, for that taxable year, and an interest charge would be imposed on the amount allocated to that taxable year. Further, to the extent that any distribution received by a U.S. Holder on its ADSs exceeds 125% of the average of the annual distributions on the ADSs received during the preceding three years or the U.S. Holder’s holding period, whichever is shorter, that distribution would be subject to taxation in the same manner as gain, described immediately above.

A U.S. Holder can avoid certain of the adverse rules described above by making a mark-to-market election with respect to its ADSs, provided that the ADSs are “marketable.” ADSs will be marketable if they are “regularly traded” on a “qualified exchange” or other market within the meaning of applicable Treasury regulations. The NASDAQ, on which the ADSs are expected to be listed, is a qualified exchange for this purpose. If a U.S. Holder makes the mark-to-market election, it generally will recognize as ordinary income any excess of the fair market value of the ADSs at the end of each taxable year over their adjusted tax basis, and will recognize an ordinary loss in respect of any excess of the adjusted tax basis of the ADSs over their fair market value at the end of the taxable year (but only to the extent of the net amount of income previously included as a result of the mark-to-market election). If a U.S. Holder makes the election, the U.S. Holder’s tax basis in the ADSs will be adjusted to reflect the income or loss amounts recognized. Any gain recognized on the sale or other disposition of ADSs in a year when we are a PFIC will be treated as ordinary income and any loss will be treated as an ordinary loss (but only to the extent of the net amount of income previously included as a result of the mark-to-market election). U.S. Holders should consult their tax advisers regarding the availability and advisability of making a mark-to-market election in their particular circumstances. In particular, U.S. Holders should consider carefully the impact of a mark-to-market election with respect to their ADSs because we may have Lower-tier PFICs for which a mark-to-market election may not be available.

Alternatively, a U.S. Holder can make an election, if we provide the necessary information, to treat us and each Lower-tier PFIC as a qualified electing fund, or a QEF election, in the first taxable year that we and each Lower-tier PFIC are treated as PFICs with respect to the U.S. Holder. A U.S. Holder must make the QEF Election for each PFIC by attaching a separate properly completed IRS Form 8621 for each PFIC to the U.S. Holder's timely filed U.S. federal income tax return. If we determine that we are a PFIC for 2015 or any future year, upon request of a U.S. Holder, we will provide the information necessary for a U.S. Holder to make a QEF Election with respect to us and cause each Lower-tier PFIC that we control to provide such information with respect to such Lower-tier PFIC.

If we are a PFIC for any year and a U.S. Holder makes a QEF Election with respect to us and any Lower-tier PFIC in the first taxable year that we and each Lower-tier PFIC are treated as PFICs with respect to the U.S. Holder, the U.S. Holder will be currently taxable on its *pro rata* share of the relevant PFIC's ordinary earnings and net capital gain (at ordinary income and capital gain rates, respectively) for each taxable year that the entity is classified as a PFIC. If a U.S. Holder makes a QEF Election with respect to us, any distributions paid by us out of our earnings and profits that were previously included in the U.S. Holder's income under the QEF Election would not be taxable to the U.S. Holder. A U.S. Holder will increase its tax basis in its ADSs by an amount equal to any income included under the QEF Election and will decrease its tax basis by any amount distributed on the ADSs that is not included in the U.S. Holder's income. In addition, a U.S. Holder will recognize capital gain or loss on the disposition of ADSs in an amount equal to the difference between the amount realized and the U.S. Holder's adjusted tax basis in the ADSs, as determined in U.S. dollars. U.S. Holders should note that if they make QEF Elections with respect to us and any Lower-tier PFICs, they may be required to pay U.S. federal income tax with respect to their ADSs for any taxable year significantly in excess of any cash distributions received on the ADSs for such taxable year. U.S. Holders should consult their tax advisers regarding making QEF Elections in their particular circumstances.

In addition, if we were a PFIC or, with respect to a particular U.S. Holder, were treated as a PFIC for the taxable year in which we paid a dividend or for the prior taxable year, the preferential rates discussed above with respect to dividends paid to certain non-corporate U.S. Holders would not apply.

If a U.S. Holder owns ADSs during any year in which we are a PFIC, the U.S. Holder generally must file annual reports containing such information as the U.S. Treasury may require on IRS Form 8621 (or any successor form) with respect to us (regardless of whether a QEF or mark-to-market election is made), generally with the U.S. Holder's federal income tax return for that year.

U.S. Holders should consult their tax advisers regarding whether we are or may become a PFIC and the potential application of the PFIC rules.

Information Reporting and Backup Withholding

Payments of dividends and sales proceeds that are made within the United States or through certain U.S.-related financial intermediaries generally are subject to information reporting, and may be subject to backup withholding, unless (i) the U.S. Holder is a corporation or other exempt recipient or (ii) in the case of backup withholding, the U.S. Holder provides a correct taxpayer identification number and certifies that it is not subject to backup withholding.

The amount of any backup withholding from a payment to a U.S. Holder will be allowed as a credit against the holder's U.S. federal income tax liability and may entitle it to a refund, provided that the required information is timely furnished to the IRS.

UNDERWRITING

RBC Capital Markets, LLC and Stifel, Nicolaus & Company, Incorporated are acting as representatives of the underwriters named below. Subject to the terms and conditions set forth in an underwriting agreement dated the date of this prospectus, each of the underwriters named below has severally agreed to purchase from us the aggregate number of the ADSs set forth opposite their respective names below:

<u>Name</u>	<u>Number of ADSs</u>
RBC Capital Markets, LLC	1,410,532
Stifel, Nicolaus & Company, Incorporated	1,410,532
JMP Securities LLC	658,248
Roth Capital Partners, LLC	282,106
Total	<u>3,761,418</u>

The underwriting agreement provides that the obligations of the several underwriters are subject to various conditions, including approval of legal matters by counsel. The nature of the underwriters' obligations commits them to purchase and pay for all of the ADSs listed above if any are purchased. The underwriters reserve the right to withdraw, cancel or modify offers to the public and to reject orders in whole or in part.

The underwriters expect to deliver the ADSs to purchasers on or about June 16, 2015.

Certain of our existing investors and certain members of our board of directors have indicated an interest in purchasing up to an aggregate of \$17 million of the ADSs in this offering at the public offering price. However, because indications of interest are not binding agreements or commitments to purchase, these entities and persons may determine to not purchase any ADSs in this offering. It is also possible that these entities and persons and additional existing investors could indicate an interest in purchasing more of the ADSs. In addition, the underwriters could determine to sell fewer ADSs to any of these entities or persons than such entities or persons indicate an interest in purchasing or to not sell any ADSs to these entities and persons.

Option to Purchase Additional American Depositary Shares

We intend to grant an option to the underwriters, exercisable for 30 days from the date of this prospectus, to purchase up to a total of 44,629 additional ADSs from us at the initial public offering price, less the underwriting discount payable by us, and the selling shareholder intends to grant an option to the underwriters, exercisable for 30 days from the date of this prospectus, to purchase up to a total of 519,583 ADSs from it at the initial public offering price, less the underwriting discount payable by it. If the underwriters exercise this option in whole or in part, then each of the underwriters will be separately committed, subject to the conditions described in the underwriting agreement, to purchase the additional ADSs in proportion to their respective commitments set forth in the table above on a pro rata basis from us and the selling shareholder based on the total number of ADSs available for sale by us and the selling shareholder pursuant to the underwriters' option to purchase additional ADSs.

Determination of Offering Price

Prior to this offering, there has been no public market for the ADSs. The initial public offering price will be determined through negotiations between us and the representatives. In addition to currently

prevailing general conditions in the equity securities markets, including current market valuations of publicly traded companies considered comparable to our company, the factors to be considered in determining the initial public offering price will include:

- the trading price of our shares on the Finnish Stock Exchange;
- our results of operations;
- our current financial condition;
- our future prospects;
- our management;
- the economic conditions in and future prospects for the industry in which we compete; and
- other factors we deem relevant.

We cannot assure you that an active or orderly trading market will develop for the ADSs or that the ADSs will trade in the public markets subsequent to this offering at or above the initial public offering price.

Commissions and Discounts

The underwriters propose to offer the ADSs directly to the public at the initial public offering price set forth on the cover page of this prospectus, and at this price less a concession not in excess of \$0.625 per ADS to other dealers specified in a master agreement among underwriters who are members of the Financial Industry Regulatory Authority, Inc. After this offering, the offering price, concessions and other selling terms may be changed by the underwriters. The ADSs are offered subject to receipt and acceptance by the underwriters and to the other conditions, including the right to reject orders in whole or in part.

The following table summarizes the compensation to be paid to the underwriters by us and the proceeds, before expenses, payable to us:

	<u>Per ADS</u>	<u>Total</u>
Public offering price	\$14.888	\$55,999,991
Underwriting discount	\$ 1.042	\$ 3,919,999
Proceeds, before expenses, to us (assuming no exercise of the underwriters' option)	\$13.846	\$52,079,992
Proceeds, before expenses, to us (assuming full exercise of the underwriters' option)	\$13.846	\$52,697,918
Proceeds, before expenses, to the selling shareholder (assuming full exercise of the underwriters' option)	\$13.846	\$ 7,194,063

We estimate that our total expenses in connection with this offering, excluding underwriting discounts and commissions, will be \$3,000,000, all of which will be paid by us. We have also agreed to reimburse the underwriters up to \$20,000 for certain of their expenses and application fees incurred in connection with, and clearance of the offering by, the Financial Industry Regulatory Authority, Inc.

Indemnification of Underwriters

We and the selling shareholder will indemnify the underwriters against some civil liabilities, including liabilities under the Securities Act and liabilities arising from breaches of our representations and warranties contained in the underwriting agreement. If we are unable to provide this indemnification, we or the selling

shareholder, as applicable, will contribute to payments the underwriters may be required to make in respect of those liabilities. We will also indemnify the underwriters for losses if ADSs (other than those purchased pursuant to the underwriters' option) are not delivered to the underwriters' accounts on the initial settlement date.

No Sales of Similar Securities

All of our directors and officers and certain of our shareholders are subject to lock-up restrictions pursuant to which they may not offer, sell, contract to sell (including any short sale), pledge, hypothecate, establish an open "put equivalent position" within the meaning of Rule 16a-1(h) under the Exchange Act, grant any option, right or warrant for the sale of, purchase any option or contract to sell, sell any option or contract to purchase or otherwise encumber, dispose of or transfer, grant any rights with respect to, directly or indirectly, any shares, ADSs or other share capital or securities convertible into or exchangeable for shares, ADSs or other share capital, enter into a transaction which would have the same effect or other arrangement that transfers, in whole or in part, any of the economic consequences of ownership of the shares, ADSs or other share capital, whether such aforementioned transaction is to be settled by delivery of the shares or ADSs or such other securities, in cash or otherwise, or publicly disclose the intention to make any such offer, sale, pledge or disposition, or to enter into any such transaction, swap hedge or other arrangement without, in each case, the prior written consent of RBC Capital Markets, LLC and Stifel, Nicolaus & Company, Incorporated for a period of 180 days after the date of this prospectus, subject to specified limited exceptions. The selling shareholder's shares are subject to the same restrictions for 30 days after the date of this prospectus, except to the extent that such shares are sold to the underwriters in connection with this offering. RBC Capital Markets, LLC and Stifel, Nicolaus & Company, Incorporated, in their sole discretion, may release any of the securities subject to these restrictions at any time, which, in the case of officers and directors, shall be with notice.

We have agreed that for a period of 180 days after the date of this prospectus, we will not, without the prior written consent of RBC Capital Markets, LLC and Stifel, Nicolaus & Company, Incorporated, offer, sell or otherwise dispose of any shares or ADSs, except for the ADSs offered in this offering, the shares issuable upon exercise of options, warrants and convertible securities outstanding on the date of this prospectus and other specified limited exceptions.

Listing

The ADSs have been approved for listing on the NASDAQ Global Select Market under the symbol "BITI." Our shares are listed on the Finnish Stock Exchange under the symbol "BTH1V."

Short Sales, Stabilizing Transactions and Penalty Bids

In order to facilitate this offering, persons participating in this offering may engage in transactions that stabilize, maintain, or otherwise affect the price of the ADSs during and after this offering. Specifically, the underwriters may engage in the following activities in accordance with the rules of the SEC.

Short Sales

Short sales involve the sales by the underwriters of a greater number of ADSs than they are required to purchase in the offering. Covered short sales are short sales made in an amount not greater than the underwriters' over-allotment option to purchase additional ADSs from us in this offering. The underwriters may close out any covered short position by either exercising their over-allotment option to purchase ADSs or purchasing shares in the open market. In determining the source of ADSs to close out the covered short position, the underwriters will consider, among other things, the price of ADSs available for purchase in the open market as compared to the price at which they may purchase ADSs through the over-allotment option.

Naked short sales are any short sales in excess of such over-allotment option. The underwriters must close out any naked short position by purchasing ADSs in the open market. A naked short position is more likely to be created if the underwriters are concerned that there may be downward pressure on the price of the ADSs in the open market after pricing that could adversely affect investors who purchase in this offering.

Stabilizing Transactions

The underwriters may make bids for or purchases of the ADSs for the purpose of pegging, fixing, or maintaining the price of the ADSs, so long as stabilizing bids do not exceed a specified maximum.

Penalty Bids

If the underwriters purchase ADSs in the open market in a stabilizing transaction or syndicate covering transaction, they may reclaim a selling concession from the underwriters and selling group members who sold those ADSs as part of this offering. Stabilization and syndicate covering transactions may cause the price of the ADSs to be higher than it would be in the absence of these transactions. The imposition of a penalty bid might also have an effect on the price of the ADSs if it discourages presales of the ADSs.

The transactions above may occur on the NASDAQ or otherwise. Neither we nor the underwriters make any representation or prediction as to the effect that the transactions described above may have on the price of the ADSs. If these transactions are commenced, they may be discontinued without notice at any time.

Discretionary Sales

The underwriters have informed us that they do not expect to confirm sales of the ADSs offered by this prospectus to accounts over which they exercise discretionary authority without obtaining the specific approval of the account holder.

Electronic Distribution

A prospectus in electronic format may be made available on the Internet sites or through other online services maintained by one or more of the underwriters participating in this offering, or by their affiliates. Other than the prospectus in electronic format, the information on any underwriter's website and any information contained in any other website maintained by an underwriter is not part of the prospectus or the registration statement of which this prospectus forms a part, has not been approved or endorsed by us or any underwriter in its capacity as underwriter and should not be relied upon by investors.

Relationships

The underwriters and their respective affiliates are full service financial institutions engaged in various activities, which may include securities trading, commercial and investment banking, financial advisory, investment management, principal investment, hedging, financing and brokerage activities. Certain of the underwriters and their affiliates have in the past provided, and may in the future from time to time provide, investment banking and other financing and banking services to us, for which they have in the past received, and may in the future receive, customary fees and reimbursement for their expenses. In the ordinary course of their various business activities, the underwriters and their respective affiliates may make or hold a broad array of investments and actively trade debt and equity securities (or related derivative securities) and financial instruments including bank loans for their own account and for the accounts of their customers and may at any time hold long and short positions in such securities and instruments. Such investment and securities activities may involve our securities and instruments.

Notice to Residents of the European Economic Area

In relation to each member state of the European Economic Area that has implemented the Prospectus Directive (each, a relevant member state), with effect from and including the date on which the Prospectus Directive is implemented in that relevant member state (the relevant implementation date), an offer of securities described in this prospectus may not be made to the public in that relevant member state other than:

- to any legal entity which is a qualified investor as defined in the Prospectus Directive;
- to fewer than 100, or if the relevant member state has implemented the relevant provision of the 2010 PD Amending Directive (2010/73/EU) 150, natural or legal persons (other than qualified investors as defined in the Prospectus Directive), as permitted under the Prospectus Directive, subject to obtaining the prior consent of the representatives; or
- in any other circumstances that do not require the publication of a prospectus pursuant to Article 3 of the Prospectus Directive,

provided that no such offer of securities shall require us or any underwriter to publish a prospectus pursuant to Article 3 of the Prospectus Directive. For purposes of this provision, the expression an “offer of securities to the public” in any relevant member state means the communication in any form and by any means of sufficient information on the terms of the offer and the securities to be offered so as to enable an investor to decide to purchase or subscribe the securities, as the expression may be varied in that member state by any measure implementing the Prospectus Directive in that member state, and the expression “Prospectus Directive” means Directive 2003/71/EC and includes any relevant implementing measure in each relevant member state.

We have not authorized and do not authorize the making of any offer of securities through any financial intermediary on their behalf, other than offers made by the underwriters with a view to the final placement of the securities as contemplated in this prospectus. Accordingly, no purchaser of the securities, other than the underwriters, is authorized to make any further offer of the securities on behalf of us or the underwriters.

Notice to Residents of the United Kingdom

This prospectus is only being distributed to, and is only directed at, persons in the United Kingdom that are qualified investors within the meaning of Article 2(1)(e) of the Prospectus Directive (Qualified Investors) that are also (i) investment professionals falling within Article 19(5) of the Financial Services and Markets Act 2000 (Financial Promotion) Order 2005 (the Order) or (ii) high net worth entities, and other persons to whom it may lawfully be communicated, falling within Article 49(2)(a) to (d) of the Order (all such persons together being referred to as relevant persons). This prospectus and its contents are confidential and should not be distributed, published or reproduced (in whole or in part) or disclosed by recipients to any other persons in the United Kingdom. Any person in the United Kingdom that is not a relevant person should not act or rely on this document or any of its contents.

Notice to Residents of Switzerland

The securities which are the subject of the offering contemplated by this prospectus may not be publicly offered in Switzerland and will not be listed on the SIX Swiss Exchange, or SIX, or on any other stock exchange or regulated trading facility in Switzerland. This prospectus has been prepared without regard to the disclosure standards for issuance prospectuses under art. 652a or art. 1156 of the Swiss Code of Obligations or the disclosure standards for listing prospectuses under art. 27 ff. of the SIX Listing Rules or the listing rules of any other stock exchange or regulated trading facility in Switzerland. None of this prospectus or any other offering or marketing material relating to the securities or the offering may be publicly distributed or otherwise made publicly available in Switzerland.

None of this prospectus or any other offering or marketing material relating to the offering, us or the securities have been or will be filed with or approved by any Swiss regulatory authority. In particular, this prospectus will not be filed with, and the offer of securities will not be supervised by the Swiss Financial Market Supervisory Authority, or FINMA and the offer of securities has not been and will not be authorized under the Swiss Federal Act on Collective Investment Schemes, or CISA. The investor protection afforded to acquirers of interests in collective investment schemes under the CISA does not extend to acquirers of the securities.

Notice to Residents of Japan

The underwriters will not offer or sell any of the ADSs directly or indirectly in Japan or to, or for the benefit of, any Japanese person or to others, for reoffering or resale directly or indirectly in Japan or to any Japanese person, except in each case pursuant to an exemption from the registration requirements of, and otherwise in compliance with, the Financial Instruments and Exchange Law of Japan and any other applicable laws and regulations of Japan. For purposes of this paragraph, “Japanese person” means any person resident in Japan, including any corporation or other entity organized under the laws of Japan.

Notice to Residents of Hong Kong

The underwriters and each of their affiliates have not (i) offered or sold, and will not offer or sell, in Hong Kong, by means of any document, any ADSs other than (a) to “professional investors” within the meaning of the Securities and Futures Ordinance (Cap. 571) of Hong Kong and any rules made under that Ordinance or (b) in other circumstances which do not result in the document being a “prospectus” as defined in the Companies Ordinance (Cap. 32) of Hong Kong or which do not constitute an offer to the public within the meaning of that Ordinance; and (ii) issued or had in its possession for the purposes of issue, and will not issue or have in its possession for the purposes of issue, whether in Hong Kong or elsewhere any advertisement, invitation or document relating to the ADSs which is directed at, or the contents of which are likely to be accessed or read by, the public in Hong Kong (except if permitted to do so under the securities laws of Hong Kong) other than with respect to the ADSs which are or are intended to be disposed of only to persons outside Hong Kong or only to “professional investors” within the meaning of the Securities and Futures Ordinance and any rules made under that Ordinance. The contents of this document have not been reviewed by any regulatory authority in Hong Kong. You are advised to exercise caution in relation to the offer. If you are in any doubt about any of the contents of this document, you should obtain independent professional advice.

Notice to Residents of Singapore

This document has not been registered as a prospectus with the Monetary Authority of Singapore. Accordingly, this document and any other document or material in connection with the offer or sale, or invitation for subscription or purchase, of shares of the ADSs may not be circulated or distributed, nor may the ADSs be offered or sold, or be made the subject of an invitation for subscription or purchase, whether directly or indirectly, to persons in Singapore other than (i) to an institutional investor under Section 274 of the Securities and Futures Act, Chapter 289 of Singapore (the Securities and Futures Act), (ii) to a relevant person, or any person pursuant to Section 275(1A), and in accordance with the conditions, specified in Section 275 of the Securities and Futures Act or (iii) otherwise pursuant to, and in accordance with the conditions of, any other applicable provision of the Securities and Futures Act.

Where the ADSs stock are subscribed or purchased under Section 275 by a relevant person, which is:

(a) a corporation (which is not an accredited investor) the sole business of which is to hold investments and the entire share capital of which is owned by one or more individuals, each of whom is an accredited investor; or

(b) a trust (where the trustee is not an accredited investor) whose sole purpose is to hold investments and each beneficiary is an accredited investor, shares, debentures and units of shares and debentures of that corporation or the beneficiaries' rights and interest in that trust shall not be transferable for six months after that corporation or that trust has acquired the ADSs under Section 275 except:

(1) to an institutional investor or to a relevant person, or to any person pursuant to an offer that is made on terms that such rights or interest are acquired at a consideration of not less than \$200,000 (or its equivalent in a foreign currency) for each transaction, whether such amount is to be paid for in cash or by exchange of securities or other assets;

(2) where no consideration is given for the transfer; or

(3) by operation of law.

EXPENSES OF THE OFFERING

We estimate that our expenses in connection with this offering, other than underwriting discounts and commissions, will be as follows:

<u>Expenses</u>	<u>Amount</u>
SEC registration fee	\$ 7,484
NASDAQ listing fee	125,000
FINRA filing fee	10,160
Printing and engraving expenses	350,000
Legal fees and expenses	1,396,305
Accounting fees and expenses	1,005,835
Miscellaneous costs	<u>105,216</u>
Total	<u>\$3,000,000</u>

All amounts in the table are estimates except the SEC registration fee, the NASDAQ listing fee and the FINRA filing fee. We will pay all of the expenses of this offering.

LEGAL MATTERS

The validity of the ADSs and certain other matters of U.S. federal and New York State law will be passed upon for us by Davis Polk & Wardwell LLP, New York, New York. Certain legal matters will be passed upon for the underwriters by Wilmer Cutler Pickering Hale and Dorr LLP, New York, New York. The validity of the shares represented by the ADSs offered in this offering and certain other matters of Finnish law will be passed upon for us by Hannes Snellman Attorneys Ltd.

EXPERTS

The consolidated financial statements as of December 31, 2014 and 2013, and for each of the two years in the period ended December 31, 2014, included in this prospectus have been so included in reliance on the report of, PricewaterhouseCoopers Oy, an independent registered public accounting firm, given on the authority of such firm as experts in accounting and auditing.

The current address of PricewaterhouseCoopers Oy is Itämerentori 2, FI-00100 Helsinki, an audit firm chartered by the Finnish Central Chamber of Commerce.

SERVICE OF PROCESS AND ENFORCEMENT OF JUDGMENTS

We are incorporated under the laws of Finland. Some of our assets are located outside the United States and certain of our directors and members of senior management reside outside of the United States. As a result, it may not be possible for investors to effect service of process within the United States upon such persons or to enforce against them or us in U.S. courts judgments predicated upon the civil liability provisions of the federal securities laws of the United States.

We have appointed Biotie Therapies, Inc., our wholly-owned subsidiary, as our authorized agent upon whom process may be served in any action instituted in any U.S. federal or state court having subject matter jurisdiction arising out of or based upon the ADSs, the deposit agreement or the underwriting agreement related to the ADSs.

We have been advised by Hannes Snellman Attorneys Ltd, our Finnish counsel, that there is currently no treaty between the United States and Finland providing for reciprocal recognition and enforceability of judgments rendered in connection with civil and commercial disputes and, accordingly, a final judgment rendered by a U.S. court based on civil liability would not be enforceable in Finland as such. However, a U.S. judgment may carry evidentiary value in any proceedings for civil liability brought in the Finnish courts.

WHERE YOU CAN FIND MORE INFORMATION

We have filed with the SEC a registration statement (including amendments and exhibits to the registration statement) on Form F-1 under the Securities Act. A related registration statement on Form F-6 will be filed with the SEC to register the ADSs. This prospectus, which is part of the registration statement, does not contain all of the information set forth in the registration statement and the exhibits and schedules to the registration statement. For further information, we refer you to the registration statement and the exhibits and schedules filed as part of the registration statement. If a document has been filed as an exhibit to the registration statement, we refer you to the copy of the document that has been filed. Each statement in this prospectus relating to a document filed as an exhibit is qualified in all respects by the filed exhibit.

Upon completion of this offering, we will become subject to the informational requirements of the Exchange Act. Accordingly, we will be required to file reports and other information with the SEC, including annual reports on Form 20-F and reports on Form 6-K. You may inspect and copy reports and other information filed with the SEC at the Public Reference Room at 100 F Street NE, Washington, D.C. 20549. Information on the operation of the Public Reference Room may be obtained by calling the SEC at 1-800-SEC-0330. In addition, the SEC maintains an Internet website that contains reports and other information about issuers, like us, that file electronically with the SEC. The address of that website is www.sec.gov.

We are not currently subject to the informational requirements of the Exchange Act. Upon completion of this offering, we will be subject to the information reporting requirements of the Exchange Act that are applicable to foreign private issuers, and under those requirements will file reports with the SEC. Those other reports or other information may be inspected without charge at the locations described above. As a foreign private issuer, we will be exempt from the rules under the Exchange Act related to the furnishing and content of proxy statements, and our officers, directors and principal shareholders will be exempt from the reporting and short-swing profit recovery provisions contained in Section 16 of the Exchange Act. In addition, we will not be required under the Exchange Act to file annual, quarterly and current reports and financial statements with the SEC as frequently or as promptly as U.S. companies whose securities are registered under the Exchange Act. However, we will file with the SEC, within four months after the end of each fiscal year, or such applicable time as required by the SEC, an annual report on Form 20-F containing financial statements audited by an independent registered public accounting firm, and will submit to the SEC, on Form 6-K, unaudited quarterly financial information for the first three quarters of each fiscal year.

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Biotie Therapies Oyj
Condensed Consolidated Statements of Comprehensive Income (Unaudited)

(€ in thousands, except per share data)	Note	For the three month period ended March 31,	
		2015	2014
Revenue	3	871	5,096
Research and development expenses		(4,766)	(4,803)
General and administrative expenses		(1,730)	(1,950)
Other operating income		—	135
Operating loss		(5,625)	(1,522)
Interest income		1	—
Interest expenses		(151)	(152)
Other net financial income (expenses)		(119)	(45)
Loss before taxes		(5,894)	(1,719)
Income tax	4	—	—
Net loss		(5,894)	(1,719)
Other comprehensive income			
Items that may be subsequently reclassified to profit or loss:			
Currency translation differences*		8,181	315
Total other comprehensive income		8,181	315
Total comprehensive income (loss)		2,287	(1,404)
Net loss attributable to equity holders of the parent		(5,894)	(1,719)
Total comprehensive income (loss) attributable to equity holders of the parent		2,287	(1,404)
Loss per share (EPS) basic & diluted, €	5	(0.01)	(0.00)

*The translation differences mainly arise in relation to in-process R&D assets and goodwill. The movement for the three month period ended March 31, 2015 is due to the significant devaluation in the Euro against the United States Dollar and Swiss Franc.

All activities relate to continuing operations.

The accompanying notes are an integral part of these condensed consolidated financial statements.

Biotie Therapies Oyj
Condensed Consolidated Statements of Financial Position

<u>(€ in thousands)</u>	<u>Note</u>	<u>As at March 31, 2015 (unaudited)</u>	<u>As at December 31, 2014</u>
ASSETS			
Non-current assets			
Intangible assets	6	53,721	47,356
Goodwill	6	6,597	5,799
Property, plant and equipment	7	714	653
Other financial assets		358	324
Total non-current assets		<u>61,390</u>	<u>54,132</u>
Current assets			
Accounts receivable, other receivables and prepaid expenses		5,357	1,806
Financial assets at fair value through profit or loss	8	21,513	24,941
Cash and cash equivalents		6,315	7,452
Total current assets		<u>33,185</u>	<u>34,199</u>
Total assets		<u>94,575</u>	<u>88,331</u>
EQUITY AND LIABILITIES			
Shareholders' equity			
Share capital		193,285	193,285
Reserve for invested unrestricted equity		5,389	5,378
Other reserves		17,210	9,029
Retained earnings		(160,789)	(155,069)
Total equity		<u>55,095</u>	<u>52,623</u>
Non-current liabilities			
Non-current financial liabilities	8	20,690	20,690
Pension benefit obligation		670	670
Other non-current liabilities		9,842	9,671
Non-current deferred revenues		2,000	2,000
Total non-current liabilities		<u>33,202</u>	<u>33,031</u>
Current liabilities			
Accounts payable and other current liabilities		6,278	2,677
Total current liabilities		<u>6,278</u>	<u>2,677</u>
Total liabilities		<u>39,480</u>	<u>35,708</u>
Total shareholders' equity and liabilities		<u>94,575</u>	<u>88,331</u>

The accompanying notes are an integral part of these condensed consolidated financial statements.

Biotie Therapies Oyj
Condensed Consolidated Statements of Changes in Shareholders' Equity (Unaudited)

		Attributable to equity holders of the parent company				
(€ in thousands)	Note	Share capital	Reserve for invested unrestricted equity	Other reserves	Retained earnings	Shareholders' equity total
Balance at January 1, 2014		193,285	5,252	2,517	(120,688)	80,366
Net loss for the period		—	—	—	(1,719)	(1,719)
Other comprehensive income		—	—	315	—	315
Total comprehensive income (loss)		—	—	315	(1,719)	(1,404)
Share based compensation	10	—	—	—	198	198
Options and RSU exercised	10	—	3	—	—	3
		—	3	315	(1,521)	(1,202)
Balance at March 31, 2014		193,285	5,255	2,833	(122,209)	79,164
Balance at January 1, 2015		193,285	5,378	9,029	(155,069)	52,623
Net loss for the period		—	—	—	(5,894)	(5,894)
Other comprehensive income		—	—	8,181	—	8,181
Total comprehensive income (loss)		—	—	8,181	(5,894)	2,287
Share based compensation	10	—	—	—	174	174
Options and RSU exercised	10	—	11	—	—	11
		—	11	8,181	(5,720)	2,472
Balance at March 31, 2015		193,285	5,389	17,210	(160,789)	55,095

The accompanying notes are an integral part of these condensed consolidated financial statements

Biotie Therapies Oyj
Condensed Consolidated Statements of Cash Flows (Unaudited)

<u>(€ in thousands)</u>	<u>Note</u>	<u>For the three month period ended March 31,</u>	
		<u>2015</u>	<u>2014</u>
Cash flow from operating activities			
Net loss		(5,894)	(1,719)
Adjustments for:			
Non-cash transactions	11	301	419
Interest income		(1)	—
Interest expenses		151	152
Other net financial income (expenses)		119	45
Change in working capital:			
Change in accounts receivables, other receivables and prepaid expenses		(3,333)	(179)
Change in accounts payable and other liabilities		3,300	(2,373)
Change in deferred revenue		—	(1,726)
Interest paid		(27)	(27)
Net cash used in operating activities		(5,384)	(5,409)
Cash flow from investing activities			
Investments in financial assets at fair value through profit and loss		—	(9)
Proceeds from sale of financial assets at fair value through profit and loss		3,996	—
Change in other financial assets		—	(51)
Investments in property, plant and equipment		(51)	(102)
Investments in intangible assets		—	(13)
Net cash from (used in) investing activities		3,945	(175)
Cash flow from financing activities			
Proceeds from share issue and option exercise		11	3
Net cash from financing activities		11	3
Net decrease in cash and cash equivalents		(1,428)	(5,581)
Effect of changes in exchange rates on cash and cash equivalents		291	31
Cash and cash equivalents at the beginning of the period		7,452	10,221
Cash and cash equivalents at the end of the period		6,315	4,670

The accompanying notes are an integral part of these condensed consolidated financial statements

Biotie Therapies Oyj

Notes to the Unaudited Condensed Consolidated Financial Statements

1. General Information

Biotie Therapies Oyj (“Biotie” or the “Company”) is a specialized drug development company incorporated and domiciled in Finland, with its headquarters at Joukahaisenkatu 6, Turku, Finland, focused on products for neurodegenerative and psychiatric disorders. Biotie operates primarily in Finland and in the United States. Biotie’s development has delivered Selincro (nalmefene) for alcohol dependence, which received European marketing authorization in 2013 and is currently being rolled out across Europe by partner Lundbeck. The current development products include tozadenant for Parkinson’s disease, which is transitioning into Phase 3 development, and two additional compounds which are in Phase 2 development for cognitive disorders including Parkinson’s disease dementia and primary sclerosing cholangitis, a rare fibrotic disease of the liver. Biotie’s shares are listed on NASDAQ Helsinki. As used in these condensed consolidated financial statements, unless the context indicates otherwise, all references to “Biotie” or the “Company” or the “Group” refer to Biotie Therapies Oyj and all its consolidated subsidiaries.

The condensed consolidated financial statements were approved for issue by the Board of Directors on May 6, 2015.

2. Summary of Significant Accounting Policies

2.1 Basis of Preparation

These unaudited condensed consolidated financial statements for the three months ended March 31, 2015 of the Company have been prepared in accordance with International Accounting Standard IAS 34, “Interim Financial Reporting”. The Company’s annual audited consolidated financial statements are prepared in accordance with International Financial Reporting Standards (IFRS) as issued by the International Accounting Standards Board. Certain information and disclosures normally included in consolidated financial statements prepared in accordance with IFRS have been condensed or omitted. However, in the opinion of management, these financial statements contain all adjustments necessary to present a fair statement of results. All adjustments are deemed to be of a normal, recurring nature. The results of operations for the interim periods are not necessarily indicative of the results to be expected for the full year. Accordingly, these condensed consolidated financial statements should be read in conjunction with the annual consolidated financial statements for the year ended December 31, 2014.

The preparation of financial statements in conformity with IFRS requires management to make judgments, estimates and assumptions that affect the reported amounts of assets and liabilities, and the disclosure of contingent assets and liabilities at the end of the reporting period, as well as the reported amounts of income and expenses during the reporting period. Although these estimates are based on management’s best knowledge of current events and actions, actual results may ultimately differ from them. The areas involving a higher degree of judgment or complexity, or areas where assumptions and estimates are significant to the unaudited condensed consolidated financial statements are disclosed in note 2.10.

The notes to the condensed consolidated financial statements have been rounded to thousand Euros, unless otherwise stated.

2.2 Changes in Accounting Policies and Disclosures

The Company adopted new IFRS standards, amendments or interpretations during the three months ended March 31, 2015 that had no material impact to the condensed consolidated financial statements. The accounting policies applied are consistent with those discussed in the Company’s annual consolidated financial statements.

Biotie Therapies Oyj

Notes to the Unaudited Condensed Consolidated Financial Statements — (Continued)

a) New and amended IFRS standards and IFRIC interpretations not yet adopted by the Company

The Company has decided not to implement early IFRS 9 “Financial Instruments”, which is effective for accounting periods ending on or after January 1, 2018 with early adoption permitted, or IFRS 15 “Revenue from Contracts with Customers”, which is effective for accounting periods ending on or after January 1, 2017 with retrospective effect. The Company is currently assessing the impact of both new standards. There are no other standards which are currently available for early adoption which are expected to have a significant effect on the condensed consolidated financial statements of the Company.

2.3 Consolidation

Subsidiaries are all entities over which the Company has control. The Company controls an entity when it is exposed to, or has rights to, variable returns from its involvement with the entity and has the ability to affect those returns through its power over the entity. Subsidiaries are consolidated from the date at which control is transferred to the Company and are de-consolidated from the date that control ceases. The acquisition method of accounting is used to account for subsidiaries acquired through a business combination.

Intra-group transactions, balances and unrealized gains and losses on transactions between group companies are eliminated. Unrealized losses are also eliminated, unless the transaction provides evidence of an impairment of the asset transferred. Accounting policies of subsidiaries have been changed where necessary to ensure consistency with the policies adopted by the Company.

2.4 Segment Reporting

Biotie continues to operate in one reportable segment, which comprises the development of pharmaceutical products. The Chief Executive Officer is identified as the chief operating decision maker. The Chief Executive Officer reviews the consolidated operating results regularly to make decisions about the resources and to assess overall performance.

2.5 Seasonality of Operations

The Company’s results have varied substantially, and are expected to continue to vary, from quarter to quarter depending on the royalty streams and level of development activities within the quarter. The Company, therefore, believes that period to period comparisons should not be relied upon as indicative of future financial results. The Company believes that its ordinary activities are not linked to any particular seasonal factors.

2.6 Cash and Cash Equivalents

Cash and cash equivalents comprise cash on hand, demand deposits and other short-term highly liquid investments with original maturities of less than three months.

2.7 Income taxes

Income tax expense consists of current and deferred taxes. The income tax effects of items recognized in other comprehensive income or directly in equity are similarly recognized in other comprehensive income or equity, respectively. The current income tax charge is calculated on the basis of the tax laws enacted in the countries where the Company operates and generates taxable income. Taxes on income in interim periods are accrued using tax rates that would be expected to be applicable to total annual profit or loss.

Biotie Therapies Oyj

Notes to the Unaudited Condensed Consolidated Financial Statements — (Continued)

Management periodically evaluates positions taken in tax returns with respect to situations in which applicable tax regulation is subject to interpretation. It establishes provisions where appropriate on the basis of amounts expected to be paid to the tax authorities.

Deferred income tax is recognized on temporary differences arising between the tax bases of assets and liabilities and their carrying amounts in the financial statements. Temporary differences arise primarily from in-process R&D intangible assets, R&D credits and deferrals, depreciation on property, plant and equipment and net operating loss tax carryforwards.

Deferred income tax assets are recognized only to the extent that it is probably that future taxable profit will be available against which the temporary differences can be utilized.

Deferred taxes are determined using a tax rate enacted, or substantially enacted, as of the date of the balance sheet date in the respective countries. However, deferred taxes are not recognized if they arise from the initial recognition of goodwill, or in the initial recognition of an asset or liability in a transaction other than a business combination that at the time of the transaction affects neither accounting nor taxable profit nor loss.

2.8 Earnings (loss) per share

Basic earnings (loss) per share is calculated by dividing the net income (loss) attributable to shareholders by the weighted average number of ordinary shares in issue during the period, excluding ordinary shares purchased by the Company and held as treasury shares.

Diluted earnings (loss) per share is calculated by adjusting the weighted average number of ordinary shares outstanding assuming the conversion of all dilutive potential ordinary shares.

2.9 Provisions and Contingent Liabilities

Provisions are recognized when the Company has a present legal or constructive obligation as a result of past events, it is probable that an outflow of resources will be required to settle the obligation, and a reliable estimate of the amount can be made. Provisions are measured at the present value of the expenditures expected to be required to settle the obligation using a pre-tax rate that reflects the current market assessments of the time value of money and the risks specific to the obligation. The increase in a provision due to passage of time is recognized in interest expenses.

2.10 Critical Accounting Estimates and Judgments

The preparation of condensed consolidated financial statements requires management to make judgments, estimates and assumptions about the carrying amounts of assets and liabilities that are not readily apparent from other sources. The estimates and associated assumptions are based on historical experience and other factors that are considered to be relevant. Actual results may differ from these estimates.

In preparing these condensed consolidated financial statements, the significant judgments made by management in applying the Company's accounting policies and the key sources of estimation uncertainty were the same as those that applied to the Company's annual consolidated financial statements. The condensed consolidated financial statements do not include all disclosures for critical accounting estimates and judgment that are required for the annual consolidated financial statements and should be read in conjunction with the Company's annual consolidated financial statements for the year ended December 31, 2014.

Biotie Therapies Oyj
Notes to the Unaudited Condensed Consolidated Financial Statements — (Continued)

3. Revenue

<u>(€ in thousands)</u>	<u>For the three month period ended March 31,</u>	
	<u>2015</u>	<u>2014</u>
Royalties from Lundbeck license agreement	658	49
Phase 3 development milestones from UCB collaboration agreement	—	5,047
Phase 3 development funding from UCB	213	—
Total	<u>871</u>	<u>5,096</u>

During the three months ended March 31, 2014, the Company recognized €5,047 thousand of revenue related to Phase 3 development milestones from UCB that did not recur during the three months ended March 31, 2015 as a result of the termination of UCB collaboration agreement. The royalties earned from the Lundbeck license agreement increased as a result of increased sales of Selincro. The Phase 3 development funding from UCB was €213 thousand which did not arise in 2014.

4. Income Tax

No income tax charge or benefit has been recognized in the three month period ended March 31, 2015, or the corresponding period in 2014. Management's judgement is that sufficient evidence is not currently available that future taxable profits will be available against which the unused tax losses or unused tax credits can be utilized by the fiscal entities and, therefore, a deferred tax asset has not been recognized.

5. Loss Per Share

a) Basic loss per share

Basic loss per share is calculated by dividing the net loss attributable to equity holders of the parent by the weighted average number of ordinary shares in issue during the period, excluding ordinary shares purchased by the Company and held as treasury shares.

	<u>For the three month period ended March 31,</u>	
	<u>2015</u>	<u>2014</u>
Net loss attributable to equity holders of the parent (€ in thousands)	(5,894)	(1,719)
Weighted average number of outstanding shares (in thousands)	452,273	456,032
Basic loss per share (€ per share)	<u>(0.01)</u>	<u>(0.00)</u>

b) Diluted loss per share

Diluted loss per share is calculated by adjusting the weighted average number of ordinary shares outstanding assuming conversion of all dilutive potential ordinary shares. The Company has three kinds of potentially dilutive instruments comprising stock options, restricted share units ("RSU") and a convertible capital loan. For the three month periods ended March 31, 2015 and March 31, 2014, because there was a loss for the period the potential dilutive shares have an anti-dilutive effect (i.e. decrease the loss per share) and are, therefore, excluded from the calculation of diluted loss per share. Consequently, the dilutive loss per share is the same as the basic loss per share shown above.

Biotie Therapies Oyj
Notes to the Unaudited Condensed Consolidated Financial Statements — (Continued)

6. Intangible Assets and Goodwill

(€ in thousands)	In-process R&D	Production licenses	Software	Other intangible assets	Intangible assets total	Goodwill
Book value January 1, 2015	46,830	454	62	10	47,356	5,799
Amortization	—	(10)	(27)	(10)	(47)	—
Translation differences	6,412	—	—	—	6,412	798
Book value March 31, 2015	53,242	444	35	—	53,721	6,597
At March 31, 2015						
Acquisition cost	98,297	762	317	10	99,386	5,549
Accumulated amortization and impairment	(55,368)	(318)	(282)	(10)	(55,978)	—
Translation differences	10,313	—	—	—	10,313	1,048
Book value March 31, 2015	53,242	444	35	—	53,721	6,597

The amortization charge was €47 thousand for the three month period ended March 31, 2015 (€42 thousand for the three month period ended March 31, 2014).

In-process R&D assets represents the fair value assigned to development projects that the Company acquired through business combinations, which at the time of the acquisition had not led to marketing approvals that are required for commercialization. Until December 31, 2014 in-process R&D assets comprised the tozadenant (SYN115), SYN120 and nepicastat (SYN117) programs, which were acquired in the Synosia 2011 acquisition; however, at December 31, 2014 the nepicastat (SYN117) in-process R&D asset was written off in full and, therefore, at March 31, 2015 in-process R&D assets only comprised the tozadenant (SYN115) and SYN120 in-process R&D assets. Amounts capitalized as in-process R&D assets are not amortized until marketing approval has been received for the relevant regulatory authorities. In-process R&D assets are tested for impairment annually, at December 31, and whenever there is an indication that the asset may be impaired; there have been no such indications during the three months ended March 31, 2015.

Biotie Therapies Oyj
Notes to the Unaudited Condensed Consolidated Financial Statements — (Continued)

For goodwill, the Company assesses the aggregate fair value of the business as a whole, as there is only one cash generating unit, on an annual basis at December 31 and whenever there is an indication that goodwill may be impaired; there have been no such indications in the three months ended March 31, 2015.

7. Property Plant & Equipment

<u>(€ in thousands)</u>	<u>Machinery and equipment</u>
Book value January 1, 2015	653
Additions	51
Depreciation	(36)
Translation differences	46
Book value March 31, 2015	714
At March 31, 2015	
Acquisition cost	4,892
Accumulated depreciation	(4,224)
Translation differences	46
Book value March 31, 2015	714

The depreciation charge was €36 thousand for the three month period ended March 31, 2015 (€28 thousand for the three month period ended March 31, 2014).

8. Financial Assets Held at Fair Value through Profit and Loss and Non-Current Financial Liabilities

<u>(€ in thousands)</u>	<u>As at</u>	
	<u>March 31, 2015</u> <u>(unaudited)</u>	<u>December 31, 2014</u>
Assets		
Financial assets held at fair value through profit or loss	21,513	24,491
Liabilities		
Non-current financial liabilities	20,690	20,690

Financial assets held at fair value through profit or loss, consisting mainly of investments to money market funds, are measured at their fair value based on quoted bid prices at the reporting date. The fair values are based on fund manager reports and are classified either within Level 1 or Level 2 in the fair value hierarchy. For Level 1, the fair value measurement is directly obtained from an active market. For Level 2, the fair value measurement is based on observable quoted market information, although it is not directly obtained from an active market (Level 1). According to the Company's investment policy, money market funds held in Europe must have a Morningstar rating of three stars or higher. Money market funds in the U.S. must be rated AAA by Moody's or AAA by Standard and Poor's.

Non-current financial liabilities consist of non-convertible capital loans from Tekes, long-term R&D loans from Tekes and a convertible capital loan which are carried at amortized cost. For fair value disclosure purposes only, the valuation technique that would be used to measure the non-current financial liabilities would rely on unobservable market data and therefore, the fair value measures of the loans would be classified as Level 3 in the fair value hierarchy. The Company has determined that it would not be

Biotie Therapies Oyj

Notes to the Unaudited Condensed Consolidated Financial Statements — (Continued)

reasonable to present fair values for the loans, as the Group only has access to Tekes loans and a convertible loan, i.e. similar government grant loans the Company already has with largely identical terms to the current loans.

9. Financial Risk Management and Financial Instruments

The operations of the Company expose it to financial risks. The main risk that the Company is exposed to is liquidity risk, with capital management being another important area given the Company's financing structure. The Company's risk management principles focus on the unpredictability of the financial markets and aims at minimizing any undesired impacts on the Group's financial result. The Board of Directors defines the general risk management principles and approves operational guidelines concerning specific areas including but not limited to liquidity risk, foreign exchange risk, interest rate risk, credit risk, the use of derivatives and investment of the Company's liquid assets. During the periods presented, the Company or its subsidiaries have not entered into any derivative contracts.

The condensed consolidated financial statements do not include all financial risk management information and disclosures required in the annual consolidated financial statements and should be read in conjunction with the Company's annual consolidated financial statements as at December 31, 2014. There have been no changes in the financial management team that is responsible for financial risk management or in the Company's financial risk management policies since December 31, 2014.

The Company has low risk securities (money market funds) and bank accounts which are as follows:

(€ in thousands)	As at	
	March 31, 2015	December 31, 2014
Money market funds	21,513	24,941
Bank accounts	6,315	7,452
Total	27,828	32,393

As at March 31, 2015, the contractual maturities of loans and interest are as follows:

(€ in thousands)	2015	2016	2017	2018-thereafter	Total
Capital loans					
Repayment of loans	—	—	—	18,000	18,000
Interest expenses	—	—	—	9,602	9,602
R&D loans					
Repayment of loans	—	—	538	2,152	2,690
Interest expenses	—	27	22	32	81
Total	—	27	560	29,786	30,373

As at March 31, 2015, the Company also has accounts payables €3,856 thousand and other current liabilities €2,421 thousand due within one year.

10. Share Based Payments

The condensed consolidated financial statements do not include all disclosures for share based payments that are required in the annual consolidated financial statements and should be read in conjunction with the Company's annual consolidated financial statements for the year ended December 31, 2014.

Biotie Therapies Oyj

Notes to the Unaudited Condensed Consolidated Financial Statements — (Continued)

a) Stock Option Plan 2011 and Equity Incentive Plan 2011

The Stock Option Plan 2011, primarily for European employees, and the Equity Incentive Plan 2011, primarily for US employees, were approved at the Company's 2011 general shareholders' meeting as part of the Company's incentive scheme determined by the Board of Directors. These plans contain both a service requirement condition at vesting and individual specified non-market performance targets during the year of grant.

i. Stock Option Plan 2011

The fair value of the options was determined at the grant date by using the Black-Scholes option valuation model and expensed over the vesting period. The maximum number of stock options that could be awarded under the plan was 7,401,000, in three equal tranches designated as 2011A, 2011B and 2011C. As at March 31, 2015 there were no options outstanding for the 2011A tranche.

The changes in the number of options in the plan during the three months ended March 31, 2015 is shown in the table below.

<u>Number of options</u>	<u>2011B</u>	<u>2011C</u>
Outstanding at January 1, 2015	1,793,000	2,230,000
Forfeitures	—	(272,500)
Exercised	(1,072,500)	—
Outstanding at March 31, 2015	720,500	1,957,500

All options were fair valued at grant date and recognized as an expense, over the vesting period, to personnel expenses included in research and development costs and general and administrative costs based on the employee's function over the vesting period. The net reversal of the expense recognized during the three months ended March 31, 2015 was €(7) thousand (the expense for three months ended March 31, 2014 was €120 thousand). The subscription price for all options is €0.01.

ii. Equity Incentive Plan 2011

The Equity Incentive Plan 2011 includes three consecutive discretionary periods, calendar years 2011 (2011A), 2012 (2011B) and 2013 (2011C) in which the restricted share units may be granted. Each discretionary period is followed by an approximately two year vesting period, ending on January 5, 2014, January 5, 2015 and January 5, 2016, respectively after which the Company's shares will be delivered to employees on the basis of the granted share units. A maximum of 4,599,000 shares may be delivered under the plan, but there is no maximum that can be issued in any one year. As at December 31, 2014, all shares had been delivered under the 2011A tranche.

The changes in the number of share units in the plan during the three months ended March 31, 2015 is shown in the table below.

<u>Number of Share Units</u>	<u>2011B</u>	<u>2011C</u>
Outstanding at January 1, 2015	654,375	795,000
Exercised	(504,375)	—
Outstanding at March 31, 2015	150,000	795,000

Biotie Therapies Oyj

Notes to the Unaudited Condensed Consolidated Financial Statements — (Continued)

The fair value of the restricted share units was determined as the closing share price for Biotie share on the grant date. The expense recognized during the three months ended March 31, 2015 was €30 thousand (the net reversal of the expense for the three months ended March 31, 2014 was €(29) thousand). The exercise price for all share units is €0.

b) Swiss option plan

The Company's Swiss subsidiary, Biotie Therapies AG, also has a stock option plan approved in 2008. Vesting of the options is related to continued service to the Company. The maximum contractual term of each option is ten years. The plan has been closed to new grants from February 1, 2011. An aggregate maximum of 14,912,155 shares in Biotie Therapies Corp. has been subscribed to under the plan and such shares have been issued to Biotie Therapies AG to be further conveyed to the option holders when they potentially exercise their option rights in accordance with the terms and conditions of the option rights. The last day for the share subscriptions based on the option rights in the Swiss option plan is December 7, 2020.

There has been no change in the number of options in the plan during the three months ended March 31, 2015, with the 2,824,772 options outstanding at March 31, 2015 and December 31, 2014 having a weighted average exercise price of €0.24 and €0.24 respectively.

The expense recognized during the three months ended March 31, 2015 was nil thousand (the net reversal of the expense for the three months ended March 31, 2014 was €(10) thousand).

c) Stock Option Plan 2014 and Equity Incentive Plan 2014

The Stock Option Plan 2014, primarily for European employees, and the Equity Incentive Plan 2014, primarily for US employees, were approved at the Company's 2014 general shareholders' meeting as part of the Company's incentive scheme determined by the Board of Directors. These plans contain both a service requirement condition at vesting for all awards and for the management awards, designated 2014M awards, there is an additional specified market performance requirement that determines the number of awards earned.

i. Stock Option Plan 2014

The fair value of the options was determined at the grant date by using the Black-Scholes option valuation model and expensed over the vesting period. The maximum number of options that could be awarded under the plan is 10,337,500, of which 4,320,000 are 2014M awards that are subject to an additional specified market performance requirement at vesting. The 2014M awards include an additional incentive (a market condition) for the senior management team to have a portion of their potential awards over the three years ending December 31, 2016 to be based solely on an increase in the share price of the Company for the vesting period. The 2014M awards will not vest unless the Company's share price growth during that three year period is greater than 35%; however, if the share price growth is greater than 35%, there will be an increasing return up to a maximum of three times the initial awards for a share price growth of at least 100% over the three year vesting period. The 2014M market condition has been incorporated into the Black-Scholes model, by determining the probability of the share price growth increase over the three year period based on historical share price movements.

Biotie Therapies Oyj
Notes to the Unaudited Condensed Consolidated Financial Statements — (Continued)

The changes in the number of options, or senior management option units in the case of the 2014M tranche, in the plan during the three months ended March 31, 2015 is shown in the table below.

<u>Number of options</u>	<u>2014A</u>	<u>2014B</u>	<u>2014C</u>	<u>2014D</u>	<u>2014M</u>
Outstanding at January 1, 2015	458,750	1,376,250	—	—	1,440,000
Forfeitures	(75,000)	(225,000)	—	—	—
Granted	—	—	389,250	1,167,750	—
Outstanding at March 31, 2015	383,750	1,151,250	389,250	1,167,750	1,440,000

All options were fair valued at grant date and will be recognized to personnel expenses, as research and development expenses or general and administrative expenses, over the vesting period. The most significant inputs used to estimate the fair value of the stock options granted during the three months ended March 31, 2015 are as follows:

<u>Option plan</u>	<u>2014C</u>	<u>2014D</u>
Share price at grant date	€0.20	€0.20
Subscription price	€0.01	€0.01
Volatility*	50%	50%
Maturity, years	3	4
Interest rate	0.00%	0.00%
Expected dividends	—	—
Valuation model	Black-Scholes	Black Scholes
Option fair value, €	0.19	0.19
Effect on earnings, € in thousands	8	16

* Expected volatility was determined by calculating the historical volatility of the Company's share using monthly observations over corresponding maturity.

The expense recognized during the three months ended March 31, 2015 was €56 thousand (for the three months ended March 31, 2014: €69 thousand).

ii. Equity Incentive Plan 2014

The Equity Incentive Plan 2014 includes three consecutive discretionary periods, calendar years 2014, 2015 and 2016 in which the restricted share units, or senior management units, may be granted. Each discretionary period is followed by a subscription period of approximately two years (for 2014A, 2014C and 2014E awards) or approximately three years (for 2014B, 2014D, 2014F and 2014M awards), ending on January 5, 2016, January 5, 2017, January 5, 2018 or January 5, 2019, after which the Company's shares will be delivered to employees on the basis of the granted share units. A maximum of 14,002,500 shares may be delivered under the plan, of which 2,520,000 are 2014M awards that are subject to an additional specified market performance requirement at vesting, which is the same as that described in the Stock Option Plan 2014 above. There is no maximum number of share units that can be awarded in any one year, but all the 2014M awards must be awarded in 2014.

Biotie Therapies Oyj
Notes to the Unaudited Condensed Consolidated Financial Statements — (Continued)

The changes in the number of share units, or senior management share units in the case of the 2014M tranche, in the plan during the three months ended March 31, 2015 is shown in the table below.

<u>Number of Share Units</u>	<u>2014A</u>	<u>2014B</u>	<u>2014C</u>	<u>2014D</u>	<u>2014M</u>
Outstanding at January 1, 2015	409,687	1,229,063	—	—	840,000
Granted	—	—	542,500	1,627,500	—
Outstanding at March 31, 2015	409,687	1,229,063	542,500	1,627,500	840,000

The effect on the Company's earnings for the three months ended March 31, 2015 was €95 thousand (for the three months ended March 31, 2014: €47 thousand). The fair value of the restricted share units was determined by using the closing share price of the Company's shares on the grant date. The fair value of the share units granted in the three months ended March 31, 2015 was €0.19 per share for the 2014C and 2014D. The exercise price for all units is the USD equivalent of €0.01.

11. Non-cash Transactions to Cash Flow from Operating Activities

<u>(€ in thousands)</u>	<u>For the three month period ended March 31,</u>	
	<u>2015</u>	<u>2014</u>
Depreciation and amortization	73	82
Share-based compensation	174	198
Other adjustments	54	139
Non-cash adjustments to cash flow from operating activities	301	419

12. Commitments and Contingencies

Operating lease commitments

<u>(€ in thousands)</u>	<u>As at</u>	
	<u>March 31, 2015</u>	<u>December 31, 2014</u>
Due within a year	911	843
Due in 1-5 years	2,100	1,937
Due later than 5 years	—	—
Total	3,011	2,780

Operating lease commitments comprise rent commitments for leasehold properties and lease commitments for motor vehicles, machines and equipment with leases of 3 to 5 years. The Company's operating leases are non-cancellable and they do not include redemption or extension options.

On March 31, 2015, Biotie had outstanding contractual payment obligations (contractual commitments), primarily for contract research work services related to ongoing clinical development programs, totaling €910 thousand (December 31, 2014: €232 thousand).

13. Transactions with Related Parties

During the periods ended March 31, 2015 and 2014, the Company's management team was paid regular salaries and contributions to post-employment benefit schemes. Additionally, the members of the

Biotie Therapies Oyj
Notes to the Unaudited Condensed Consolidated Financial Statements — (Continued)

Board of Directors were paid regular Board and committee fees. No loans, advances or guarantees were made to the management team or Board of Directors as of March 31, 2015 or 2014.

The condensed consolidated financial statements do not include all disclosures for related party transactions that are required in the annual consolidated financial statements and should be read in conjunction with the Company's annual consolidated financial statements for the year ended December 31, 2014.

14. Events After the Reporting Date

On April 23, 2015, the Company announced further detail on its Phase 3 clinical development plan for tozadenant.

On April 23, 2015, the Company announced plans to strengthen its capital structure in aggregate by approximately €95 million, to finance a Phase 3 double-blinded clinical trial, including the open label extension, of its lead product candidate tozadenant, through a direct issuance of up to €42.5 million of convertible promissory notes and other equity-based instruments to certain US investors and certain existing shareholders, as well as a potential US public offering ("US IPO") and potential other offerings in connection with the US IPO. The issue of the related shares is conditional on the granting of necessary authorizations and election of new Board members by the Annual General Meeting.

On April 23, 2015 and May 7, 2015, the Company and certain new and existing investors entered into subscription agreements for €27.5 million and €5.6 million, respectively of convertible promissory notes ("Convertible Notes") and other equity-based instruments ("Warrants"). The Convertible Notes can be converted into new shares in the Company by their holders at any time prior to the repayment of the Convertible Notes, which is scheduled to occur on or after May 1, 2035. Further, the Convertible Notes would automatically convert into new shares in the Company upon completion of a proposed US IPO. If the US IPO does not take place by May 1, 2016, the Company can force the conversion of the Convertible Notes at any time thereafter until the repayment date. The Warrants will entitle to subscribe for shares in the Company until November 1, 2020.

Report of Independent Registered Public Accounting Firm

To the Board of Directors and Shareholders of Biotie Therapies Oyj

In our opinion, the accompanying consolidated statements of financial position and the related consolidated statements of comprehensive income, of changes in shareholders' equity and of cash flows present fairly, in all material respects, the financial position of Biotie Therapies Oyj and its subsidiaries at December 31, 2014 and 2013, and the results of their operations and their cash flows for each of the two years in the period ended December 31, 2014 in conformity with International Financial Reporting Standards as issued by the International Accounting Standards Board. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits. We conducted our audits of these statements in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

/s/ PricewaterhouseCoopers Oy
Helsinki, Finland
March 17, 2015

Biotie Therapies Oyj

Consolidated Statements of Comprehensive Income

<u>(€ in thousands, except per share data)</u>	<u>Note</u>	<u>For the year ended December 31,</u>	
		<u>2014</u>	<u>2013</u>
Revenue	3	14,901	27,712
Research and development expenses	4, 5, 6	(17,192)	(17,807)
Impairment of in-process research and development assets	11	(27,605)	—
General and administrative expenses	5, 6	(7,326)	(8,971)
Other operating income	7	1,132	565
Operating (loss) income		(36,090)	1,499
Interest income	8	—	37
Interest expenses	8	(687)	(726)
Other net financial income (expenses)	8	1,612	2,841
(Loss) income before taxes		(35,165)	3,651
Income tax benefit	9, 24	—	2,195
Net (loss) income		(35,165)	5,846
Other comprehensive income (loss)			
Items that will not be reclassified to profit and loss:			
Remeasurements of post-employment benefit obligations	18, 21	(81)	—
Items that may be subsequently reclassified to profit and loss:			
Currency translation differences	18	6,593	(2,629)
Total other comprehensive income (loss)		6,512	(2,629)
Total comprehensive (loss) income		(28,653)	3,217
Net (loss) income attributable to equity holders of the parent		(35,165)	5,846
Total comprehensive (loss) income attributable to equity holders of the parent ..		(28,653)	3,217
(Loss) earnings per share (EPS) basic & diluted, €	10	(0.08)	0.01

All activities relate to continuing operations.

The accompanying notes form an integral part of the consolidated financial statements.

Biotie Therapies Oyj
Consolidated Statements of Financial Position

<u>(€ in thousands)</u>	<u>Note</u>	<u>As at December 31,</u>	
		<u>2014</u>	<u>2013</u>
ASSETS			
Non-current assets			
Intangible assets	11	47,356	68,744
Goodwill	11	5,799	5,315
Property, plant and equipment	12	653	627
Investment property	13	—	817
Other financial assets	14	324	242
Total non-current assets		54,132	75,745
Current assets			
Accounts receivables and other receivables	15	1,806	575
Financial assets at fair value through profit or loss	16	24,941	33,457
Cash and cash equivalents	17	7,452	10,221
Total current assets		34,199	44,253
Total assets		88,331	119,998
EQUITY AND LIABILITIES			
Shareholders' equity			
Share capital	18	193,285	193,285
Reserve for invested unrestricted equity	18	5,378	5,252
Other reserves	18	9,029	2,517
Retained earnings.		(155,069)	(120,688)
Total equity		52,623	80,366
Non-current liabilities			
Non-current financial liabilities	20	20,690	20,690
Pension benefit obligation	21	670	569
Other non-current liabilities	22	9,671	8,918
Non-current deferred revenues	23	2,000	2,972
Total non-current liabilities		33,031	33,149
Current liabilities			
Current deferred revenues	23	—	743
Accounts payable and other current liabilities	25	2,677	5,740
Total current liabilities		2,677	6,483
Total liabilities		35,708	39,632
Total shareholders' equity and liabilities		88,331	119,998

The accompanying notes form an integral part of the consolidated financial statements.

Biotie Therapies Oyj
Consolidated Statements of Changes in Shareholders' Equity

ATTRIBUTABLE TO EQUITY HOLDERS OF THE PARENT

<u>(€ in thousands)</u>	<u>Note</u>	<u>Share capital</u>	<u>Reserve for invested unrestricted equity</u>	<u>Other reserves</u>	<u>Retained earnings</u>	<u>Shareholders' equity total</u>
Balance at January 1, 2013		193,285	4,882	5,146	(128,282)	75,031
Net income for the period		—	—	—	5,846	5,846
Other comprehensive loss	18	—	—	(2,629)	—	(2,629)
Total comprehensive income (loss)		—	—	(2,629)	5,846	3,217
Share based compensation	19	—	—	—	1,748	1,748
Options and RSU exercised	19	—	370	—	—	370
		—	370	(2,629)	7,594	5,335
Balance at December 31, 2013		193,285	5,252	2,517	(120,688)	80,366
Net loss for the period		—	—	—	(35,165)	(35,165)
Other comprehensive income	18	—	—	6,512	—	6,512
Total comprehensive income (loss)		—	—	6,512	(35,165)	(28,653)
Share based compensation	19	—	—	—	784	784
Options and RSU exercised	19	—	126	—	—	126
		—	126	6,512	(34,381)	(27,743)
Balance at December 31, 2014		193,285	5,378	9,029	(155,069)	52,623

The accompanying notes form an integral part of the consolidated financial statements.

Biotie Therapies Oyj
Consolidated Statements of Cash Flows

<u>(€ in thousands)</u>	<u>Note</u>	<u>For the year ended December 31,</u>	
		<u>2014</u>	<u>2013</u>
Cash flow from operating activities			
Net (loss) income		(35,165)	5,846
Adjustments			
Non-cash impairment of in-process R&D assets	11	27,605	—
Other non-cash transactions	26	777	1,814
Interest expenses	8	687	726
Other financial income/expenses, net	8	(1,612)	(2,841)
Interest income	8	—	(37)
Income taxes	9	—	(2,195)
Change in working capital			
Change in accounts receivables and other receivables		(1,108)	2,241
Change in accounts payable and other liabilities		(3,479)	3,305
Change in deferred revenue		(1,770)	1,731
Interest paid		(27)	(44)
Interest received		—	31
Cash flow from (used in) operating activities		<u>(14,092)</u>	<u>10,577</u>
Cash flow from investing activities			
Investments in financial assets at fair value through profit and loss	16	—	(15,492)
Proceeds from sale of financial assets at fair value through profit and loss	16	9,773	2,000
Proceeds from sale of investment property	13	1,350	—
Change in other financial assets	14	(53)	(192)
Investments in property, plant and equipment	12	(146)	(329)
Investments in intangible assets	11	(50)	(52)
Net cash from (used in) investing activities		<u>10,874</u>	<u>(14,065)</u>
Cash flow from financing activities			
Proceeds from share issue and option exercise		126	370
Net cash from financing activities		<u>126</u>	<u>370</u>
Net decrease in cash and cash equivalents		<u>(3,092)</u>	<u>(3,118)</u>
Effect on changes in exchange rates on cash and cash equivalents		323	(214)
Cash and cash equivalents at the beginning of the period		10,221	13,553
Cash and cash equivalents at the end of the period	17	<u>7,452</u>	<u>10,221</u>

The accompanying notes form an integral part of the consolidated financial statements.

Biotie Therapies Oyj

Notes to the Consolidated Financial Statements

1. General Information

Biotie Therapies Oyj (“Biotie” or the “Company”) is a specialized drug development company incorporated and domiciled in Finland, with its headquarters at Joukahaisenkatu 6, Turku, Finland, focused on products for neurodegenerative and psychiatric disorders. Biotie operates primarily in Finland and in the United States. Biotie has developed Selincro (nalmefene) for alcohol dependence, which received European marketing authorization in 2013 and is currently being rolled out across Europe by partner Lundbeck. The current development products include tozadenant for Parkinson’s disease, which is transitioning into Phase 3 development, and two additional compounds which are in Phase 2 development for cognitive disorders including Parkinson’s disease dementia and primary sclerosing cholangitis, a rare fibrotic disease of the liver. Biotie’s shares are listed on Nasdaq Helsinki. As used in these consolidated financial statements, unless the context indicates otherwise, all references to “Biotie” or the “Company” or the “Group” refer to Biotie Therapies Oyj and all its consolidated subsidiaries.

The financial statements were approved for issue by the Board of Directors on March 13, 2015.

2. Summary of Significant Accounting Policies

2.1 Basis of Preparation

The consolidated financial statements of Biotie have been prepared in accordance with International Financial Reporting Standards (“IFRS”) and IFRIC Interpretations, as issued by the International Accounting Standards Board (“IASB”).

The principal accounting policies applied in the preparation of these consolidated financial statements are set out below. These policies have been consistently applied to all the years presented, unless otherwise stated.

The consolidated financial statements have been prepared assuming that the Company will continue as a going concern and under the historical cost convention, except for financial assets at fair value through profit and loss. The Directors have considered the financial position of the Company, its cash position and forecast cash flows for the twelve month period from the date of signing these financial statements in its going concern consideration. They have also considered the Company’s business activities, the key policies for managing financial risks and the key factors affecting the likely development of the business in 2015. In the light of this review, the Directors have a reasonable expectation that the Company has adequate resources to continue in operational existence for the foreseeable future. Accordingly, they continue to adopt the going concern basis in preparing these financial statements.

The preparation of financial statements under IFRS requires management to make judgments, estimates and assumptions that affect the reported amounts of assets and liabilities, and the disclosure of contingent assets and liabilities at the end of the reporting period, as well as the reported amounts of income and expenses during the reporting period. Although these estimates are based on management’s best knowledge of current events and actions, actual results may ultimately differ from them. The areas involving a higher degree of judgment or complexity, or areas where assumptions and estimates are significant to the consolidated financial statements are disclosed in note 2.24.

The Notes to the consolidated financial statements are presented in thousands of euros, rounded to the nearest thousand, unless otherwise stated. As a result, rounding differences may exist.

Biotie Therapies Oyj

Notes to the Consolidated Financial Statements — (Continued)

2.2 Changes in accounting policy and disclosures

(a) The following amendment to IFRS standards became effective for annual periods beginning on January 1, 2014 and has been adopted by the Company in the preparation of the consolidated financial statements

- Amendments to IAS 32 Financial statements – presentation

The adoption of this amendment did not impact the Company's financial position or results of operations. Other standards, amendments to standards and interpretations which are effective for the financial year beginning on January 1, 2014 are not material to the Group.

(b) New and amended IFRS standards and IFRIC interpretations effective after December 31, 2014

The following standards have been issued, but are not effective until after December 31, 2014, and are considered relevant for the Company. The Company is currently assessing their potential impact on the accounting policies, financial position and performance of the Company.

i. IFRS 9, Financial Instruments

IFRS 9, 'Financial instruments', addresses the classification, measurement and recognition of financial assets and financial liabilities. The complete version of IFRS 9 was issued in July 2014. It replaces the guidance in IAS 39 that relates to the classification and measurement of financial instruments. IFRS 9 retains, but simplifies, the mixed measurement model and establishes three primary measurement categories for financial assets: amortized cost, fair value through other comprehensive income (loss) and fair value through profit and loss. The basis of classification depends on the entity's business model and the contractual cash flow characteristics of the financial asset. Investments in equity instruments are required to be measured at fair value through profit or loss with the irrevocable option to present changes in fair value in other comprehensive income (loss) not recycling. There is a new expected credit losses model that replaces the incurred loss impairment model used in IAS 39. For financial liabilities there were no changes to classification and measurement except for the recognition of changes in own credit risk in other comprehensive income (loss) and for liabilities designated at fair value through profit or loss. IFRS 9 relaxes the requirements for hedge effectiveness by replacing the bright line hedge effectiveness tests. It requires an economic relationship between the hedged item and hedging instrument and for the 'hedged ratio' to be the same as the one management actually uses for risk management purposes. Contemporaneous documentation is still required, but is different to that currently prepared under IAS 39. The standard is effective for accounting periods beginning on or after January 1, 2018. Early adoption is permitted. The Company is assessing the impact of IFRS 9.

ii. IFRS 15, Revenue from Contracts with Customers

IFRS 15, 'Revenue from contracts with customers' deals with revenue recognition and establishes principles for reporting useful information to users of financial statements about the nature, amount, timing and uncertainty of revenue and cash flows arising from an entity's contracts with customers. Revenue is recognized when a customer obtains control of a good or service and thus has the ability to direct the use of, and obtain the benefits from, the good or service. The standard replaces IAS 18 'Revenue' and IAS 11 'Construction contracts' and related interpretations. The standard is effective for annual periods beginning on or after January 1, 2017 and earlier application is permitted. The Company is assessing the impact of IFRS 15.

Biotie Therapies Oyj
Notes to the Consolidated Financial Statements — (Continued)

2.3 Consolidation

(a) Subsidiaries

Subsidiaries are all entities over which the Company has control. The Company controls an entity when it is exposed to, or has rights to, variable returns from its involvement with the entity and has the ability to affect those returns through its power over the entity. Subsidiaries are consolidated from the date on which control is transferred to the Company and are de-consolidated from the date that control ceases. The acquisition method of accounting is used to account for subsidiaries acquired through a business combination.

Intra-group transactions, balances and unrealized gains and losses on transactions between group companies are eliminated. Unrealized losses are also eliminated, unless the transaction provides evidence of an impairment of the asset transferred. Accounting policies of subsidiaries have been changed where necessary to ensure consistency with the policies adopted by the Company.

(b) Business combinations

Business combinations are accounted for using the acquisition method. The acquisition cost is measured as the aggregate of the fair value of consideration transferred, measured at acquisition date, and the amount of any non-controlling interest in the acquiree. Acquisition costs incurred are expensed and included in general and administrative expenses.

2.4 Foreign currency translation

(a) Functional and presentation currency

Items included in the financial statements of each of the Group entities are measured using the currency of the primary economic environment in which the entity operates (the functional currency). The consolidated financial statements are presented in euros, which is the parent company's functional and the Group's presentation currency.

(b) Transactions and balances

Foreign currency transactions are translated into the functional currency using the exchange rates prevailing at the dates of the transactions. Foreign exchange gains and losses resulting from the settlement of such transactions and from the translation at year-end exchange rates of monetary assets and liabilities denominated in foreign currencies are recognized in the statement of comprehensive income.

Foreign exchange gains and losses that relate to borrowings and cash and cash equivalents are presented in the statement of comprehensive income within other net financial income (expenses), except when deferred in the cumulative translation account included in other comprehensive income as part of qualifying net investments. All other foreign exchange gains or losses are presented in the consolidated statement of comprehensive income within operating income.

(c) Group companies

The results and financial position of all group entities that have a functional 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.

Biotie Therapies Oyj

Notes to the Consolidated Financial Statements — (Continued)

- Income and expenses for each income statement are translated at average exchange rate (unless this average is not a reasonable approximation of the cumulative effect of the rates prevailing on the transaction dates, in which case income and expenses are translated at the rate on the dates of the transactions).
- All resulting exchange differences are recognized in other comprehensive income (loss).

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. Exchange differences arising are recognized in other comprehensive income (loss).

2.5 Notes to the statement of cash flows

The statement of cash flows has been prepared using the indirect method. The cash disclosed in the statement of cash flows comprise cash and cash equivalents, excluding restricted cash balances. Cash comprises cash on hand and demand deposits. Cash equivalents are short-term, highly liquid investments with original maturities of three months or less that are readily convertible to known amounts of cash and are subject to an insignificant risk of changes in value. Cash flows denominated in foreign currencies have been translated at the average exchange rates. Exchange differences, if any, affecting cash items are shown separately in the statement of cash flows. Interest paid and received, dividends received and income tax are included in the cash flow from operating activities.

2.6 Segment reporting

Biotie operates in one reportable segment, which comprises the development of pharmaceutical products. The Chief Executive Officer is identified as the chief operating decision maker. The Chief Executive Officer reviews the consolidated operating results regularly to make decisions about resources and to assess overall performance.

In 2014, €7,978 thousand (2013: €23,557 thousand) of the total revenue was received from Belgium and €6,923 thousand (2013: €4,155 thousand) of the total revenue was received from Denmark.

Non-current assets (other than financial instruments and deferred income tax assets) by country were €2,652 thousand (2013: €1,305 thousand) in Finland, €19,142 thousand (2013: €26,360 thousand) in Switzerland and €28,054 thousand (2013: €42,136 thousand) in the United States.

2.7 Revenue recognition

The Company's revenue arises from collaboration and licensing agreements with pharmaceutical companies that may include a) licenses, b) development and approval milestone payments, c) development funding income, d) commercial milestone payments and e) royalties. For these agreements, the Company applies revenue recognition criteria to the separately identifiable components of a single transaction. The total arrangement consideration is allocated to separately identifiable components by reference to their fair values. Revenue is recognized when the amount can be measured reliably, when it is probable that future economic benefits will flow to the Company, when costs incurred in respect of the sale can be measured reliably, and, if applicable, when specific criteria have been met for each of the Company's activities, in accordance with the principles described below. Costs under these types of arrangements are expensed as incurred and therefore the pattern of cost recognition may be different than revenue recognition.

Biotie Therapies Oyj

Notes to the Consolidated Financial Statements — (Continued)

(a) Licenses

Revenues in connection with out-licensing of the Company's patents and other intellectual property are recognized when the following criteria have been met:

- The Company has transferred to the buyer the significant risks and rewards of ownership of the patents and intellectual property; and
- The Company does not retain either the continuing managerial involvement to the degree usually associated with ownership or the effective control over the patent and intellectual property.

Where the above criteria are not met, up-front and option payments received in connection with product out-licensing activities are deferred and recognized over the period of the license term or the option period on a straight-line basis, even where such fees are non-refundable.

(b) Development and approval milestone payments

Revenue related to non-refundable fixed-fee development and approval milestone payments are recognized when a milestone has been achieved and the Company has no further performance obligations in respect of the milestone.

In certain agreements, where the non-refundable milestone payments are primarily received to reimburse development costs for specific development activities, revenue is recognized as the lower of the non-refundable cash received under the agreement and that based on the percentage of completion method until the contingency is resolved, which is measured on the efforts and costs incurred to date in relation to the total estimated costs to complete the contract.

Any milestone payments that have been received but for which the earnings process has not been completed are accounted for as deferred revenue (a liability) on the statement of financial position.

(c) Development funding income

Development funding income is recognized once the development activities have been incurred and the Company has no further performance obligations.

(d) Commercial milestone payments

Commercial milestone payments are non-refundable and are due when sales by license partners have reached certain pre-agreed levels. The milestone payments are recognized in full when the Company can verify that the milestone has been reached, which is normally evidenced through partner acceptance in accordance with the license agreement terms.

(e) Royalties

Royalty revenue is recognized on an accrual basis in accordance with the relevant agreement.

2.8 Grants

The Company has received grants, from time to time, from government and certain charitable organizations, such as the Michael J. Fox Foundation, to support certain research projects. These grants are recognized as income and presented in other operating income when management has reasonable assurance that the Company will comply with the conditions attached to those grants and that such grants will be

Biotie Therapies Oyj

Notes to the Consolidated Financial Statements — (Continued)

received. Income is recognized when costs under each grant are incurred in accordance with the terms and conditions of the grant and the collectability of the receivable is probable. Further, grants relating to costs are deferred and recognized in the consolidated statement of comprehensive income over the period necessary to match them with the costs they are intended to compensate and only to the extent that the cumulative accrued eligible costs at the time of recognition are less than the cumulative received grant to reflect any obligation to return any portion of the grant for which the related costs have not been incurred at the end of the grant period.

2.9 Property, plant and equipment

Property, plant and equipment comprises mainly machinery and technical equipment used in research and development and leasehold improvements. They are stated at historical cost less depreciation and any impairment loss. Historical cost includes expenditure that is directly attributable to the acquisition of the items. Depreciation is calculated using the straight-line method to allocate each item's acquisition cost or impaired amount to its residual value during its estimated useful life, as follows:

<u>Asset group</u>	<u>Useful life</u>
Machinery and technical equipment	3–12 years
Other equipment	3–8 years
Leasehold improvements	5 years

The residual value and the useful life of an asset are reviewed, and adjusted if appropriate, at each balance sheet date.

Gains and losses on the disposals are determined by comparing proceeds with the carrying amount and are recognized in the consolidated statement of comprehensive income within other operating income.

2.10 Investment property

Investment properties are land and buildings which are held to earn rental income or for capital appreciation or for both.

Investment properties are initially recorded at cost, including transaction costs, and after initial recognition stated at historical cost less depreciation (at straight-line) and any impairment losses. The fair values for the investment properties are disclosed in Note 13. The fair values are generally assessed using internationally accepted valuation methods, such as taking comparable properties as a guide to current market prices or by applying the discounted cash flow method, unless a property specific valuation is available.

As at December 31, 2014, the Company's investment property had been disposed of and, accordingly, the Company no longer holds assets in this category.

2.11 Intangible assets

(a) Goodwill

Goodwill arising in a business combination is recognized as an asset at the date that control is acquired. Goodwill is measured as the excess of the sum of consideration transferred, the amount of any non-controlling interest in the acquiree and the fair value of the acquirer's previously held equity interest (if any) in the entity over the fair value of the identifiable assets acquired and liabilities assumed.

Biotie Therapies Oyj

Notes to the Consolidated Financial Statements — (Continued)

Goodwill is not amortized but is tested for impairment annually, or more frequently when there is an indication that goodwill may be impaired. For the purpose of impairment testing, goodwill is allocated to a cash-generating unit (CGU) or groups of CGUs expected to benefit from the synergies of the business combination giving rise to the goodwill. The company has determined that it only has one CGU as its material assets are used in the development of all the products and management regularly reviews all activities of the group as a single component and, as a result, goodwill is monitored at the operating segment level. If the recoverable amount, which is the higher of value in use and the fair value less cost of disposal, of the CGU is less than its carrying amount, the impairment loss is allocated first to reduce the carrying amount of any goodwill to nil and then to the other assets of the unit pro-rata on the basis of the carrying amount of each asset in the CGU. An impairment loss recognized for goodwill is not reversed in a subsequent period.

On disposal of a CGU, the attributable amount of goodwill is included in the determination of the profit or loss on disposal.

(b) Research and development expenses

Research expenditures are recognized as expenses as incurred. Costs include salaries and support costs, such as rent and leasing, which are directly attributable to the Company's research and development programs. Costs incurred on development projects are recognized as intangible assets as of the date that it meets all the criteria for recognition, one of which is to establish that it is probable that future economic benefits that are attributable to the asset will flow to the Company. Given the current stage of the development of the Company's products and product candidates, no internal development expenditures have yet been capitalized as management considers that the uncertainties inherent in developing pharmaceutical products prohibits the capitalization of internal development expense as an intangible asset until marketing approval has been received from the relevant regulatory agencies.

(c) Other intangible assets

Intangible assets include in-process research and development, production licenses, computer software and other intangible assets.

In-process research and development projects acquired in a business combination are capitalized at their fair values at the date of acquisition. They will be amortized from the date when marketing approval has been received from the relevant regulatory agencies. Prior to that, acquired in-process research and development projects are not amortized, but are subject to annual impairment testing, or more frequently when there is an indicator of impairment.

Production licenses, computer software and other intangible assets are capitalized on the basis of the costs incurred and amortized using straight-line depreciation over their estimated useful lives. The amortization periods are as follows:

<u>Asset group</u>	<u>Useful life</u>
Production licenses	17–20 years
Computer software	3–4 years

2.12 Impairment of non-financial assets

Non-financial assets that are subject to amortization are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount may not be recoverable. Intangible assets that

Biotie Therapies Oyj

Notes to the Consolidated Financial Statements — (Continued)

have an indefinite useful life, such as goodwill, or intangible assets not ready to use, such as in-process R&D assets, are not subject to amortization and are tested annually for impairment, or whenever events or changes in circumstances indicate that the carrying amount may not be recoverable.

An impairment loss is recognized for the amount by which the asset's carrying amount exceeds its recoverable amount. The recoverable amount is the higher of an asset's fair value less cost of disposal and value in use. The Company's impairment review methodology applied is based on the fair value less cost of disposal. The fair value of the asset is determined from the discounted future net cash flows expected to be derived from the asset or, in the case of goodwill, the CGU. The discounted future net cash flows of development assets are adjusted for the probability of future development success; the discount rate used reflects the time value of money and appropriate risk premiums for the asset. The fair value less cost of disposal is then compared to the carrying amount of the asset. An impairment charge is recognized in the consolidated statement of comprehensive income for the amount by which the asset's carrying amount exceeds its fair value less cost of disposal. Intangible assets, other than goodwill, that have been previously impaired, are reviewed for possible reversal of the impairment at each subsequent reporting date; any such reversal would be recognized in the consolidated statement of comprehensive income on the period in which it was identified.

2.13 Financial assets

The Company classifies its financial assets in the following categories:

- at fair value through profit or loss
- loans and receivables

The classification depends on the purpose for which the financial assets were acquired and in which they were classified at initial recognition. The Company applies a consistent policy in recognizing an asset based on the trade date, which is the date that the Company commits to buy or sell the asset. Financial assets are initially recognized at fair value, transaction costs are included in the fair value unless the asset is recognized at fair value through profit or loss.

(a) Financial assets at fair value through profit and loss

Financial assets are classified as at fair value through profit and loss when they are either acquired for trading purposes or when the management designates them initially as at fair value through profit or loss. The Company's financial assets in this category comprise investments in money market and investment funds that have been designated at fair value through profit and loss at initial recognition. Financial assets at fair value through profit and loss are measured and their performance is evaluated by management on a fair value basis.

Realized and unrealized gains and losses arising from changes in their fair value are recognized in the consolidated statement of comprehensive income within other financial income (expense) in the period in which they arise.

(b) Loans and receivables

Loans and receivables are non-derivative financial assets with fixed or determinable payments that are not quoted in an active market nor held by the Company for trading. Accounts receivable and other receivables are included in this category. These are initially measured at fair value plus transaction costs.

Biotie Therapies Oyj

Notes to the Consolidated Financial Statements — (Continued)

Subsequent to initial recognition assets are carried at amortized cost using the effective interest method less any impairment. Interest income is recognized in the consolidated statement of comprehensive income within interest income.

(c) Impairment of loans and receivables

Accounts and other receivables are assessed for indicators of impairment at each reporting date. Receivables are impaired where there is objective evidence that, as a result of one or more events that occurred after initial recognition, the estimated future cash flows of the receivables have been affected. Evidence of impairment may include indicators such as a debtor's significant financial difficulty, default or delinquency in interest or principal payments, or the probability that it will enter bankruptcy.

If in a subsequent period, the amount of the impairment loss decreases and the decrease can be related objectively to an event occurring after the impairment was recognized, the reversal of the previously recognized impairment loss is recognized in the consolidated statement of comprehensive income.

2.14 Leases

(a) Group companies as the lessee

Leases of tangible assets, where the Company has substantially all the risks and rewards of ownership, are classified as finance leases. Finance leases are capitalized at the inception of the lease at the lower of the fair value of the leased property or the present value of the minimum lease payments. Each lease payment is allocated between the finance charge and the reduction of the outstanding liability so as to achieve a constant rate on the finance balance outstanding. Lease obligations are included in current and non-current financial liabilities net of finance charges. The interest element of the payments is expensed. An asset recognized under a finance lease is depreciated over its useful life.

Leases where a significant portion of the risks and rewards of ownership are retained by the lessor are classified as other operating leases. Payments made under operating leases are charged to the consolidated statement of comprehensive income on a straight-line basis over the period of the lease.

(b) Group companies as the lessor

Leases in which the Company has not transferred substantially all the risks and rewards of ownership are classified as operating leases. Rental payments received are recorded in other operating income on a straight-line basis over the lease term.

2.15 Cash and cash equivalents

Cash and cash equivalents comprise cash on hand, demand deposits and other short-term, highly liquid investments with original maturities of less than three months.

2.16 Trade payables

Trade payables are obligations to pay for goods or services that have been acquired in the ordinary course of business from suppliers. Trade payables are classified as current liabilities if payment is due within one year or less (or in the normal operating cycle of the business if longer). If not, they are presented as non-current liabilities.

Biotie Therapies Oyj

Notes to the Consolidated Financial Statements — (Continued)

2.17 Share capital

Shares are classified as equity. Incremental costs directly attributable to the issue of new shares or options are shown in equity as a deduction, net of tax, from the proceeds of the share issue.

When a Group company purchases Parent Company's shares (treasury shares), the consideration paid, including any directly attributable incremental costs (net of income taxes) is deducted from equity attributable to the Company's equity holders until the shares are cancelled, reissued or disposed of. Where such shares are subsequently sold or reissued, any consideration received, net of any directly attributable incremental transaction costs and the related income tax effect, is included in the equity attributable to the Company's equity holders.

Reserve for invested unrestricted equity includes, under the Finnish Companies Act, the exercise value of shareholders' investment comprising the share subscription prices and exercise prices of share options.

2.18 Borrowings

Borrowings are recognized initially at fair value net of transaction costs incurred. Financial liabilities are included in current and non-current liabilities based on their maturities. Borrowings are subsequently recognized at amortized cost, any difference between the proceeds, net of transaction costs, and the redemption value is recognized in the consolidated statement of comprehensive income over the period of the borrowings using the effective interest method.

Compound financial instruments issued by the Group comprise of a convertible note that can be converted to share capital at the option of the holder and the number of shares to be issued is fixed and does not vary with changes in their fair value. The liability component of a compound financial instrument is recognized initially at the fair value of a similar liability that does not have an equity conversion option. The equity component is recognized initially at the difference between the fair value of the compound financial instrument as a whole and the fair value of the liability component. Any directly attributable transaction costs are allocated to the liability and equity components in proportion to their initial carrying amounts. Subsequent to initial recognition, the liability component of a compound financial instrument is measured at amortized cost using the effective interest method. The equity component of a compound financial instrument is not re-measured subsequent to initial recognition except on conversion or expiry.

The fair value of the liability portion of the convertible loan was determined at inception using a market interest rate for the equivalent non-convertible loan. Based on the fair value calculation at the date of inception in 1999, there was no significant separate conversion option component in the convertible capital loan and as such the entire convertible loan has been classified as a financial liability.

For loans from a government agency (such as Finnish Funding Agency for Technology and Innovation, Tekes) issued at below market rates and awarded post IAS 20 amendment (effective January 1, 2009), the Company separately accounts for the grant and liability components and records the benefit of the below market rate loan as grant income. The remaining liability is measured at amortized cost. Following the forgiveness of certain of the Tekes loans in 2013, the grant components related to such loans have been fully utilized.

A financial liability, or a portion of a financial liability, is derecognized when it is extinguished i.e. when the obligation specified in the contract is discharged, cancelled or expires. For government loans that have been forgiven as a result of a separate event not part of the original terms and conditions, the

Biotie Therapies Oyj

Notes to the Consolidated Financial Statements — (Continued)

forgiveness of the loan is treated as a gain on extinguishment and the resulting gain has been recorded through the consolidated statement of comprehensive income within other financial income (expense). Interest costs on interest-bearing liabilities are expensed as incurred using the effective interest method.

2.19 Income taxes

Income tax expense consists of current and deferred taxes. The income tax effects of items recognized in other comprehensive income or directly in equity are similarly recognized in other comprehensive income or equity, respectively. The current income tax charge is calculated on the basis of the tax laws enacted in the countries where the Group operates and generates taxable income.

Management periodically evaluates positions taken in tax returns with respect to situations in which applicable tax regulation is subject to interpretation. It establishes provisions where appropriate on the basis of amounts expected to be paid to the tax authorities.

Deferred income tax is recognized on temporary differences arising between the tax bases of assets and liabilities and their carrying amounts in the financial statements. Temporary differences arise primarily from in-process R&D intangible assets, R&D credits and deferrals, depreciation on property, plant and equipment and net operating tax loss carryforwards.

Deferred income tax assets are recognized only to the extent that it is probable that future taxable profit will be available against which temporary differences can be utilized.

Deferred taxes are determined using a tax rate enacted, or substantially enacted, as of the date of the balance sheet date in the respective countries. However, deferred taxes are not recognized if they arise from the initial recognition of goodwill, or in the initial recognition of an asset or liability in a transaction other than a business combination that at the time of the transaction affects neither accounting nor taxable profit nor loss.

2.20 Earnings (loss) per share

Basic earnings (loss) per share is calculated by dividing the net income (loss) attributable to shareholders by the weighted average number of shares in issue during the year, excluding shares purchased by the Company and held as treasury shares.

Diluted earnings (loss) per share is calculated by adjusting the weighted average number of shares outstanding assuming conversion of all dilutive potential shares.

2.21 Employee benefits

The Company has both defined contribution and defined benefit plans.

(a) Defined contribution plans

A defined contribution plan is a pension plan under which the Company pays fixed contributions into a separate entity, which is not part of the Group. The Company has no legal or constructive obligations to pay further contributions if the fund does not hold sufficient assets to pay all employees the benefits relating to employee service in the current and prior periods. The contributions are recognized as employee benefit expense when they are due. Prepaid contributions are recognized as an asset to the extent that a cash refund or a reduction in the future payments is available.

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Notes to the Consolidated Financial Statements — (Continued)

(b) Defined benefit plans

The Company has two closed schemes classified as defined benefit plans related to former German employees based on a defined amount of pension benefit that these former employees will receive at retirement. The liability recognized in the consolidated statement of financial position in respect of these defined benefit pension plans is the present value of the defined benefit obligation at the reporting date less the fair value of plan assets. The defined benefit obligation is calculated annually by independent actuaries using the projected unit credit method. The present value of the defined benefit obligation is determined by discounting the estimated future cash outflows using interest rates of high quality corporate bonds that are denominated in the currency in which the benefits will be paid, and that have terms to maturity approximating to the terms of the related pension liability. In countries where there is no deep market in such bonds, the market rates on government bonds are used.

Actuarial gains and losses arising from experience adjustments and changes in actuarial assumptions are charged or credited to equity in other comprehensive income in the period in which they arise.

Past-service costs are recognized immediately as an expense. As the Company's remaining defined benefit obligations are closed schemes, the Company does not incur current service costs and the charge in the statement of comprehensive income comprises the interest cost that is presented within personnel expenses.

2.22 Share-based compensation

The Company operates a number of equity-settled share-based compensation plans (share option rights and restricted share units "RSU") plans under which it receives services from employees as consideration for equity instruments of the Company. Option rights and RSU have been measured at their fair values at the grant dates and the fair values are expensed on a straight-line basis over the vesting period, based on the Company's estimate of shares that will eventually vest. The fair value is determined using the Black-Scholes option pricing model with market-based inputs.

At each reporting date, the Company revises its estimate of the number of equity instruments that are expected to vest. The impact of the revision of the original estimates, if any, is recognized in consolidated statement of comprehensive income with a corresponding adjustment to equity. When options are exercised and RSU subscribed for, generally the Company issues new shares from treasury shares. Option rights that are exercised and RSU subscribed for with an exercise price are recognized in the reserve for invested unrestricted equity.

2.23 Provisions and contingent liabilities

Provisions are recognized when the Company has a present legal or constructive obligation as a result of past events, it is probable that an outflow of resources will be required to settle the obligation, and a reliable estimate of the amount can be made. Provisions are measured at the present value of the expenditures expected to be required to settle the obligation using a pre-tax rate that reflects current market assessments of the time value of money and the risks specific to the obligation. The increase in a provision due to passage of time is recognized in interest expenses.

2.24 Critical accounting estimates and judgments in applying the Company's accounting policies

In the application of the Company's accounting policies, which are described above, management is required to make judgments, estimates and assumptions about the carrying amounts of assets and liabilities

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that are not readily apparent from other sources. The estimates and associated assumptions are based on historical experience and other factors that are considered to be relevant. Actual results may differ from these estimates.

The estimates and assumptions are reviewed on an on-going basis. Revisions to accounting estimates are recognized in the period in which the estimate is revised if the revision affects only that period or in the period of the revisions and future periods if the revision affects both current and future periods.

The following are the critical judgments, apart from those involving estimations (which are dealt with separately below), that management has made in the process of applying the Company's accounting policies and that have the most significant effect on the amounts recognized in the financial statements.

(a) Revenue recognition

The Company's revenue arises from collaboration and licensing agreements with pharmaceutical companies that may include licenses, development and approval milestone payments, development funding income, commercial milestone payments and royalties. These agreements which often require significant analysis and judgment by management in order to determine the appropriate method of revenue recognition.

Where such arrangements can be divided into separate units of accounting (each unit constituting a separate earnings process), the arrangement consideration is allocated to the different units based on their relative fair values and recognized over the respective performance period. This analysis requires considerable estimates and judgments, including estimates of the relative fair values of the various elements included in such agreements and the estimated length of the respective performance periods. Depending upon how such judgment is exercised, the timing and amount of revenue recognized could differ significantly. Revenue in the various accounting units containing elements is recognized when the criteria for revenue recognition regarding the elements of that accounting unit have been met according to their type and only to the extent of the consideration that is not contingent upon completion or performance of the remaining elements in the contract.

Revenues on licenses are recognized when, in the judgment of management, significant risks and rewards of ownership have been transferred to the buyer and where the Company does not retain either the continuing managerial involvement to the degree usually associated with ownership or effective control.

Non-refundable development, approval and commercial milestone payments are recognized when a milestone has been achieved and the Company has no further performance obligations. This is normally when the Company is informed by the partner that the milestone has been achieved.

Any milestone payments that have been received but for which earnings process has not been completed are reported as deferred revenue (liability) in the statement of financial position. Any change in the estimated development period may lead to an adjustment of the recognition amount and time. In case the estimated development schedule was to be delayed, the annual income would lessen since the amount of the total revenue would be allocated over a longer period of time.

In certain agreements, where development milestones are primarily received to reimburse development costs for specific development activities, revenue is recognized as the lower of the non-refundable cash received under the agreement and that based on the percentage of completion method. This is based on the efforts and costs incurred to date in relation to the total estimated costs to complete the contract. Any change in the estimated costs to complete could cause a change in the amount of revenue that should have been recognized to date. Refer to note 3 for details in revenue.

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(b) Share-based payments

Option rights and share units have been measured at their fair value at the grant date and are recognized as an expense in the consolidated statement of comprehensive income over the vesting period. A Black-Scholes pricing model is used to value the option rights and share units that have been granted and critical judgments need to be exercised in determining the appropriate assumptions to include in the model, as well as to determine the most appropriate way of recognizing the compensation expense. The Company's shares are listed on the Nasdaq OMX Helsinki Ltd., or the Finnish Stock Exchange and therefore, the market based inputs used to fair value the option rights and share units include company-specific historical share price and volatility information. The key assumptions in the model are detailed in note 19. The Group reviews and updates, as appropriate, each of the underlying assumptions at the date of the financial statements. The impact of any changes in the estimates or assumptions is recorded in the statement of comprehensive income.

(c) Impairment of intangible assets and goodwill

The Group has significant investments in intangible assets and goodwill, which are tested for impairment in accordance with the accounting policies above. The recoverable amounts of the assets have been determined based on fair value less cost of disposal. The determination of the fair values requires management to make a number of estimates and assumptions related to future expectations of success and to use discount rates and other inputs that are relevant to the specific assets. Should it be required to recognize impairments in the consolidated statement of comprehensive income as a result of the impairment testing, this could have a material effect on the Group's results and financial position, although this would not have any impact on the Company's cash or liquid resources balances. Key assumptions regarding intangible assets and goodwill impairment testing, including the impairments recognized in 2014, are discussed in note 11.

(d) Research and development expenses

The stage of a particular development asset generally forms the basis for the decision whether costs incurred on research and development projects can be capitalized or not. In general, the Company's view is that research and development expenses may not be capitalized until marketing approval has been received from the relevant regulatory agencies, as this is considered to be the first point at which it may be appropriate to conclude the future revenues can be generated. Expenses before that point are recognized as they are incurred in the consolidated statement of comprehensive income and when a project reaches that point, it is reviewed at each reporting period to assess whether in management's judgment it meets the capitalization criteria.

As of each balance sheet date, the Company estimates the level of service performed by its vendors or other counterparties and the associated costs incurred for the services performed. As part of the process of preparing the Company's financial statements, the Company is required to estimate its accrued expenses, which are predominantly in respect of research and development activities. This process involves reviewing quotations and contracts, identifying services that have been performed on the Company's behalf, estimating the level of service performed and the associated cost incurred for the service when it has not yet been invoiced or notified of the actual cost; in most cases, this is done by discussion with the vendors. The majority of the Company's service providers invoice the Company monthly in arrears for services performed. The Company makes estimates of its accrued expenses at each balance sheet date in its financial statements based on the facts and circumstances known to it at that date. Although the Company does not

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expect its estimates to be materially different from the amounts actually incurred, its understanding of the status and timing of services performed relative to actual status and timing may vary and could result in it reporting amounts that are too high or too low in a particular period. When the actual amounts are known, any difference is recognized in the consolidated statement of comprehensive income. Refer to note 4 for detail.

(e) Income taxes

The Company is subject to income taxes in Finland, the United States, Switzerland and Germany. Significant judgment is required in determining the use of net operating loss carry forwards and the taxation of up-front and milestone payments for income tax purposes. There are many transactions and calculations for which the ultimate tax determination is uncertain. Where the final tax outcome of these matters is different from the amounts that were initially recorded, such differences may impact the current and deferred income tax assets and liabilities in the period in which such determination is made.

The companies in the Biotie group generally have a history of recent tax losses and the Group recognizes deferred tax assets arising from unused tax losses or tax credits only to the extent the relevant fiscal entity has sufficient taxable temporary differences or there is convincing other evidence that sufficient taxable profits will be available against which the unused tax losses or unused tax credits can be utilized by the fiscal entity. Management's judgment is currently that sufficient convincing other evidence is not available and a deferred tax asset is, therefore, not recognized. Refer to notes 9 and 24 for detail on income taxes.

3. Revenue

<u>(€ in thousands)</u>	For the year ended December 31,	
	2014	2013
Commercial milestone payments from Lundbeck license agreement	6,000	4,000
Royalties from Lundbeck license agreement	923	155
Phase 2 development milestones from UCB collaboration agreement	—	15,286
Phase 3 development milestones from UCB collaboration agreement	5,047	8,271
Phase 3 development funding income from UCB	2,931	—
Total	14,901	27,712

Lundbeck License Agreement

In 2007, the Company entered into a license agreement with Lundbeck to develop, manufacture and commercialize Selincro (nalmefene) for any purpose. Lundbeck is responsible for the manufacturing and commercialization of Selincro (nalmefene), as well as registration, maintenance and defense of all trademarks related to such products. Pursuant to the license agreement, Lundbeck agreed to make milestone payments to the Company upon the achievement of specified regulatory and commercial milestones as well as royalties on sales of Selincro (nalmefene).

UCB License and Collaboration Agreement and UCB Termination and Transition Agreement

As part of an acquisition in February 2011, the Company assumed a license and collaboration agreement with UCB to develop and commercialize tozadenant. Following a review of the tozadenant Phase

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2 data in February 2013, UCB exercised an option and paid the Company a nonrefundable Phase 2 development milestone. Until the end of March 2014, UCB paid Phase 3 development milestones. In March 2014, UCB terminated the collaboration agreement and the Company and UCB entered into a termination and transition agreement pursuant to which UCB agreed to fund certain transitional activities.

4. Research and development expenses

<u>(€ in thousands)</u>	For the year ended December 31,	
	2014	2013
Outsourced services	(10,088)	(10,816)
Internal research and development expenses	(1,478)	(1,373)
Personnel costs	(5,456)	(5,511)
Depreciation and amortization	(170)	(107)
Total	(17,192)	(17,807)

5. Personnel costs

<u>(€ in thousands)</u>	For the year ended December 31,	
	2014	2013
Salaries	(6,488)	(5,817)
Obligatory personnel expenses	(509)	(347)
Voluntary personnel expenses (including fringe benefits)	(914)	(895)
Pension expenses — contribution-based pension plans	(343)	(281)
Pension expenses — benefit-based pension plans	(20)	(21)
Share based compensation	(784)	(1,748)
Total	(9,058)	(9,109)
Personnel costs by operation		
Research and development personnel costs	(5,456)	(5,511)
General and administrative personnel costs	(3,602)	(3,598)
Total	(9,058)	(9,109)

The average number of personnel in 2014 was 36 (2013: 35). Share-based compensation disclosures are included in Note 19 and management benefits in Note 29.

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Notes to the Consolidated Financial Statements — (Continued)

6. Depreciation and amortization

	For the year ended December 31,	
<u>(€ in thousands)</u>	<u>2014</u>	<u>2013</u>
Depreciation and amortization by type of asset		
Intangible assets	(74)	(53)
Machinery and equipment	(183)	(75)
Investment property	(24)	(39)
Total	(281)	(167)
Depreciation and amortization by operation		
Research and development	(170)	(107)
Administration	(111)	(60)
Total	(281)	(167)

7. Other operating income

	For the year ended December 31,	
<u>(€ in thousands)</u>	<u>2014</u>	<u>2013</u>
Rent from investment property	366	565
Net gain on sale of investment property, see note 13	433	—
Grant income	333	—
Total	1,132	565

Grant income has been recognized in respect of the grant from the Michael J. Fox Foundation in relation to the SYN120 Phase 2a study.

8. Financial income and expenses

	For the year ended December 31,	
<u>(€ in thousands)</u>	<u>2014</u>	<u>2013</u>
Interest income		
Interest income	—	37
Total	—	37
Interest expenses		
Interest on Tekes loans	(519)	(558)
Interest on convertible capital loan	(168)	(168)
Total	(687)	(726)
Other net financial income (expenses)		
Unrealized and realized gains from assets recorded at fair value in profit and loss	264	242
Extinguishment of debt (Tekes loan forgiveness)	—	3,175
Net gains (losses) from foreign exchange	1,348	(576)
Total	1,612	2,841

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Notes to the Consolidated Financial Statements — (Continued)

9. Income tax benefit

<u>(€ in thousands)</u>	<u>For the year ended December 31,</u>	
	<u>2014</u>	<u>2013</u>
Current income tax	—	—
Deferred income tax	—	2,195
Total	—	2,195
(Loss) income before tax	(35,165)	3,651
Tax benefit (charge) calculated at domestic tax rates applicable to (loss) income in the respective countries	11,881	(745)
Tax effects of:		
Expenses not deductible for tax purposes	—	(106)
Utilization of previously unrecognized tax losses	93	3,128
Tax losses for which no tax asset was recognized	(11,974)	(82)
Income tax benefit	—	2,195

10. (Loss) earnings per share

(a) Basic (loss) earnings per share

Basic (loss) earnings per share is calculated by dividing the net (loss) income attributable to equity holders of the parent by the weighted average number of shares in issue during the year, excluding shares purchased by the Company and held as treasury shares.

	<u>For the year ended December 31,</u>	
	<u>2014</u>	<u>2013</u>
Net (loss) income attributable to equity holders of the parent (€ in thousands)	(35,165)	5,846
Weighted average number of outstanding shares (thousands)	450,686	446,214
Basic (loss) earnings per share (€ per share)	(0.08)	0.01

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Notes to the Consolidated Financial Statements — (Continued)

(b) Diluted (loss) earnings per share

Diluted (loss) earnings per share is calculated by adjusting the weighted average number of shares outstanding assuming conversion of all dilutive potential shares. The Company has three kinds of potentially dilutive instruments comprising stock options, restricted share units (RSU) and the convertible capital loan. For the year ended December 31, 2014, because there was a loss for the year the potential dilutive shares had an anti-dilutive effect (i.e. decrease loss per share) and are, therefore, excluded from the calculation of diluted earnings (loss) per share.

	For the year ended December 31,	
	2014	2013
Net (loss) income attributable to equity holders of the parent (€ in thousands)	(35,165)	5,846
Interest expense on convertible debt (net of tax) (€ in thousands)	—	127
Net (loss) income used to determine diluted earnings (loss) per share (€ in thousands)	(35,165)	5,973
Weighted average number of outstanding shares (thousands)	450,686	446,214
Adjustments for:		
Share options and RSU (thousands)	—	5,296
Assumed conversion of convertible debt (thousands)	—	828
Weighted average number of outstanding shares for diluted (loss) earnings per share (thousands)	450,686	452,338
Diluted (loss) earnings per share (€ per share)	(0.08)	0.01

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Notes to the Consolidated Financial Statements — (Continued)

11. Intangible assets and goodwill

(€ in thousands)	In-process R&D	Production licenses	Software	Other intangible assets	Intangible assets total	Goodwill	Total
Book value January 1, 2013	70,534	530	21	—	71,085	5,497	76,582
Additions	—	—	42	10	52	—	52
Amortization	—	(38)	(15)	—	(53)	—	(53)
Translation differences	(2,340)	—	—	—	(2,340)	(182)	(2,522)
Book value December 31, 2013 ...	68,194	492	48	10	68,744	5,315	74,059
At December 31, 2013							
Acquisition cost	98,297	762	267	10	99,336	5,549	104,885
Accumulated amortization and impairment	(27,763)	(270)	(219)	—	(28,252)	—	(28,252)
Translation differences	(2,340)	—	—	—	(2,340)	(234)	(2,574)
Book value December 31, 2013 ...	68,194	492	48	10	68,744	5,315	74,059
Book value January 1, 2014	68,194	492	48	10	68,744	5,315	74,059
Additions	—	—	50	—	50	—	50
Amortization	—	(38)	(36)	—	(74)	—	(74)
Impairment	(27,605)	—	—	—	(27,605)	—	(27,605)
Translation differences	6,241	—	—	—	6,241	484	6,725
Book value December 31, 2014 ...	46,830	454	62	10	47,356	5,799	53,155
At December 31, 2014							
Acquisition cost	98,297	762	317	10	99,386	5,549	104,935
Accumulated amortization and impairment	(55,368)	(308)	(255)	—	(55,931)	—	(55,931)
Translation differences	3,901	—	—	—	3,901	250	4,151
Book value December 31, 2014 ...	46,830	454	62	10	47,356	5,799	53,155

In-process R&D assets represent the fair value assigned to development projects that the Company acquired through business combinations, which at the time of the acquisition have not led to marketing approvals that are required for commercialization. Until December 31, 2014, in-process R&D (IPR&D) assets comprised the SYN115, SYN120 and SYN117 programs, which were acquired in the Synosia 2011 acquisition. Amounts capitalized as IPR&D are not amortized until marketing approval has been received from the relevant regulatory agencies. These assets are tested for impairment annually and whenever there is an indication that the asset may be impaired.

IPR&D and goodwill have been tested for impairment at December 31, 2014 and December 31, 2013, our annual testing date, by assessing their respective recoverable amounts to their carrying values. For the purpose of this analysis, fair value less costs of disposal was deemed to be the recoverable amount. The fair value less costs of disposal is determined from the discounted future net cash flows expected to be derived from the asset or, in the case of goodwill, the CGU utilizing market participant assumptions. The fair values represent a Level 3 fair value measurement category in the fair value hierarchy.

For IPR&D, the factors and assumptions used in the determination of the discounted future net cash flows expected to be derived from the asset are highly sensitive, as market prices for the individual assets are

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not available and depend on assumptions specific to the nature of the Group's activities, including: the selected discount rates; the expected development costs; the probability of success of the clinical trials; the time to commercialization; the expected revenue that will be generated from the expected market size and market penetration; the expected treatment costs; the expected sales and marketing resources that will be required; the expected patent life; and the tax rates that will be applicable in any year. Management projects cash flows for each development asset for three years beyond the end of the expected patent life and, therefore, does not include any terminal value. Due to the above factors, actual cash flows and values could vary significantly from forecasted cash flows and related recoverable amount derived using discounting techniques.

The analyses concluded at December 31, 2014 and December 31, 2013, in respect of the in-process R&D assets, that:

- Tozadenant (SYN115) was not subject to impairment at either balance sheet date and has increased its fair value during 2014 as a result of UCB's decision to terminate the license agreement and return its rights to the Company. This resulted in the Company having global rights to the asset as opposed to shared economics through the in-license agreement in place in 2013.
- The development pathway for SYN120 in 2013 was a Phase 2a study in Alzheimer's disease for which the recoverable amount supported the carrying value as of December 31, 2013. Following the receipt of funding in July 2014 for a study in Parkinson's disease dementia and the termination of the UCB license agreement with respect to tozadenant, management concluded as of December 31, 2014 that the Company could not immediately fund the Alzheimer's disease study. Accordingly, the Company's development efforts are currently targeted to the development pathway in Parkinson's disease dementia and the December 31, 2014 impairment review has been conducted in relation to the development for Parkinson's disease dementia. This has resulted in SYN120 being subject to an impairment charge of €16,458 thousand as at December 31, 2014, which has been recorded through the statement of comprehensive income as impairment of in-process R&D assets. As the asset has been written-down to its recoverable amount as at December 31, 2014, any changes in the assumptions could result in either a further impairment being recognized or, alternatively, in a reversal of the impairment charge. This could be the case if the Company's development plans change, for example if the planned Alzheimer's disease study could be funded, which could increase the fair value of the asset.
- Nepicastat (SYN117) was concluded to have a recoverable amount of nil as of December 31, 2014, as a result of the receipt of negative top-line data in respect of the Phase 2a study in January 2015 following the completion of the clinical treatment phase in August 2014. As a result, the IP&D for nepicastat (SYN117) asset was fully impaired as at the reporting date and a non-cash impairment charge of €11,147 thousand has been recorded through the statement of comprehensive income as impairment of in-process R&D assets". The 2013 carrying value was not impaired as the study was still in progress and the recoverable amount fully supported its carrying value.

For goodwill, the Company assesses the aggregate fair value of the business as a whole, as there is only one CGU. The fair value of the business as a whole is determined by projecting cash flows for the business through to three years beyond the expected longest patent life of its current products and, consequently, does not include a terminal value; these projections include a fair value for Selincro license agreement, which has no carrying value in the statements of financial position because it was an internally generated asset. The analyses of the aggregate fair value of the business concluded that there was no impairment of goodwill at either December 31, 2014 or December 31, 2013.

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Notes to the Consolidated Financial Statements — (Continued)

The sensitivity analysis conducted for each asset and for goodwill in 2014 and 2013 indicated, as stated above, that only with respect to SYN120, any reasonably possible negative change in any of the key assumptions would cause further impairment as the asset has been written down to its fair value in 2014. In 2013, the only asset where any reasonable possible negative change in any of the key assumptions would cause impairment was SYN120, for which an increase in the discount rate of approximately 1.5 percentage points or a reduction in revenues of approximately 3 percentage points might have resulted in an impairment loss being recognized.

The discount rates used in the determination of the recoverable amount for IPR&D asset was 14.5% as at December 31, 2013 and December 31, 2014 and for goodwill 14.0-14.5% as at December 31, 2014 and December 31, 2013, respectively.

All of the IPR&D assets that remain in development are subject to inherent risks and uncertainties in drug development and it is possible that additional non-cash impairment charges are recognized in the future.

12. Property, plant and equipment

<u>(€ in thousands)</u>	<u>Machinery and equipment</u>
Book value on January 1, 2013	256
Additions	446
Depreciation	(75)
Book value December 31, 2013	<u>627</u>
At December 31, 2013	
Acquisition cost	4,667
Accumulated depreciation	(4,040)
Book value December 31, 2013	<u>627</u>
Book value on January 1, 2014	627
Additions	209
Depreciation	(183)
Book value December 31, 2014	<u>653</u>
At December 31, 2014	
Acquisition cost	4,876
Accumulated depreciation	(4,223)
Book value December 31, 2014	<u>653</u>

The table includes assets the Company has leased through finance leases, comprising of equipment used in research and development which is as follows:

<u>(€ in thousands)</u>	<u>As at December 31,</u>	
	<u>2014</u>	<u>2013</u>
Acquisition cost — capitalized on the basis of finance lease	1,907	1,907
Accumulated depreciation	(1,649)	(1,592)
Book value December 31	<u>258</u>	<u>315</u>

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Notes to the Consolidated Financial Statements — (Continued)

Finance lease agreements are made for 2 to 3 years. Monthly lease payments are fixed, and include bargain purchase options which correspond approximately to one month's lease payment. In 2014, no new finance leases were made.

13. Investment property

<u>(€ in thousands)</u>	<u>2014</u>	<u>2013</u>
Book value January 1	817	846
Additions	3	10
Depreciation	(24)	(39)
Disposals	(796)	—
At December 31	<u>—</u>	<u>817</u>

As at December 31, 2013, the fair value of the investment property was estimated to be €1,100 thousand based on a purchase offer for the property received from an external party contemplating the purchase of the property (a level 2 disclosure) representing a price that the Company would have received to sell the asset in an orderly transaction between market participants.

During 2014, the investment property was sold realizing a net gain after related costs of €433 thousand.

14. Other financial assets

Other financial assets comprise primarily restricted cash balances in escrow securing long-term operating lease commitments. Other financial assets amounted to €324 thousand as at December 31, 2014 compared to €242 thousand as at December 31, 2013.

15. Accounts receivables and other receivables

<u>(€ in thousands)</u>	<u>As at December 31,</u>	
	<u>2014</u>	<u>2013</u>
Accounts receivable	1,270	102
VAT receivables	41	65
Income tax receivable	—	48
Other receivables	91	213
Prepaid expenses and accrued income	404	147
Total	<u>1,806</u>	<u>575</u>

Accounts receivables are classified as loans and receivables and, therefore, measured at amortized cost. The provision for impairment was nil at December 31, 2014 and December 31, 2013, respectively. The fair values of current accounts receivable and other receivables correspond to their carrying values due to their short maturities. Further, the carrying value represents the maximum credit risk exposure for the Company. As at December 31, 2014 and December 31, 2013 there were no past due or impaired account receivables.

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Notes to the Consolidated Financial Statements — (Continued)

16. Financial assets at fair value through profit or loss

<u>(€ in thousands)</u>	<u>As at December 31,</u>	
	<u>2014</u>	<u>2013</u>
Short term	24,941	33,457
Total	24,941	33,457

Financial assets at fair value through profit and loss, consisting mainly of investments to money market funds, are measured at their fair value based on quoted bid prices at the reporting date. The fair values are based on fund manager reports and are classified either within Level 1 or Level 2 in the fair value hierarchy. For Level 1, the fair value measurement is directly obtained from an active market. For Level 2, the fair value measurement is based on observable quoted market information, although it is not directly obtained from an active market (Level 1). According to the Company's investment policy, money market funds held in Europe must have a Morning Star rating of three stars or higher. Money market funds in the U.S. must be rated AAA by Moody's or AAA by Standard & Poor's.

17. Cash and cash equivalents

<u>(€ in thousands)</u>	<u>As at December 31,</u>	
	<u>2014</u>	<u>2013</u>
Bank accounts	7,452	10,221
Total	7,452	10,221

There are no significant concentrations of credit risk as the cash balance is diversified with cash deposits in the respective operating countries of the Company.

18. Shareholders' equity

(a) Share Capital

Movements in our shares outstanding, treasury shares and our total registered shares are as follows:

<u>(Number of shares)</u>	<u>Outstanding shares</u>	<u>Treasury shares</u>	<u>Total registered shares</u>
As at January 1, 2013	444,098,961	8,611,777	452,710,738
Share options and RSU exercised	2,114,987	(2,114,987)	—
As at December 31, 2013	446,213,948	6,496,790	452,710,738
As at January 1, 2014	446,213,948	6,496,790	452,710,738
New shares issued at no consideration (treasury shares)	—	5,769,035	5,769,035
Cancellations of treasury shares	—	(2,511,599)	(2,511,599)
Share options and RSU exercised	4,482,067	(4,482,067)	—
As at December 31, 2014	450,696,015	5,272,159	455,968,174

The Company's total authorized number of shares is 455,968,174. All issued shares are fully paid. The shares have no par value. On 31 December 2014 the total number of shares held in treasury represented

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approximately 1.2% (2013: 1.4%) of the total registered shares. Treasury shares have been issued without consideration for the purpose of the Company's share-based compensation plans.

The total number of stock options and restricted stock units outstanding as at December 31, 2014 was 2,824,772, for which the Company holds an equivalent amount of treasury shares which it will use to settle these if they are exercised.

(b) Reserve for invested unrestricted equity

Reserve of invested unrestricted equity includes, under the Finnish Companies Act, the exercise value of shareholders' investment comprising share subscription prices and exercise prices of share options.

(c) Other reserves

Other reserves include the foreign currency translation reserve and a reserve for the remeasurements of the post-employment pension obligations recorded through other comprehensive income.

<u>(€ in thousands)</u>	<u>2014</u>	<u>2013</u>
Balance at January 1,	2,517	5,146
Change in foreign currency translation reserve	6,593	(2,629)
Re-measurement of post-employment benefit obligations	(81)	—
Balance at December 31,	<u>9,029</u>	<u>2,517</u>

19. Share based payments

(a) Stock Option Plan 2011 and Equity Incentive Plan 2011

The Stock Option Plan 2011, primarily for European employees, and the Equity Incentive Plan 2011, primarily for US employees, were approved at the Company's 2011 general shareholders' meeting as part of the Company's incentive scheme determined by the Board of Directors. These plans contain both a service requirement condition at vesting and individual specified non-market performance targets during the year of grant.

i. Stock Option Plan 2011

The options are forfeited in case the employee leaves the Company before the options vest, unless the Board of Directors approves otherwise. After the beginning of the share subscription period, the vested options may be freely transferred or exercised. The fair value of the options was determined at the grant date by using the Black & Scholes option valuation model and expensed over the vesting period. Grant dates for the option plan may vary depending on the date when the company and employees agree to the key terms and conditions of the share-based payment arrangement. The maximum number of stock options that could be awarded under the plan was 7,401,000, in three equal tranches designated as 2011A, 2011B and 2011C.

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Notes to the Consolidated Financial Statements — (Continued)

Key characteristics and terms of the option plan are listed in the table below.

Stock Option Plan 2011			
Option rights	2011A	2011B	2011C
Maximum number of stock options	2,467,000	2,467,000	2,467,000
The number of shares subscribed by one option	1	1	1
Exercise price, €	0.01	0.01	0.01
Dividend adjustment	No	No	No
Beginning of subscription period, date	January 1, 2014	January 1, 2015	January 1, 2016
End of subscription period, date (expiration) . .	February 28, 2015	February 29, 2016	February 28, 2017
Vesting conditions	Service until beginning of the subscription period		

The changes in the number of options in the plan during the years ended December 31, 2014 and 2013 is shown in the table below.

Number of options	2014			2013		
	2011A	2011B	2011C	2011A	2011B	2011C
Outstanding at 1 January	1,844,250	1,830,500	2,267,500	2,119,250	2,178,000	—
Granted	—	—	—	—	200,000	2,267,500
Forfeited	—	(37,500)	(37,500)	(275,000)	(547,500)	—
Exercised	(1,844,250)	—	—	—	—	—
Outstanding at 31 December . . .	—	1,793,000	2,230,000	1,844,250	1,830,500	2,267,500

All options were fair valued at grant date and recognized as an expense to personnel expenses included in research and development costs and general and administrative costs based on the employee's function over the vesting period. The effect of stock option plans 2011A, 2011B and 2011C on the Company's earnings 2014 (2013) was €472 (916) thousand. The fair values of the stock options have been determined by using the Black-Scholes option valuation model. The most significant inputs used to estimate the fair value of the stock options granted during the year ended December 31, 2013 are as follows:

Determination of fair value	Granted 2013	
Option plan	2011B	2011C
Share price at grant date	€0.42	€0.34
Subscription price	€0.01	€0.01
Volatility *	45.0%	45.0%
Maturity, years	3.01	3.87
Interest rate	0.37%	0.30%
Expected dividends	—	—
Valuation model	Black-Scholes	Black-Scholes
Option fair value, €	0.41	0.33
Effect on earnings 2013, € in thousands	38	192
Effect on earnings 2014, € in thousands	44	298

* Expected volatility was determined by calculating the historical volatility of the Company's share using monthly observations over corresponding maturity.

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ii. Equity Incentive Plan 2011

The Equity Incentive Plan 2011 includes three consecutive discretionary periods, calendar years 2011 (2011A), 2012 (2011B) and 2013 (2011C) in which the restricted share units may be granted. Each discretionary period is followed by an approximately two year vesting period, ending on January 5, 2014, January 5, 2015 and January 5, 2016, respectively after which the Company's shares will be delivered to employees on the basis of the granted share units. Should an employee's employment or service in the Company end before the end of a vesting period, the corresponding share units will be forfeited, unless the Board of Directors approves otherwise. Grant dates for the equity incentive plan may vary depending on the date when the company and employees agree to the key terms and conditions of the share-based payment arrangement. A maximum of 4,599,000 of our shares may be delivered under the plan, but there is no maximum that can be issued in any one year.

Key characteristics and terms of the plan are listed in the table below.

	2011A	2011B	2011C
The number of shares delivered for one share unit	1	1	1
Exercise price	€0	€0	€0
Dividend adjustment	No	No	No
Vesting date	January 5, 2014	January 5, 2015	January 5, 2016
Beginning of delivery of shares	January 6, 2014	January 6, 2015	January 6, 2016
End of delivery of shares *	February 28, 2014	February 28, 2015	February 29, 2016
Vesting conditions	Service until the vesting date		

* The end delivery of shares may be extended up to March 15 in the following year, should the employee holding the share units be in a period in which they are not able to trade shares.

The changes in the number of share units in the plan during the years ended December 31, 2014 and 2013 is shown in the table below.

Number of share units	2014			2013		
	2011A	2011B	2011C	2011A	2011B	2011C
Number of share units at						
January 1	1,477,410	1,389,000	1,482,500	1,514,910	1,614,000	—
Granted	—	—	—	—	150,000	1,482,500
Forfeited	—	(734,625)	(687,500)	(37,500)	(375,000)	—
Delivered	(1,477,410)	—	—	—	—	—
Number of share units at						
December 31	—	654,375	795,000	1,477,410	1,389,000	1,482,500

The total effect of the Equity Incentive Plan 2011 on the Company's 2014 (2013) earnings was credit of €114 thousand (an expense of €708 thousand). The fair value of the restricted share units was determined as the closing share price for Biotie share on the grant date. The fair value of the 2011A and 2011B grants was €0.47 per share. The fair value for the 2011C grants was €0.41 per share.

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Notes to the Consolidated Financial Statements — (Continued)

(b) Swiss option plan

The Company's Swiss subsidiary, Biotie Therapies AG, also has a stock option plan approved in 2008. Vesting of the options is related to continued service to the Company. The maximum contractual term of each option is ten years. The plan has been closed to new grants from February 1, 2011. An aggregate maximum of 14,912,155 shares in Biotie Therapies Corp. has been subscribed to under the plan and such shares have been issued to Biotie Therapies AG to be further conveyed to the option holders when they potentially exercise their option rights in accordance with the terms and conditions of the option rights. Grant dates for the option plan may vary depending on the date when the company and employees agree to the key terms and conditions of the share-based payment arrangement. The last day for the share subscriptions based on the option rights in the Swiss option plan is December 7, 2020.

The key characteristics and terms of the option plan are listed in the table below:

Swiss Option Plan

Maximum number of stock options	14,912,155
The number of shares subscribed by one option	1
Exercise price range	€0.08–0.37
Dividend adjustment	No

	2014		2013	
	Number of options	Weighted average exercise price, €	Number of options	Weighted average exercise price, €
Transactions during the period — Swiss Option Plan				
Outstanding at January 1, 2014	5,295,754	0.28	8,256,813	0.24
Forfeited	(1,310,575)	0.35	(846,072)	0.33
Exercised	(1,160,407)	0.08	(2,114,987)	0.18
Outstanding at December 31, 2014 ...	2,824,772	0.26	5,295,754	0.24

At December 31, 2014 there were no unvested options; at December 31, 2013 there were 483,866 unvested options. Share options outstanding at December 31, 2014 have the following expiry dates and exercise prices:

Grant date	Vesting date	Expiry date	Exercise price, €	Number of option rights
June 18, 2008	June 18, 2012	June 18, 2018	0.17	684,670
June 18, 2008	June 18, 2012	June 18, 2018	0.29	155,588
June 18, 2008	June 18, 2012	June 18, 2018	0.23	67,296
June 18, 2008	June 18, 2012	June 18, 2018	0.22	29,094
September 15, 2008 .	December 10, 2011	September 15, 2018	0.30	134,592
January 23, 2009 ...	December 10, 2012	January 23, 2019	0.32	422,843
March 11, 2010	March 11, 2014	March 11, 2020	0.08	351,151
December 7, 2010 ..	December 7, 2014	December 7, 2020	0.37	979,538

The total effect of the Swiss Option Plan on the Company's 2014 (2013) earnings was a credit of €50 thousand (expense of €124 thousand).

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Notes to the Consolidated Financial Statements — (Continued)

(c) Stock Option Plan 2014 and Equity Incentive Plan 2014

The Stock Option Plan 2014, primarily for European employees, and the Equity Incentive Plan 2014, primarily for US employees, were approved at the Company's 2014 general shareholders' meeting as part of the Company's incentive scheme determined by the Board of Directors. These plans contain both a service requirement condition at vesting for all awards and for the management awards, designated 2014M awards, there is an additional specified market performance requirement that determines the number of awards earned.

i. Stock Option Plan 2014

The options are forfeited in case the employee leaves the Company before the options vest, unless the Board of Directors approves otherwise. After the beginning of the share subscription period, the vested options may freely be transferred or exercised. The fair value of the options was determined at the grant date by using the Black & Scholes option valuation model and expensed over the vesting period. Grant dates for the option plan may vary depending on the date when the company and employees agree to the key terms and conditions of the share-based payment arrangement. The maximum number of options that could be awarded under the plan is 10,337,500, of which 4,320,000 are 2014M awards that are subject to an additional specified market performance requirement at vesting. The 2014M awards include an additional incentive (a market condition) for the senior management team to have a portion of their potential awards over the three year period ending December 31, 2016 based solely on the increase in the share price of the Company for the vesting period. The 2014M awards will not vest unless the Company's share price growth during that three year period is greater than 35%; however, if the share price growth is greater than 35%, there will be an increasing return up to a maximum of three times the initial awards for a share price growth of at least 100% over the three year vesting period. The 2014M market condition has been incorporated into the Black-Scholes model, by determining the probability of the share price growth increase over the three year period based on historical share price movements.

Key characteristics and terms of the option plan are listed in the table below.

Option rights	Option Plan 2014						
	2014A	2014B	2014C	2014D	2014E	2014F	2014M
Maximum number of stock options	468,125	1,404,375	518,125	1,554,375	518,125	1,554,375	4,320,000
The number of shares subscribed by one option	1	1	1	1	1	1	1
Exercise price, €	0.01	0.01	0.01	0.01	0.01	0.01	0.01
Dividend adjustment	No	No	No	No	No	No	No
Beginning of subscription period	January 1, 2016	January 1, 2017	January 1, 2017	January 1, 2018	January 1, 2018	January 1, 2019	January 1, 2017
End of subscription period	February 28, 2017	February 28, 2018	February 28, 2018	February 28, 2019	February 28, 2019	February 29, 2020	February 28, 2018
Vesting conditions	Service condition until beginning of the subscription period.						Market performance condition and a service condition until beginning of the subscription period

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Notes to the Consolidated Financial Statements — (Continued)

The change in the number of options, or senior management option units in the case of the 2014M tranche, in the plan during the year ended December, 31 2014 are shown in the table below.

<u>Number of options</u>	<u>2014</u>		
	<u>2014A</u>	<u>2014B</u>	<u>2014M</u>
Outstanding at 1 January	—	—	—
Granted	468,125	1,404,375	1,440,000
Forfeited	(9,375)	(28,125)	—
Exercised	—	—	—
Outstanding at 31 December	458,750	1,376,250	1,440,000

All options were fair valued at grant date and will be recognized as an expense to personnel expenses included in research and development costs and general and administrative costs based on the employee's function over the vesting period. Stock options 2014A, 2014B and 2014M were still unvested at December 31, 2014 and their effect on the Company's earnings 2014 was €279 thousand (no impact to 2013 as the plan had not started). The fair values of the stock options have been determined by using the Black-Scholes option valuation model. The most significant inputs used to estimate the fair value of the stock options granted during the year ended December 31, 2014 are as follows:

<u>Determination of fair value</u>	<u>Granted 2014</u>		
	2014A	2014B	2014M
Option plan	2014A	2014B	2014M
Share price at grant date	€0.31	€0.31	€0.31
Subscription price	€0.01	€0.01	€0.01
Volatility *	50.0%	50.0%	50.0%
Maturity, years	3.14	4.14	4.14
Interest rate	0.29%	0.43%	0.43%
Expected dividends	—	—	—
Valuation model	Black-Scholes	Black-Scholes	Black-Scholes
Option fair value, €	0.30	0.30	0.15
Effect on earnings 2014, € in thousands	69	138	73

* Expected volatility was determined by calculating the historical volatility of the Company's share using monthly observations over corresponding maturity.

ii. Equity Incentive Plan 2014

The Equity Incentive Plan 2014 includes three consecutive discretionary periods, calendar years 2014, 2015 and 2016, in which the restricted share units, or senior management units, may be granted. Each discretionary period is followed by a subscription period of approximately two years (for 2014A, 2014C and 2014E awards) or approximately three years (for 2014B, 2014D, 2014F and 2014M awards), ending on January 5, 2016, January 5, 2017, January 5, 2018 or January 5, 2019, after which the Company's shares will be delivered to employees on the basis of the granted share units. Should an employee's employment or service with the Company end before the end of a subscription period, the corresponding share units will be forfeited, unless the Board of Directors agree otherwise. A maximum of 14,002,500 of our shares may be delivered under the plan, of which 2,520,000 are 2014M awards that are subject to an additional specified market performance requirement at vesting, which is the same as that described in the Stock Option Plan 2014 above. Grant dates for the equity incentive plan may vary depending on the date when the company and employees agree to the key terms and conditions of the share-

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Notes to the Consolidated Financial Statements — (Continued)

based payment arrangement. There is no maximum number of share units that can be awarded in any one year, but all the 2014M awards must have been awarded in 2014.

Key characteristics and terms of the Equity Incentive Plan 2014 are listed in the table below.

	<u>2014A</u>	<u>2014B</u>	<u>2011C</u>	<u>2014D</u>	<u>2014E</u>	<u>2014F</u>	<u>2014M</u>
The number of shares delivered for one restricted share unit	1	1	1	1	1	1	1
Exercise price, USD equivalent of	€0.01	€0.01	€0.01	€0.01	€0.01	€0.01	€0.01
Dividend adjustment	No	No	No	No	No	No	No
Vesting date	January 5, 2016	January 5, 2017	January 5, 2017	January 5, 2018	January 5, 2018	January 5, 2019	January 5, 2017
Beginning of delivery of shares	January 6, 2016	January 6, 2017	January 6, 2017	January 6, 2018	January 6, 2018	January 6, 2019	January 6, 2017
End of delivery of shares	February 29, 2016	February 28, 2017	February 28, 2017	February 28, 2018	February 28, 2018	February 28, 2019	February 28, 2017
Vesting conditions	Service condition until the vesting date						Market performance condition and a service condition until beginning of the subscription period

The change in the number of share units, or senior management share units in the case of the 2014M tranche, in the plan during the year ended December, 31 2014 are shown in the table below.

	<u>2014A</u>	<u>2014B</u>	<u>2014M</u>
Number of share units at January 1	—	—	—
Granted	622,812	1,868,438	840,000
Forfeited	(213,125)	(639,375)	—
Exercised	—	—	—
Number of share units at December 31	409,687	1,229,063	840,000

The total effect of the Equity Incentive Plan 2014 on the Company's 2014 earnings was an expense of €197 thousand (no impact to 2013 as the plan had not started). The fair value of the restricted share units was determined as the closing share price of the Company's shares on the grant date. The fair value of the 2014A, 2014B was €0.30 per share and for the 2014M grants the fair value was €0.15 per share.

20. Non-current financial liabilities

	<u>Carrying amount as at December 31,</u>	
<u>(€ in thousands)</u>	<u>2014</u>	<u>2013</u>
Non-convertible capital loans from Tekes	16,318	16,318
Long-term R&D loans from Tekes	2,690	2,690
Convertible capital loan	1,682	1,682
Total	<u>20,690</u>	<u>20,690</u>

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Notes to the Consolidated Financial Statements — (Continued)

Fair values of the loans are determined by discounting estimated future cash flows of the loans using appropriate spot interest rates at the reporting date. The discount rate considers the specific features of each loan (as described below), and estimated margin for the Company's own credit risk. Future cash flows are based on the Company's best estimate on the timing of the repayment of the loan principal and payment of related capitalized interests. Given that the inputs to the valuation technique rely on unobservable market data, fair value measures of the loans are classified in Level 3 in the fair value hierarchy.

After considering the relevant inputs as described above, the Company has determined that it would not be reasonable to present fair values for the loans, as the Group only has access to Tekes loans and a convertible loan, i.e. similar government grant loans the Group already has. As the financing cost and other terms of such loans would be largely identical to the Company's current loans, there would be no difference in the nominal amount of the loans the Group would receive, if it refinanced its existing loan package.

Capital loans and R&D loans (excluding the capitalized interest) are due as follows:

<u>(€ in thousands)</u>	<u>As at December 31,</u>	
	<u>2014</u>	<u>2013</u>
Under 1 year	—	—
1–5 years	1,614	2,152
Over 5 years	19,076	18,538
Total	<u>20,690</u>	<u>20,690</u>

€18,000 thousand of the capital loans are due for repayment in less than one year. Nonetheless, the repayment of capital loans and accrued interest is governed by a restrictive condition, according to which the capital plus the accrued interest must only be returned if the restricted equity of the parent company, including the equity of the consolidated subsidiaries, for the last financial period is fully covered. Interest on the non-convertible capital loans shall be paid only if the parent company, including the equity of the consolidated subsidiaries, has sufficient funds for profit distribution as per the adopted balance sheet for the most recently ended fiscal year. The loans shall also accrue interest in fiscal years in which retained earnings are not sufficient for distributions to equity holders. All capital loans are therefore classified as long-term debt.

(a) Non-convertible capital loans from Tekes

As at December 31, 2014, non-convertible capital loans granted by Tekes comprised a total of 14 non-convertible capital loans, comprising an aggregate amount of €16,318 thousand following the forgiveness of two loans (carrying value €1,088 thousand) in 2013. The proceeds from the loans have been fully used to fund a number of research & development projects. The majority of the remaining loans were drawn prior to 2009 and the maturities range from 8 to 10 years from draw down. The interest rate per annum for these loans is the base rate set by the Ministry of Finance minus one (1) percentage point, subject to a minimum rate of 3%. As the base rate has been lower than the minimum of 3%, the interest rate for these loans has been 3% for both periods presented. Further, these loans and accumulated accrued interest are not repayable until the Company's restricted equity on a consolidated basis is fully covered. Restricted equity of the Company represents share capital and as of December 31, 2014 (the last financial period) totaled €193,285 thousand. Distributable funds totalled a debit of €140,662 thousand as of December 31, 2014 (for the last financial period) and are not greater than zero. Therefore, restricted equity is not considered to be fully covered as defined under the Finnish Companies Act. Since the Company has not had distributable funds since the drawdown of these loans, interest recorded through the financial expenses is accrued and

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presented under other non-current liabilities in the statement of financial position as the Company does not expect it will have distributable funds in the foreseeable future. The accumulated interest on non-convertible capital loans amounts to €6,034 thousand as at December 31, 2014 (€5,545 thousand as at December 31, 2013).

(b) R&D loans from Tekes

As at December 31, 2014, the Company had €2,690 thousand of R&D loans granted by Tekes. R&D loans amounting to €1,714 thousand were extinguished in 2013 following the Tekes' decision to forgive such loans. R&D loans are granted to a defined product development project and cover a contractually defined portion of the projects' R&D expenses. The interest rate for these loans is the base rate set by the Ministry of Finance minus three (3) percentage points, subject to a minimum rate of 1%. Repayment of these loans shall be initiated after 5 years, thereafter loan principals shall be paid back in equal installments over a 5 year period. More information on repayment schedule is provided in the Note 27. The accumulated interest on R&D loans amounts to €108 thousand as at December 31, 2014 (€81 thousand as at December 31, 2013).

(c) Convertible capital loan

As at December 31, 2014, the Company had a convertible capital loan that was issued originally in 1999 to certain shareholders and venture capital organizations in the aggregate amount of €1,682 thousand. The original subscription period began on June 1, 2000, and ended on December 31, 2005. As of December 31, 2014, the convertible capital loan can be converted, at any time at the option of the holder, into 828,000 of our shares, the interest rate is 10% per annum. The repayment of the capital loan and its interest is governed by a restrictive condition, according to which the capital may only be returned if the restricted equity of the parent company, including the consolidated subsidiaries, for the last financial period is fully covered. Interest on the convertible capital loan shall be paid only if the parent company, including the consolidated subsidiaries, has sufficient funds for profit distribution as of the most recently ended fiscal year. The loan shall also yield interest from the fiscal years in which the financial statements do not present sufficient funds available for profit distribution. As at December 31, 2014, accumulated interest on convertible capital loan amounted to €3,379 thousand and is recorded in other non-current liabilities in the statement of financial position. The convertible capital loan can also be converted into shares of the Company under the terms of the agreement. The accumulated interest on the convertible capital loan amounts to €3,379 thousand as at December 31, 2014 (€3,211 thousand as at December 31, 2013).

21. Pension benefit obligations

Pension benefit obligations are recognized for certain former employees in Biotie Therapies GmbH under two separate closed defined pension benefit schemes. The calculations are based on the Heubeck Mortality Charts RT 2005G. As the schemes are closed schemes in nature, there is no current service cost and accordingly, the income statement charge comprises interest expenses and past service costs, if applicable, and is presented under research and development or general and administrative expenses, as applicable.

(a) Principal actuarial assumptions for calculation of pension benefit obligations:

	2014	2013
Discount rate	2.2%	3.5%
Future pension increases	1.8%	2.0%
Rate of fluctuation of employees	2.0%	2.0%

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(b) *Liabilities in the statement of financial position:*

<u>(€ in thousands)</u>	<u>As at</u> <u>December 31,</u>	
	<u>2014</u>	<u>2013</u>
Present value of unfunded pension obligations; equal to net liability in the statement of financial position	670	569

(c) *Personnel expenses recognized in the consolidated statement of comprehensive income from defined benefit obligations:*

<u>(€ in thousands)</u>	<u>For the year ended</u> <u>December 31,</u>	
	<u>2014</u>	<u>2013</u>
Interest expenses	20	21
Total defined benefit pension expenses	20	21
Remeasurements recognized in other comprehensive income	(81)	—

(d) *Changes in the present value of the defined pension obligation:*

<u>(€ in thousands)</u>	<u>2014</u>	<u>2013</u>
Opening defined pension obligation January 1	569	573
Interest expenses	20	21
Actuarial losses (gains)	81	(25)
Defined pension obligation December 31	670	569

The sensitivity of the defined obligation to changes in the weighted principal assumptions is as follows:

	<u>Impact on defined benefit obligation</u>		
	<u>Change in assumption</u>	<u>Increase in assumption</u>	<u>Decrease in assumption</u>
Discount rate	0.25%	Decrease by 3.7%	Increase by 3.9%
Future pension increase	0.25%	Increase by 3.1%	Decrease by 3.0%

The two closed schemes have a total of 7 participants and the expected duration of the arrangements is 15.4 years.

22. Other non-current liabilities

<u>(€ in thousands)</u>	<u>As at December 31,</u>	
	<u>2014</u>	<u>2013</u>
Accrued accumulated interest	9,438	8,780
Deferred rent	140	18
Finance lease	93	120
Total	9,671	8,918

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Accumulated accrued interest comprises accrued interest from Tekes loans and convertible capital loan.

Interest on the Tekes loans and convertible capital loan shall not be paid until there are sufficient cumulative distributable funds in the consolidated financial statements for the most recently ended fiscal year. The carrying values of other non-current liabilities are reasonable approximations of their fair values.

23. Deferred revenues

The non-current deferred revenues comprises of up-front license fees of €2,000 thousand as at December 31, 2014 and 2013, under the Lundbeck license agreement, which will be recorded as revenue when the product receives the related marketing authorization. Management cannot estimate the exact timing for the recognition of the Lundbeck fee as revenues due to uncertainties in the marketing approval process, which is outside the Company's control.

The remaining deferred revenue balance as at December 31, 2013 related to the developmental milestone payments from the UCB license agreement, which have been recorded as revenue when the associated costs were incurred during 2014.

<u>(€ in thousands)</u>	<u>As at December 31,</u>	
	<u>2014</u>	<u>2013</u>
Deferred revenues, non-current	2,000	2,972
Deferred revenues, current	—	743
Total	<u>2,000</u>	<u>3,715</u>

24. Deferred taxes

Deferred income tax assets and liabilities are offset when there is a legally enforceable right to offset current tax assets against current tax liabilities and when the deferred income tax assets and liabilities relate to income taxes levied by the same taxation authority on either the taxable entity or different taxable entities where there is an intention to settle the balances on a net basis. The deferred tax assets have been recognized to the extent of existing deferred tax liabilities (i.e. a net zero deferred tax position). Temporary differences comprise primarily in process R&D intangible assets, R&D credits and deferrals, depreciation on property, plant and equipment and net operating loss carryforwards.

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Notes to the Consolidated Financial Statements — (Continued)

The movement in deferred tax assets and liabilities (prior to offsetting of balances within the same tax jurisdiction) during the period is as follows:

<u>(€ in thousands)</u>	<u>At January 1,</u>	<u>Credited (charged) to the statement of comprehensive income</u>	<u>Currency translation differences</u>	<u>At December 31,</u>
Deferred tax assets 2013				
Temporary differences	4,355	(4,221)	(134)	—
Tax loss carry-forwards	16,188	6,416	(501)	22,103
Total deferred tax assets	20,543	2,195	(635)	22,103
Deferred tax liabilities 2013				
In-process R&D	22,781	—	(678)	22,103
Total deferred tax liabilities	22,781	—	(678)	22,103
Net deferred tax assets (liabilities)	(2,238)	2,195	43	—

<u>(€ in thousands)</u>	<u>At January 1,</u>	<u>Credited (charged) to the statement of comprehensive income</u>	<u>Currency translation differences</u>	<u>At December 31,</u>
Deferred tax assets 2014				
Temporary differences	—	—	—	—
Tax loss carry-forwards	22,103	(9,650)	2,054	14,507
Total deferred tax assets	22,103	(9,650)	2,054	14,507
Deferred tax liabilities 2014				
In-process R&D	22,103	(9,650)	2,054	14,507
Total deferred tax liabilities	22,103	(9,650)	2,054	14,507
Net deferred tax assets (liabilities)	—	—	—	—

Deferred income tax assets are recognized to the extent that the realization of the related tax benefit is probable. The Company did not recognize deferred income tax assets of €42,743 thousand (2013: €39,448 thousand) in respect of losses amounting to €120,583 thousand (2013: €114,709 thousand) and temporary differences of €73,632 thousand (2013: €69,911 thousand) that can be carried forward against future taxable income, as it was not certain that they would be realized due to the history of operating losses.

Biotie Therapies Oyj
Notes to the Consolidated Financial Statements — (Continued)

Biotie's tax loss carryforwards at December 31, 2014 expire as follows as:

<u>Years of expiration</u>	<u>Tax loss carryforwards EUR thousand</u>
2015–16	22,754
2017–18	10,482
2019–20	12,601
2021–22	10,956
2023–24	—
After 2025	54,317
Tax loss carryforwards without expiration date*	9,473
Total	120,583

* Consists of the tax loss carryforwards of the German subsidiary.

25. Accounts payable and other current liabilities

<u>(€ in thousands)</u>	<u>As at December 31,</u>	
	<u>2014</u>	<u>2013</u>
Accounts payable	1,048	399
Payroll related accruals	441	663
Accrued expenses	1,188	4,678
Total	2,677	5,740

26. Other non-cash transactions adjustments to cash flow from operating activities

<u>(€ in thousands)</u>	<u>For the year ended December 31,</u>	
	<u>2014</u>	<u>2013</u>
Depreciation and amortization	281	167
Share-based compensation	784	1,748
(Gain) on disposal of investment property	(554)	—
Other adjustments	266	(101)
Non-cash adjustments to cash flow from operating activities	777	1,814

27. Financial risk management

The operations of the Company and its subsidiaries expose them to financial risks. The main risk that the Group is exposed to is liquidity risk, with capital management being another important area given the Group's financing structure. The Company's risk management principles focus on the unpredictability of the financial markets and aims at minimizing any undesired impacts on the Group's financial result. The Board of Directors defines the general risk management principles and approves operational guidelines

Biotie Therapies Oyj

Notes to the Consolidated Financial Statements — (Continued)

concerning specific areas including but not limited to liquidity risk, foreign exchange risk, interest rate risk, credit risk, the use of derivatives and investment of the Company's liquid assets. During the reporting periods, the Company or its subsidiaries have not entered into any derivative contracts.

(a) Capital management and liquidity risks

The Company's objective when managing capital is to safeguard the Group's ability to continue as a going concern. Capital is the equity and the capital loans and R&D loans, as reported in the Company's consolidated statement of financial position (refer to notes 18 and 20).

Significant financial resources are required to advance the drug development programs into commercialized pharmaceutical products. The Company relies on its ability to fund the operations of the Company through three major sources of financing – collaboration and licensing agreements, research and development grants and loans and equity or debt financing.

Entering into commercialization, collaboration and licensing agreements with larger pharmaceutical companies entitles the Company and its subsidiaries to receive up-front and follow-on milestones related to agreed regulatory or commercial points, as well as royalty payments from these partners. Activities in the area of business development are targeted at securing such agreements. Consideration of these activities is part of the management's duties and is monitored by the Board of Directors, which ultimately decides on entering into such agreements.

The Company relies on different sources of research and development grants and loans. These funds, which are provided through regional, national or EU level institutions or industry or therapeutic area related bodies have been historically available to the Company. The Group strictly complies with all rules and legal obligations pertaining to these funding programs and is in regular contact with the funding agencies providing these. Availability of such funds in the future cannot be guaranteed and thus this poses a potential risk to the income situation of the Company in the future.

Funding of the Group's operations is possible based on equity or debt financing. While such equity financing has been available in the past (the last such financing was a €30 million share issue in September 2012), 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. The current financial market situation and the repercussions to the overall investor's sentiment pose a severe risk of not being able to secure additional financing in the future. To partly manage this risk, the Company has secured an option to raise up to €20 million through an equity facility with a reputable US investor group until November 2015. In addition, management is in constant dialogue with financial investors, investment banks, debt providers and other market participants.

There can be no assurance that sufficient financing can be secured in order to permit the Company to carry out its planned activities. To protect the continuity of the Company's operations, sufficient liquidity and capital has to be maintained. The Company aims to have funds to finance at least one year's operations at all times. The Company can influence the amount of capital by adapting its cost basis according to the financing available. Management monitors liquidity on the basis of the amount of funds. These are reported to the Board on a monthly basis.

The Company's Board of Directors approves the operational plans and budget. The Board follows up the implementation of these plans and the financial status of the Company on a monthly basis.

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Notes to the Consolidated Financial Statements — (Continued)

The Company has low risk securities (money market funds) and bank accounts which are as follows:

<u>(€ in thousands)</u>	<u>As at December 31,</u>	
	<u>2014</u>	<u>2013</u>
Money market funds	24,941	33,457
Bank accounts	7,452	10,221
Total	32,393	43,678

As at December 31, 2014, the contractual maturity of loans and interests was as follows:

<u>(€ in thousands)</u>	<u>2015</u>	<u>2016</u>	<u>2017</u>	<u>2018- thereafter</u>	<u>Total</u>
Capital loans					
Repayment of loans	—	—	—	18,000	18,000
Interest expenses	—	—	—	9,438	9,438
R&D loans					
Repayment of loans	—	—	538	2,152	2,690
Interest expenses	27	27	22	32	108
Total	27	27	560	29,622	30,236

As at December 31, 2014, the Company also had accounts payables €1,048 thousand and other current liabilities €1,629 thousand due within one year (see note 25).

As at December 31, 2013, the contractual maturity of loans and interest was as follows:

<u>(€ in thousands)</u>	<u>2014</u>	<u>2015</u>	<u>2016</u>	<u>2017- thereafter</u>	<u>Total</u>
Capital loans					
Repayment of loans	—	—	—	18,000	18,000
Interest expenses	—	—	—	8,780	8,780
R&D loans					
Repayment of loans	—	490	538	1,662	2,690
Interest expenses	27	22	16	16	81
Total	27	512	554	28,458	29,551

As at December 31, 2013, the Company also had accounts payables €399 thousand and other current liabilities €5,341 thousand due within one year (see note 25).

(b) Market risk

i. Foreign exchange risk

The Company operates internationally but is mainly exposed to translation risk in respect of US dollar and Swiss Franc from its investments in foreign operations. Further, the Company has granted an inter-company borrowing (amount of €36,044 thousand as at December 31, 2014) to its US subsidiary that qualifies for part of the net investment and exchange differences that are deferred to the cumulative translation account which is a component of other comprehensive income (loss). The Company may also

Biotie Therapies Oyj

Notes to the Consolidated Financial Statements — (Continued)

need to consider transfer of balances between currencies as appropriate to manage the currency in which income is received and expenses are incurred. The Company's policy is not to hedge translation risk, which is not considered a significant risk.

The Company and its subsidiaries are not exposed to significant transaction risk, as the group companies mainly operate in their functional currencies. As of December 31, 2014, the Company had cash and cash equivalents of €1,334 thousand in US dollar, €222 thousand in Swiss Franc, €49 thousand in Pound Sterling and money market funds of €5,345 thousand in US dollar.

ii. Interest rate risk

The Company's interest rate risk arises from borrowings from Tekes and private investors. Borrowings carry fixed interest rates and hence do not expose the Company to variable interest rate risk. The Company's loans from Tekes are mainly tied to the base rate defined by the Finnish Ministry of Finance, which is reset rarely, with a floor at 3%. During the periods presented, the interest rate level has been below the floor, so the Company has accrued for the floor interest of 3% on the loans. Hence an increase in base rates would not have any material impact on the Group's profit or loss. Further, accumulated accrued interest is not payable until the Company is profitable, and its restricted equity is fully covered. Surplus cash is invested in short term interest funds and they also expose the Company mainly to fair value interest rate risk. Due to the current low interest rate level, the low risk profile of the funds and the interest not being immediately payable, the interest rate exposure is considered insignificant.

(c) Credit and counterparty risk

Deposit and security receivables from the banks expose the Company to credit risk. The Company prefers to work with partners with good credit ratings. Management monitors the sufficiency of the liquid assets and exposure to credit risk regularly. The Company currently derives a significant proportion of its collaborative income from a small group of partners. This risk of concentration of creditors is partly mitigated by the fact that the Company's collaboration partners are typically large and internationally reputable pharmaceutical companies which are financially solid. These collaborations are governed by contractual relationships that typically address and describe remedies for situations in which interests of The Company and the partner are no longer in line. In addition, the Company aims to collaborate on different development programs with as many partners as possible in order to spread the risk of creditor concentration.

Banks used by the Company for its deposits are among Europe's most reputable financial institutions. The Company invests liquid assets in low risk securities with high ratings and interest bearing bank accounts.

28. Commitments and contingent liabilities

	As at December 31,	
<u>(€ in thousands)</u>	<u>2014</u>	<u>2013</u>
<i>Operating lease commitments</i>		
Due within a year	843	675
Due in 1–5 years	1,937	2,287
Due later than 5 years	—	—
Total operating lease commitments	<u>2,780</u>	<u>2,962</u>

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Notes to the Consolidated Financial Statements — (Continued)

Operating lease commitments comprise rent commitments for leasehold properties and lease commitments for motor vehicles, machines and equipment with leases of 3 to 5 years. The Group's operating leases are non-cancellable and they do not include redemption or extension options.

On December 31, 2014, Biotie had outstanding contractual payment obligations (contractual commitments), primarily for contract research work services related to ongoing clinical development programs, totaling €232 thousand (December 31, 2013: €2,713 thousand).

The Company has entered into various license agreements that contingently trigger one-off payments upon achievement of certain milestones, the payment of royalties and certain other payments. Because the achievement and timing of these payments are uncertain, our commitments under these agreements have not yet been recognized.

29. Transactions with related parties

(a) Key management compensation

The Group's 2014 management team consists of Timo Veromaa (President and CEO), David Cook (Chief Financial Officer), Stephen Bandak (Chief Medical Officer) and Mehdi Paborji (Chief Operating Officer). The compensation paid or payable for key management for employee services is shown below.

	For the year ended December 31,	
(€ in thousands)	2014	2013
Salaries and other short-term employee benefits	1,995	1,388
Post-employment benefits (payments to defined contribution plans)	79	37
Share-based payments	540	582
Total	<u>2,614</u>	<u>2,007</u>

(b) Stock options awarded to management

Management was awarded 720,000 share options, 1,440,000 senior management option units, 420,000 share units and 840,000 senior management share units during 2014 under the 2014M plan (1,400,000 share options, nil senior management option units, 350,000 share units and nil senior management share units during 2013). At the end of the fiscal year, the number of outstanding options and share units granted to management amounted to 4,099,568 options, 1,440,000 senior management option units, 1,070,000 share units and 840,000 senior management share units (at the end of year 2013: 4,356,020 options and 940,000 share units). The senior management option units and senior management share units under the 2014M plan are subject to a multiplier that is dependent on the growth in the Company's share price over the three year period ending December 31, 2016 and may result in a minimum of nil options and nil share units up to a maximum of 4,320,000 options and 2,520,000 share units being awarded to senior management at the end of the period.

Biotie Therapies Oyj
Notes to the Consolidated Financial Statements — (Continued)

(c) Compensation of the President and CEO

<u>(€ in thousands)</u>	For the year ended December 31,	
	2014	2013
Salary and other short-term employee benefits	527	570
Post-employment benefits (payments to defined contribution plans)	42	—
Share-based payments	271	314
Total	840	884

The President and CEO's (Timo Veromaa) contract may be terminated by the Company with a six month notice period and by the President and CEO with a three month notice period. If the Company terminates the contract with the President and CEO, the President and CEO is, in addition to his salary during the notice period, entitled to a severance pay corresponding to 12 months of salary.

(d) Compensation of the members of the Board of Directors

<u>(€ in thousands)</u>	For the year ended December 31,	
	2014	2013
Peter Fellner*	12	48
William Burns	54	36
Merja Karhapää	42	36
Bernd Kastler	44	36
Guido Magni	42	36
Ismail Kola	39	36
Total	233	228

* Board member until April 3, 2014

30. Investments in subsidiaries

The Group had the following subsidiaries as at December 31, 2014, which have been included in the consolidation.

<u>Subsidiaries</u>	<u>Domicile</u>	<u>Nature of business</u>	<u>Share of ownership %</u>
Biotie Therapies AG	Switzerland	Operative (Drug development)	100
Biotie Therapies Inc.	USA	Operative (Drug development)	100
Biotie Therapies GmbH	Germany	Non-operative	100
Biotie Therapies International Ltd	Finland	Non-operative	100

Biotie Therapies Oyj
Notes to the Consolidated Financial Statements — (Continued)

31. Events after the reporting date

After the reporting period on January 20, 2015, the Company announced that it had transferred shares of the Company held as treasury shares, that were issued on December 17, 2014, pursuant to the Stock Option Plan 2011 (942,500 shares conveyed) and the Equity Incentive Plan 2011 (66,875 shares conveyed). As a result of the transfer, the total number of voting rights attached to the Company's shares increased to 451,705,390 votes, and the total number of the Company's shares held by the Company or its fully owned subsidiary was 4,262,784. The conveyance does not affect the number of registered shares (total of 455,968,174 shares).

In January 2015, following the completion of the clinical treatment phase in August 2014, the Company announced top-line results from a Phase 2 study investigating nepicastat for cocaine dependence. When compared to placebo, nepicastat did not meet the primary efficacy endpoint of an increased proportion of subjects remaining abstinent from cocaine during the last two weeks of the treatment period. Nepicastat was generally well tolerated in the study. The 11-week, 179-patient study was conducted at 10 US clinics under a Collaborative Research and Development Agreement (CRADA) with the National Institute on Drug Abuse (NIDA) at the US National Institutes of Health. See note 11 for further details related to the impairment of the related in-process R&D asset.

After the reporting period on February 17, 2015, the Company announced that The Committee for Orphan Medicinal Products (COMP) of the European Medicines Agency (EMA) had in its February 2015 meeting issued a positive opinion recommending orphan drug designation for BTT1023 for the treatment of primary sclerosing cholangitis (PSC).

After the reporting period on February 20, 2015, the Company announced further detail on its Phase 3 clinical development plan for tozadenant.

After the reporting period on February 27, 2015, the Company announced that it had transferred shares of the Company held as treasury shares, that were issued on December 17, 2014, pursuant to the Stock Option Plan 2011 (130,000 shares conveyed) and the Equity Incentive Plan 2011 (137,500 shares conveyed). As a result of the transfer, the total number of voting rights attached to the Company's shares increased to 451,972,890 votes and the total number of the Company's shares held by the Company or its fully owned subsidiary was 3,995,284. The conveyance does not affect the number of registered shares (total of 455,968,174 shares).

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BIOTIE THERAPIES CORP.

**3,761,418 American Depositary Shares
Representing 300,913,440 Shares**

PROSPECTUS
June 10, 2015

RBC CAPITAL MARKETS

STIFEL

JMP SECURITIES

ROTH CAPITAL PARTNERS

Through and including July 5, 2015 (the 25th day after the date of this prospectus), all dealers effecting transactions in these securities, whether or not participating in this offering, may be required to deliver a prospectus. This is in addition to the dealers' obligation to deliver a prospectus when acting as underwriters and with respect to their unsold allotments or subscriptions.
