UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 6-K

REPORT OF FOREIGN PRIVATE ISSUER
Pursuant to Section 13a-16 or 15d-16 of the Securities Exchange Act of 1934

For the month of April 2016

Commission File Number: 001-37569

STRONGBRIDGE BIOPHARMA plc

(Exact name of Registrant as specified in its charter)

900 Northbrook Drive
Suite 200
Trevose, PA 19053
(Address of principal executive offices)

Indicate by check mark whether the registrant files or will file annual reports under cover of Form 20-F or Form 40-F.

Form 20-F ☒ Form 40-F ☐

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(1): ☐

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(7): ☐

The information contained in the exhibits to this Form 6-K is being furnished to the Commission and shall not be deemed incorporated by reference into any of the Strongbridge Biopharma's registration statements or other filings with the Commission.

Exhibits

Exhibit Number	Exhibit Table
99.1	Notice of Annual General Meeting of Strongbridge Biopharma plc to be held on 12 May 2016
99.2	Directors Report and Consolidated Financial Statements for the Financial Year Ended December 31, 2015
99.3	Form of Proxy Card

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, hereunto duly authorized.

Dated: April 14, 2016

STRONGBRIDGE BIOPHARMA PLC

By: /s/ Stephen Long
Stephen Long
Chief Legal Officer

Exhibit 99.1

Notice of Annual General Meeting
to be held on 12 May 2016

Strongbridge Biopharma plc
(the "Company" or "Strongbridge")

THIS DOCUMENT IS IMPORTANT AND REQUIRES YOUR IMMEDIATE ATTENTION.

If you are in any doubt as to the action to be taken, you should consult with your independent financial adviser who, if you are taking advice in the Republic of Ireland, is authorised or exempted under the European Communities (Markets in Financial Instruments) Regulations (Nos. 1 to 3) 2007 (as amended) or the Investment Intermediaries Act, 1995 (as amended).

If you have sold or transferred your entire holding of ordinary shares in Strongbridge, please pass this document, together with the attached proxy form, to the purchaser or transferee, or to the stockbroker, bank or other agent through whom the sale was effected, for transmission to the purchaser or transferee as soon as possible.

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14 April 2016

To: All Strongbridge Shareholders

NOTICE OF THE 2016 ANNUAL GENERAL MEETING

Dear Shareholder:

This letter encloses the notice of the Annual General Meeting of Strongbridge Biopharma plc (the "**AGM**") to be held at the offices of Arthur Cox, Earlsfort Terrace, Dublin, D02 CK83, Ireland, at 10:00 a.m. (Dublin time) on 12 May 2016.

Further information on Strongbridge is available in our Annual Report on Form 20-F and in our Irish statutory financial statements and the report of the Company's directors thereon, which can be accessed on the investor relations page of our website at www.strongbridgebio.com and at www.envisionreports.com/SBBP.

Business of the AGM

Shareholders are being asked to consider two proposals at the AGM, which deal with the:

- re-election of Mårten Steen M.D., Ph.D., and Hilde Steineger, Ph.D. as Class I directors (please see section below "Strongbridge Board Update" for more details); and
- remuneration of the auditors of the Company.

There will also be a review of the affairs of the Company and a presentation by management on the Company's Irish statutory financial statements for the fiscal year ended 31 December 2015 at the AGM.

The foregoing proposals are more fully described on page 3 and the full text of the resolutions for these proposals are set out on page 5.

Strongbridge Board Update

In September 2015, both Dr. Steineger and Dr. Steen were appointed as non-executive directors. Prior to September 2015, each of Dr. Steineger and Dr. Steen served as directors of Cortendo AB, a majority-owned subsidiary of Strongbridge. We have six directors — five non-executive and one executive (Matthew Pauls, our President and Chief Executive Officer). Except for Mr. Pauls, the remaining five directors are considered independent under the Nasdaq listing rules. All members of the Audit, Governance and Compensation Committees of the board of directors meet the independence requirements under applicable Nasdaq listing rules and rules promulgated by the U.S. Securities and Exchange Commission.

At the AGM, the Class I directors of the board of directors of the Company will stand for re-election in accordance with our Articles of Association (bye-laws). This means that Dr. Steineger and Dr. Steen will offer themselves for re-election. Biographies of the directors standing for re-election are included at page 4.

Each of the directors standing for re-election demonstrates the necessary commitment to the role and provides valuable skills, knowledge and experience and makes important contributions to the working of the board of directors. I can confirm that the Strongbridge board of directors is satisfied that each director does not have a relationship that, in the opinion of the board of directors, would interfere with exercising independent judgement in carrying out his or her responsibilities.

Form of Proxy and Voting

The form of proxy for the AGM is enclosed separately. Please refer to pages 6 to 8 for details as to how to vote your shares and return your form of proxy.

A shareholder entitled to attend and vote is entitled, using the form separately enclosed (or the form in section 184 of the Irish Companies Act 2014), to appoint one or more proxies to attend, speak and vote instead of him or her at the AGM. A proxy need not be a shareholder of record.

Please refer to pages 6 to 8 for details as to how to vote your shares and return your form of proxy.

Availability of Materials

This document, the Company's Annual Report on Form 20-F for the fiscal year ended 31 December 2015 and Irish statutory financial statements for the fiscal year ended 31 December 2015, including the reports of the directors and auditors thereon, are available on the investor relations page of the Company's website at www.strongbridgebio.com and at www.envisionreports.com/SBBP.

Recommendation

Your board of directors believes that the resolutions to be proposed at the AGM are in the best interests of the Company and its shareholders. Accordingly, your directors unanimously recommend that you vote in favour of all resolutions as they intend to do in respect of any shares held by them.

Yours sincerely,

John Johnson
Chairman

SUMMARY OF AGM PROPOSALS

There are two proposals which require approval by shareholders, either in person or by proxy, at the AGM.

Proposal 1 — Re-election of Class I Directors

Shareholders are being asked to re-elect, by separate resolutions, the following non-executive directors as Class I directors:

Item 1.1 —Hilde Steineger, Ph.D., as a director.

Item 1.2 —Mårten Steen, M.D., Ph.D., as a director.

Each of the directors elected at the meeting will serve a three-year term until the conclusion of the Company's 2019 annual general meeting and until such time as their successors are duly elected and qualified.

Required Vote. In accordance with our Articles of Association, our directors are elected by a plurality of the votes present in person or represented by proxy at the AGM.

The board of directors unanimously recommends that you vote "FOR" each of these nominees for Class I director (Proposal 1 on your form of proxy).

Proposal 2 — Authorization to Determine the Remuneration of the Auditors

Shareholders are being asked to vote to authorize the board of directors, acting through its Audit Committee, to determine the remuneration of Ernst & Young.

We expect that a representative of Ernst & Young will be present at the AGM. This representative will have the opportunity to make a statement, if he or she desires, and is expected to be available to respond to appropriate questions.

Required Vote. As required under Irish law, the resolution in respect of this item of business is an ordinary resolution that requires the affirmative vote of a simple majority of the votes cast.

The board of directors unanimously recommends that you vote "FOR" the authorization of the board of directors, acting through its Audit Committee, to determine the remuneration of Ernst & Young (Proposal 2 on your form of proxy).

Presentation of Irish Statutory Financial Statements

The Company's Irish statutory financial statements for the fiscal year ended 31 December 2015, including the reports of the directors and auditors thereon, will be presented at the AGM. The Company's Irish statutory financial statements have been approved by the board of directors. There is no requirement under Irish law that such statements be approved by shareholders, and no such approval will be sought at the AGM. The Company's Irish statutory financial statements and the Company's Annual Report on Form 20-F for the fiscal year ended 31 December 2015 are available on the investor relations section of the Company's website at www.strongbridgebio.com and at www.envisionreports.com/SBBP.

CLASS I DIRECTOR NOMINEES

Hilde Steineger, Ph.D.

Dr. Steineger has served as a member of our board of directors since September 2015 and previously served as a director of Cortendo AB, a majority owned subsidiary of Strongbridge, from January 2014 until her appointment as a director of Strongbridge. She is currently Head of Strategic Innovation Management in the Nutrition & Health Division of BASF. She previously served as the Head of Global Omega-3 Innovation Management at Pronova BioPharma ASA, a BASF company, from April 2013 to May 2015. From August 2007 to June 2010, Dr. Steineger was Head of Investor Relations for Pronova BioPharma and Vice President Business Development in Pronova BioPharma from November 2009 to April 2013. Dr. Steineger is a board member and Head of the Audit Committee of Nordic Nanovector ASA. Dr. Steineger also serves as a director of PCI Biotech AS and Afiew AS. She previously served as a member of the board of directors of Algeta ASA, Weifa AS, Invent2 AS, Alertis AS, Clavis Pharma ASA and Biotech Pharmacon ASA. Dr. Steineger holds a Ph.D. in medical biochemistry from University of Oslo.

Mårten Steen, M.D., Ph.D.

Dr. Steen has served as a member of our board of directors since September 2015 and previously served as a director of Cortendo AB, a majority owned subsidiary of Strongbridge, from January 2014 until his appointment as a director of Strongbridge. Since April 2010, he has served as a Partner of HealthCap VI LP, a venture capital firm investing in life science companies. Prior to HealthCap, from February 2008 until March 2010, Dr. Steen served as director at Merck Serono SA, a biopharmaceutical company. Currently, he serves as a member of the board of directors of Wilson Therapeutics AB, Vaxin Inc. and BioClin Therapeutics Inc. He previously served on the boards of Ultragenyx Inc. and FerroKin Biosciences. Dr. Steen holds a B.Sc. in Business Administration, an M.D., and a Ph.D. in Clinical Chemistry, all from Lund University.

Further information on the experience, qualifications and industry knowledge of the directors is available from the Annual Report on Form 20-F at www.strongbridgebio.com.

NOTICE OF 2016 ANNUAL GENERAL MEETING

NOTICE is hereby given that the Annual General Meeting of the Company will be held at the offices of Arthur Cox, Earlsfort Terrace, Dublin, D02 CK83, Ireland on 12 May 2016 at 10:00 a.m. (Dublin time) to receive the Company's Irish statutory financial statements for the fiscal year ended 31 December 2015 and the reports of the directors and auditors thereon, to review the affairs of the Company and to consider, and if thought fit, pass the following resolutions:

1. To re-elect, by separate resolutions, the following individuals who retire as Directors in accordance with the Articles of Association of the Company and, being eligible, offer themselves for re-election as Class I directors:

    1.1 Hilde Steineger, Ph.D.; and

    1.2 Mårten Steen, M.D., Ph.D.

2. To authorise the board of directors, acting through its Audit Committee, to determine the remuneration of the auditors.

A shareholder entitled to attend and vote is entitled, using the form provided separately (or the form in section 184 of the Irish Companies Act 2014), to appoint one or more proxies to attend, speak and vote instead of him or her at the AGM. A proxy need not be a shareholder of record. Please refer to pages 6 to 8 for details as to how to vote your shares and return your form of proxy.

By the Order of the Board,

Stephen J. Long
Company Secretary

14 April 2016

Registered Office:
Arthur Cox Building
Earlsfort Terrace
Dublin 2
D02 CK83
Ireland

NOTES:

1. Information and Documentation

Information regarding the AGM is available on the investor relations page of the Company's website at www.strongbridgebio.com and at www.envisionreports.com/SBBP. This document, the Company's Annual Report on Form 20-F for the fiscal year ended 31 December 2015 and Irish statutory financial statements for the fiscal year ended 31 December 2015, including the reports of the directors and auditors thereon, are available on the investor relations page of the Company's website at www.strongbridgebio.com and at www.envisionreports.com/SBBP. We will provide without charge to each shareholder, including any beneficial owner, on the written or oral request of such shareholder, a copy of any of such documents. Requests for such copies should be directed to the Company Secretary at the following address: 900 Northbrook Drive, Suite 200, Trevose, PA 19053, United States of America.

2. Who is eligible to vote and how?

If your shares are actually registered in your name, you are a shareholder of record. Shareholders of record who are entered in the register of Members of the Company, as at the close of business on 23 March 2016, shall be entitled to attend, speak, ask questions and vote at the AGM, or if relevant, any adjournment thereof. Changes in the register after that time will be disregarded in determining the right of any person to attend and/or vote at the meeting. As at the record date for the AGM, the close of business on 23 March 2016, there were 21,205,382 ordinary shares in the capital of the Company outstanding and entitled to vote.

Depending on whether your shares are registered in your name or whether your shares are held in "street name" the arrangements for voting are as follows:

Shareholder of Record: Shares Registered in Your Name

As a shareholder of record you may vote in one of the following ways:

By Telephone or over the Internet. You may submit your proxy by calling the toll-free number noted on your proxy card. Telephone proxy submission is available 24 hours a day and will be accessible until 5:00 p.m. (Eastern Time) on 9 May 2016. Easy to follow voice prompts allow you to submit your proxy and confirm that your instructions have been properly recorded. You may also choose to vote over the Internet by following the instructions set out in the proxy card enclosed with this notice of meeting. Internet voting is also available 24 hours a day and will be accessible until 5:00 p.m. (Eastern Time) on 9 May 2016. As with telephone proxy submission, you may confirm that your instructions have been properly recorded. Shareholders who vote through the Internet or submit their proxy by telephone should be aware that they may incur costs, such as usage charges from telephone companies or Internet service providers, and that these costs must be borne by the shareholder.

By Mail. If you wish to vote by mail, please mark your proxy card enclosed with this notice of meeting, date and sign it, and promptly return it in the postage-paid envelope provided, to be received by 5:00 p.m. (Eastern Time) on 9 May 2016 (which will be forwarded electronically to Computershare's Irish office).

In Person at the AGM. You may vote in person by attending the AGM and submitting a ballot.

If you are a shareholder of record and you choose to submit your proxy by telephone by calling the toll-free number on your proxy card, your use of that telephone system, and in particular the entry of your pin number/other unique identifier, will be deemed to constitute your appointment, in writing and under hand, and for all purposes of the Irish Companies Act 2014, of each of A. Brian Davis and Stephen J. Long, as your proxy to vote your shares on your behalf in accordance with your telephone instructions.

If your proxy is properly completed, the shares it represents will be voted at the AGM as you instructed. If you submit your proxy, but do not provide instructions, your proxy will be voted in accordance with the Board's recommendations as set forth in this notice of meeting.

The appointment of a proxy will not preclude a shareholder of record from attending, speaking, asking questions and voting at the meeting should the shareholder subsequently wish to do so and a proxy need not be a shareholder of the Company.

Beneficial Owner: Shares Registered in the Name of a Broker, Bank or Other Agent

If, as at close of business on 23 March 2016 your shares were not held in your name, but rather in an account at a brokerage firm, bank, dealer or other similar organisation, who in turn hold through The Depository Trust Company ("**DTC**"), then you are the beneficial owner of shares held in "street name" and these proxy materials are being forwarded to you by that organisation, together with instructions as to voting. **You will need to carefully follow the instructions from your broker, bank or other agent or contact your broker, bank or other agent if you have any queries.**

As a beneficial owner, you have the right to direct your broker or other agent on how to vote the shares in your account as per the instructions enclosed by your broker. You are also invited to attend the AGM. However, since you are not the shareholder of record, you may not vote your shares in person at the AGM unless you contact your broker and obtain a valid proxy card from your broker or other agent.

Therefore as a beneficial owner of shares registered in the name of your broker, bank or other agent, who in turn hold through DTC, you should have received a voting instruction card and voting instructions with these proxy materials from that organisation rather than from us. Simply complete and mail the voting instruction card as per the instructions from your broker, bank or other agent to ensure that your vote is counted.

3. What is the "quorum" requirement for the AGM?

A quorum is required in order to proceed with any business at the AGM. A quorum requires the presence, in person or by proxy, of the holders of shares entitled to exercise a majority of the voting power of the Company. For the purposes of establishing a quorum, abstentions and "broker non-votes" (as described below) are counted as present.

4. What vote is required to approve each item on the agenda?

Every shareholder present, in person or by proxy, shall have one vote for every share carrying voting rights of which he or she is the holder or proxy.

For Proposal 1, our directors are elected by a plurality of the votes cast, in person or by proxy. Proposal 2, which is an ordinary resolution, is required to be approved by a simple majority of the votes cast, in person or by proxy.

Abstentions and "broker non-votes" (as described below) are not considered votes cast and therefore will not impact the outcomes of the items on the agenda.

5. What is a Broker Non-Vote?

A "broker non-vote" occurs when a broker holding shares for a beneficial owner (that is, in "street name") does not vote on a particular agenda item because the broker does not have discretionary voting power for that particular item and has not received instructions from the beneficial owner. Although brokers have discretionary power to vote your shares with respect to "routine" matters, they do not have discretionary power to vote your shares on "non-routine" matters pursuant to New York Stock Exchange ("**NYSE**") rules.

If you do not provide voting instructions for proposals which are considered "non-routine," a "broker non-vote" occurs. We believe that the elections of directors in Proposal 1 will be considered "non-routine" under NYSE rules and therefore your broker will not be able to vote your shares with respect to these proposals unless the broker receives appropriate instructions from you. Proposal 2 will be considered a "routine" proposal for which your broker has discretionary voting authority under the NYSE rules to vote your shares, even if the broker does not receive voting instructions from you. **Please instruct your bank or broker so your vote can be counted.**

6. Can I change my vote after submitting my proxy?

Shareholder of Record: Shares Registered in Your Name

Yes. You can revoke your proxy before it is voted at the AGM. If you are the record holder of your shares, you may revoke your proxy in any one of three ways:

- you may submit another properly completed proxy on a later date within the proxy voting deadlines described above by Internet or by telephone or by signing and returning a new proxy card with a later date;

- you may send a written notice that you are revoking your proxy to Stephen Long, Company Secretary, Strongbridge Biopharma plc at 900 Northbrook Drive, Suite 200, Trevose, PA 19053, United States of America or by email to s.long@strongbridgebio.com. Your notice must be received before the commencement of the meeting at 10:00 a.m. (Dublin time) on 12 May 2016 or if the AGM is adjourned, before the commencement of the adjourned meeting; or

- you may attend the AGM and vote in person.

Beneficial Owner: Shares Registered in the Name of a Broker, Bank or Other Agent

Persons who hold their shares through a bank, brokerage firm or other nominee may change their voting instructions by following the requirements of their bank or broker, or by obtaining a legal proxy from their bank or broker and submitting the legal proxy within the proxy voting deadlines described above.

7. What does it mean if I receive more than one set of materials?

If you receive more than one set of materials, your shares are registered in more than one name or are registered in different accounts. In order to vote all the shares you own, you must sign and return all of the proxy cards or follow the instructions for any alternative voting procedure on each of the proxy cards you receive.

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Exhibit 99.2

STRONGBRIDGE BIOPHARMA plc

Directors' Report and Consolidated Financial Statements

For the Financial Year Ended December 31, 2015

STRONGBRIDGE BIOPHARMA plc

TABLE OF CONTENTS

COMPANY INFORMATION

DIRECTORS	Marten Steen (Swedish National, appointed 4 September 2015) Hilde Steineger (Norwegian National, appointed 4 September 2015) John Johnson (US National, appointed 4 September 2015) Richard Kollender (US National, appointed 4 September 2015) Matthew Pauls (US National, appointed 4 September 2015) Garheng Kong (US National, appointed 11 September 2015) Atif Kamal, (appointed 19 June 2015, resigned 11 September 2015) Kevin Butler, (appointed 17 July 2015, resigned 11 September 2015) Maura McLaughlin (appointed 26 May 2015, resigned 19 June 2015) Liadhain Canavan (appointed 26 May 2015, resigned 19 June 2015) Imran Khan (appointed 26 May 2015, resigned 17 July 2015)
COMPANY SECRETARY	Stephen Long (appointed 29 September 2015) Bradwell Limited (appointed 26 May 2015, resigned 29 September 2015)
REGISTRATION NUMBER	562659
REGISTERED OFFICE	Arthur Cox Building Earlsfort Terrace Dublin 2, D02 CK83 Ireland
ADMINISTRATOR	TMF Administration Services Limited 3rd Floor, Kilmore House Park Lane, Spencer Dock Dublin 1 Ireland
BANKER	Bank of America Bank of America Corporate Center 100 North Tryon Street Charlotte NC 28255
SOLICITORS	Arthur Cox Earlsfort Centre Earlsfort Terrace Dublin 2 Ireland

INDEPENDENT AUDITOR	Ernst & Young Chartered Accountants Harcourt Centre Dublin 2 Ireland

DIRECTORS' REPORT
FOR THE YEAR ENDED 31 DECEMBER 2015

The directors present their first annual report and audited consolidated financial statements of Strongbridge Biopharma plc (formerly known as Cortendo plc) (the "Company") for the year ended 31 December 2015.

The directors have elected to prepare the consolidated financial statements in accordance with Section 279 of Part 6 of the Companies Act 2014, which provides that a true and fair view of the state of affairs and profit or loss may be given by preparing the financial statements in accordance with the accounting principles generally accepted in the United States of America (U.S. GAAP), as defined in Section 279(1) of Part 6 of the Companies Act 2014, to the extent that the use of those principles in the preparation of the financial statements does not contravene any provision of that part of the Companies Act 2014.

PRINCIPAL ACTIVITIES, BUSINESS REVIEW AND FUTURE DEVELOPMENTS

The Company is a public limited company, which was incorporated on May 26, 2015, in accordance with the laws of Ireland with registeration number 562659.

The Company is a biopharmaceutical entity focused on the development, in-licensing, acquisition and eventual commercialisation of multiple complementary products and product candidates within franchises that target rare diseases.

On August 7, 2015, the Company initiated an exchange offer for the outstanding shares of Cortendo AB. Cortendo AB shares were quoted on the Norwegian Over-The-Counter Market ("NOTC-A list"). On October 15, 2015, a registration statement was declared effective by the U.S. Securities and Exchange Commission and on October 16, 2015 the initial U.S. public offering of 2,500,000 ordinary shares at a price to the public of $10 per share became effective commencing the listing and trading on the NASDAQ Global Select Market under the symbol "SBBP". As a result of the above, on October 20, 2015, trading in the Company's shares ceased on the NOTC-A list.

The exchange offer was structured as a one-for-one exchange offer in which shareholders of Cortendo AB exchanged their common shares, with a par value of $0.15, for beneficial interests in ordinary shares of the Company, with a par value of $0.01, in the form of Norwegian depositary receipts and, as the case may be, Swedish depositary receipts (except for non-accredited investors who hold Cortendo AB shares located in the United States, who were offered cash in an amount equivalent to the value of the Company's shares such investors would otherwise receive for their Cortendo AB shares exchanged).

The exchange offer was settled on September 8, 2015, and Cortendo AB became a subsidiary of the Company with 99.582% of its shares being owned by the Company. The Company is a continuation of Cortendo AB, the predecessor, and the consolidated financial statements represent the assets, liabilities and results of operations of Cortendo AB, for all periods presented.

On September 8, 2015, the Company affected a 1-for-11 reverse stock split of its ordinary shares. The consolidated financial statements and notes retroactively reflect the capital structure of the Company after giving effect to the exchange offer and the reverse stock split.

PRINCIPAL RISKS AND UNCERTAINTIES

The Company's business is subject to a number of risks. These risks include, but are not limited to, the following:

PRINCIPAL RISKS AND UNCERTAINTIES (CONTINUED)

Risks Related to Our Being a Development-Stage Company

We are a development-stage biopharmaceutical company and have a limited operating history on which to assess our business, have incurred significant losses over the last several years, and anticipate that we will continue to incur losses for the foreseeable future.

We are a development-stage biopharmaceutical company with a limited operating history. We have not yet demonstrated an ability to successfully complete a large-scale, pivotal clinical trial, obtain regulatory approval or manufacture and commercialize a product candidate. Consequently, we have no meaningful commercial operations upon which to evaluate our business and predictions about our future success or viability may not be as accurate as they could be if we had a history of successfully developing and commercializing pharmaceutical products.

Since inception, we have incurred significant operating losses. Our net loss attributed to Strongbridge Biopharma was $5.3 million $9.7 million and $43.6 million for the years ended December 31, 2013, 2014 and 2015, respectively. As of December 31, 2015, we had an accumulated deficit of $80.8 million. We have devoted substantially all of our financial resources to identifying, in-licensing, acquiring and developing our product candidates, including conducting clinical trials and providing general and administrative support for these operations to build our business infrastructure.

To date, we have financed our operations primarily through private placements of equity securities and the proceeds from our initial public offering of ordinary shares in the United States in October 2015. The amount of our future net losses will depend, in part, on the rate of our future expenditures and our ability to obtain funding through equity or debt financings, strategic collaborations or grants. To become and remain profitable, we must develop and eventually commercialize one or more of our product candidates with significant market potential. Biopharmaceutical product development is a highly speculative undertaking and involves a substantial degree of risk. It may be several years, if ever, before we receive regulatory approval and have a product candidate approved for commercialization. Even if we obtain regulatory approval to market a product candidate, our future revenue will depend upon the size of any markets in which our product candidates may receive approval and our ability to achieve market acceptance and adequate market share for our product candidates in those markets. Further, because the potential markets in which our product candidates may ultimately receive regulatory approval are very small, we may never become profitable despite obtaining such market share and acceptance of our product candidates.

We expect to continue to incur significant expenses and increasing operating losses for the foreseeable future. We anticipate that our expenses will increase substantially if and as we:

- continue research and nonclinical and clinical development of our product candidates, including advancing our programs from preclinical development into clinical trials and increasing the number and size of our current clinical trials and preclinical studies;
- seek to identify, assess, in-license, acquire and develop additional product candidates;
- change or add manufacturers or suppliers;
- seek regulatory approvals for our product candidates that successfully complete clinical trials;
- establish a sales, marketing and distribution infrastructure to commercialize any products for which we may obtain regulatory approval;
- make up-front, milestone or other payments under any license arrangements;
- seek to maintain, protect and expand our intellectual property portfolio;

- seek to attract and retain skilled personnel;
- create additional infrastructure to support our operations as a U.S. listed company and our product development and planned future commercialization efforts; and
- experience any delays or encounter issues with any of the above, including, but not limited to, failed preclinical studies or clinical trials, complex results, safety issues or other regulatory challenges that may require either longer follow-up of existing preclinical studies or clinical trials or limitation of additional preclinical studies or clinical trials in order to pursue regulatory approval.

Further, the net losses we incur may fluctuate significantly from quarter-to-quarter and year-to-year, such that a period-to-period comparison of our results of operations may not be a good indication of our future performance. Moreover, if we incur substantial losses, we could be liquidated, and the value of our shares might be significantly reduced or the shares might be of no value.

We have never generated any revenue from product sales and may never be profitable.

We have no products approved for commercialization and have never generated any revenue from product sales. We will not generate revenue from product sales unless and until we successfully complete the development of, obtain regulatory approval for and commercialize one or more of our product candidates. Our ability to generate future revenue from product sales depends heavily on our success in many areas, including, but not limited to:

- completing research, preclinical or clinical development, as applicable, of our product candidates, including successfully completing clinical trials of our product candidates;
- integrating product candidates that we in-license or acquire, as well as completing research, formulation and process development, and preclinical or clinical development, as applicable, of those product candidates, including successfully completing clinical trials of those product candidates;
- obtaining regulatory approval our product candidates;
- incurring additional costs as we advance our product candidates;
- developing a sustainable and scalable manufacturing process for our product candidates, if approved;
- maintaining supply and manufacturing relationships with third parties that can conduct the manufacturing process development and provide adequate, in amount and quality, products to support clinical development and the market demand for our product candidates, if approved;
- developing a commercial organization and launching and commercializing product candidates for which we obtain regulatory approval, either directly or with a collaborator or distributor;
- obtaining market acceptance of our product candidates as viable treatment options;
- addressing any competing technological and market developments;
- identifying, assessing, in-licensing, acquiring and/or developing new product candidates;
- negotiating favorable terms in any collaboration, licensing or other arrangements into which we may enter;
- maintaining, protecting and expanding our portfolio of intellectual property rights, including patents, trade secrets and know-how; and
- attracting, hiring and retaining qualified personnel.

Given 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. Our expenses could increase beyond expectations if we are required by the FDA or the EMA, or any comparable foreign regulatory agency, to perform nonclinical and preclinical studies or clinical trials in addition to those that we currently anticipate.

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. Further, our revenue will be dependent, in part, upon the size of the markets in the territories for which we gain regulatory approval, the accepted price for the product, the ability to obtain coverage and adequate reimbursement, and whether we own the commercial rights for that territory. If the number of our addressable patients is not as significant as we estimate, the indication approved by regulatory authorities is narrower than we expect, or the treatment population is narrowed by competition, physician choice or treatment guidelines, we may not generate significant revenue from sales of our product candidates. If we are not able to generate sufficient revenue from the sale of any approved products, we may never become profitable. Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to successfully execute any of the foregoing would decrease the value of our company and could impair our ability to raise capital, expand our business or continue our operations. A decline in the value of our company could cause you to lose all or part of your investment.

We expect that we will need substantial additional funding before we can expect to complete the development of our product candidates and become profitable from sales of our approved products, if any.

We are currently advancing our product candidates through clinical development. Development of our product candidates is expensive, and we expect our research and development expenses to increase in connection with our ongoing activities, particularly as we continue our ongoing trials and initiate new trials of COR-003, COR-005 and any other product candidates we may seek to develop. We expect that we will require additional capital to obtain regulatory approval for, and to commercialize, our product candidates.

As of December 31, 2015, Strongbridge had cash and cash equivalents of $51.6 million and no outstanding debt. We currently believe that our existing cash and cash equivalents, is sufficient to fund planned operations into the fourth quarter of 2017, which is after the expected receipt of data from the COR-003 SONICS trial. However, this estimate is based on assumptions that may prove to be incorrect, our operating plans may change as a result of many factors that may currently be unknown to us, and we may need to seek additional funds sooner than planned. Our future funding requirements will depend on many factors, including, but not limited to:

- the scope, rate of progress, results and cost of our clinical trials, nonclinical testing, formulation, process development and other related activities;
- the cost of manufacturing clinical supplies and establishing commercial supplies of our product candidates, if approved, and any products that we may develop;
- the number and characteristics of product candidates that we pursue, including any additional product candidates we may in-license or acquire;
- the cost of filing, prosecuting, defending and enforcing our patent claims and other intellectual property rights;
- the cost of defending potential intellectual property disputes, including patent infringement actions brought by third parties against us or our product candidates;
- 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.

Any additional fundraising efforts may divert our management from their day-to-day activities, which may compromise our ability to develop and commercialize our product candidates, if approved. In addition, we cannot guarantee that future financing will be available in sufficient amounts or on terms acceptable to us, if at all.

Moreover, the terms of any financing may adversely affect the holdings or the rights of our shareholders and the issuance of additional securities, whether equity or debt, by us, or the possibility of such issuance, may cause the market price of our ordinary shares to decline.

If we are unable to obtain funding on a timely basis, we may be required to significantly curtail, delay or discontinue one or more of our research or development programs or the commercialization of any product candidates, if approved, or be unable to expand our operations or otherwise capitalize on our business opportunities, as desired.

Raising additional capital may cause dilution to our shareholders, restrict our operations or require us to relinquish rights to our intellectual property or future revenue streams.

Until such time, if ever, as we can generate substantial product revenue, we expect to finance our cash needs through a combination of equity offerings, debt financings, grants, and license and development agreements in connection with any collaborations. We do not have any committed external source of funds. In the event we seek additional funds, we may raise additional capital through the sale of equity or convertible debt securities. In such an event, the ownership interests of our current shareholders will be diluted, and the terms of these securities may include liquidation or other preferences that would adversely affect their rights as shareholders. Debt financing, if available, could result in increased fixed payment obligations and may involve agreements that include restrictive covenants, such as limitations on our ability to incur additional debt, make capital expenditures, acquire, sell or license intellectual property rights or declare dividends, and other operating restrictions that could hurt our ability to conduct our business.

Further, if we raise additional funds through collaborations, strategic alliances, or marketing, distribution or licensing arrangements with third parties, we may have to relinquish valuable rights to our intellectual property or future revenue streams. If we are unable to raise additional funds when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts, or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

We may not be successful in executing our growth strategy or our growth strategy may not deliver the anticipated results.

We plan to source new product candidates that are complementary to our existing product candidates by in-licensing or acquiring them from other companies or academic institutions. If we are unable to identify, in-license or acquire and integrate product candidates in accordance with this strategy, our ability to pursue our growth strategy would be compromised.

Research programs and business development efforts to identify new product candidates require substantial technical, financial and human resources. We may focus our efforts and resources on potential programs or product candidates that ultimately prove to be unsuccessful. Our research programs, business development efforts or licensing attempts may fail to yield additional complementary or successful product candidates for clinical development and commercialization for a number of reasons, including, but not limited to, the following:

- our research or business development methodology or search criteria and process may be unsuccessful in identifying potential product candidates with a high probability of success for development progression;
- we may not be able or willing to assemble sufficient resources or expertise to in-license, acquire or discover additional product candidates;
- for product candidates we seek to in-license or acquire, we may not be able to agree to acceptable terms with the licensor or owner of those product candidates;
- our product candidates may not succeed in preclinical studies or clinical trials;
- we may not succeed in formulation or process development;
- our product candidates may be shown to have harmful side effects or may have other characteristics that may make the products unmarketable or unlikely to receive regulatory approval;
- competitors may develop alternatives that render our product candidates obsolete or less attractive;
- product candidates that we develop may be covered by third parties' patents or other exclusive rights;
- product candidates that we develop may not allow us to leverage our expertise and our development and commercial infrastructure as currently expected;
- the market for a product candidate may change during our program so that such a product may become unreasonable to continue to develop;
- a product candidate may not be capable of being produced in commercial quantities at an acceptable cost, or at all; and
- a product candidate may not be accepted as safe and effective by patients, the medical community or third-party payors.

If any of these events occurs, we may not be successful in executing our growth strategy or our growth strategy may not deliver the anticipated results.

We may expend our limited resources to pursue a particular product candidate or indication and fail to capitalize on product candidates or indications that may be more profitable or for which there is a greater likelihood of success.

We have limited financial and managerial resources. As a result, we may forego or delay pursuit of opportunities with other product candidates or for other indications that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future research and development programs and product candidates for specific indications may not yield any commercially viable products. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate.

If we acquire other businesses or in-license or acquire other product candidates and are unable to integrate them successfully, our financial performance could suffer.

If we are presented with appropriate opportunities, we may acquire other businesses. We have had limited experience integrating other businesses or product candidates, or in-licensing or acquiring other product candidates. Since our formation in 1996, we have in-licensed or acquired three product candidates: COR-004, COR-005 and BP-2002. The acquisition of COR-005 occurred recently, and we are still in the early stages of integrating it into our business. The integration process following these or any future transactions may produce unforeseen operating difficulties and expenditures, and may absorb significant management attention that would otherwise be directed to the ongoing development of our business. Also, in any future in-licensing or acquisition transactions, we may issue shares of stock that would result in dilution to existing shareholders, incur debt, assume contingent liabilities or create additional expenses related to amortizing intangible assets, any of which might harm our financial results and cause our stock price to decline. Any financing we might need for future transactions may be available to us only on terms that restrict our business or impose costs that reduce our net income.

We are highly dependent on our key personnel, including our president and chief executive officer, as well as our ability to recruit, retain and motivate additional qualified personnel.

We are highly dependent on Matthew Pauls, our President and Chief Executive Officer, and Dr. Ruth Thieroff-Ekerdt, our Chief Medical Officer. Some members of our management team, including Matthew Pauls, have only been our employees since August 2014. As a result, they have limited experience working for us and working together as a team. Any member of management or employee can terminate his or her relationship with us at any time. Although we have included non-compete provisions in their respective employment or consulting agreements, as the case may be, such arrangements might not be sufficient for the purpose of preventing such key personnel from entering into agreements with any of our competitors. The inability to recruit and retain qualified personnel, or the loss of Mr. Pauls or Dr. Thieroff-Ekerdt could result in competitive harm as we could experience delays in reaching our in-licensing, acquisition, development and commercialization objectives.

We also depend substantially on highly qualified managerial, sales and technical personnel who are difficult to hire and retain. There is currently a shortage of skilled personnel in our industry, which is likely to continue. As a result, competition for skilled personnel is intense and the turnover rate can be high. We may not be able to attract and retain personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for individuals with similar skill sets. In addition, failure to succeed in preclinical studies or clinical trials may make it more challenging to recruit and retain qualified personnel. Recruiting and retaining other qualified employees, consultants and advisors for our business, including scientific and technical personnel, will be critical to our success.

We may expand our organization and experience difficulties in managing this growth, which could disrupt our operations.

As our development, commercialization, in-licensing, and acquisition plans and strategies develop, and as we advance the preclinical and clinical development of our product candidates, we expect to experience significant growth in the number of our employees and the scope of our operations, particularly in the areas of managerial, operational, sales, marketing, financial, legal and other resources. To manage our anticipated future growth, we must continue to implement and improve our managerial, operational and financial systems, expand our facilities, and continue to recruit and train additional qualified personnel. Our management may need to divert a disproportionate amount of its attention away from our day-to-day activities and devote a substantial amount of time to managing these growth activities.

Due to our limited financial resources, we may not be able to effectively manage the expansion of our operations, which may result in weaknesses in our infrastructure, operational mistakes, loss of business opportunities, loss of employees and reduced productivity among remaining employees. Any such growth could require significant capital expenditures and may divert financial resources from other projects, such as the in-licensing, acquisition and development of additional product candidates. If our management is unable to effectively manage our growth, our expenses may increase more than expected, our ability to generate or grow revenue could be reduced and we may not be able to implement our business strategy. Our future financial performance and our ability to compete effectively will depend, in part, on our ability to effectively manage any future growth.

Our business and operations would suffer in the event of system failures.

Our computer systems, as well as those of our clinical research organizations, or CROs, and other contractors and consultants, are vulnerable to damage from computer viruses, unauthorized access, natural disasters, including hurricanes, terrorism, war and telecommunication and electrical failures. If such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our product development programs. For example, the loss of preclinical study or clinical trial data from completed, ongoing or planned preclinical studies or 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 personal, confidential or proprietary information, we could incur liability and the further development of our product candidates could be delayed.

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

We depend entirely on the success of a limited number of product candidates, which are still in clinical development. If we do not obtain regulatory approval for and successfully commercialize one or more of our product candidates or we experience significant delays in doing so, we may never become profitable.

We currently have no products approved for sale and may never be able to obtain regulatory approval of or commercialize any products. We have invested, and continue to expect to invest, a significant portion of our efforts and financial resources in the development of a limited number of product candidates, which are still in clinical development. Our ability to generate product revenues, which we do not expect will occur for at least the next several years, if ever, will depend heavily on our successful development and eventual commercialization, if approved, of one or more of our product candidates. We are not permitted to market or promote any of our product candidates before we receive regulatory approval from the FDA, EMA or any comparable foreign regulatory agency, and we may never receive such regulatory approval for any of our product candidates. The success of COR-003 and COR-005 will depend on several additional factors, including, but not limited to, the following:

- successfully completing formulation and process development activities;
- successfully completing clinical trials that demonstrate the efficacy and safety of our product candidates;
- acceptance of our product candidates by patients and the medical community;
- a continued acceptable safety profile following approval;
- obtaining and maintaining healthcare coverage and adequate reimbursement; and
- competing effectively with other therapies, including with respect to the sales and marketing of our product candidates, if approved.

Many of these factors are beyond our control, including clinical development, the regulatory submission process, potential threats to our intellectual property rights and changes in the competitive landscape. 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 successfully complete clinical trials or eventually commercialize our product candidates, if approved.

Clinical trials are very expensive, time consuming and difficult to design and implement, and involve uncertain outcomes. Furthermore, results of earlier preclinical studies and clinical trials may not be predictive of results of future preclinical studies or clinical trials.

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. Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical trial process. The results of preclinical studies and earlier clinical trials may not be predictive of the results of later-stage clinical trials. For example, the results generated to date in preclinical studies or clinical trials for our product candidates do not ensure that later preclinical studies or clinical trials will demonstrate similar results. Further, we have limited clinical data for each of our product candidates and have not completed Phase 3 clinical trials for any of our product candidates. 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. Companies in the biopharmaceutical industry may suffer setbacks in advanced clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier clinical trials. For example, COR-003 was previously studied for the treatment of type 2 diabetes. In December 2005, prior to the initiation of the first clinical trial by DiObex, our licensee, the FDA placed a clinical hold relating to a safety concern for use of a dosage above 600 mg/day. DiObex modified the clinical trial protocol to limit the highest dose to 600 mg/day, and the clinical hold was lifted by the FDA in February 2006. Furthermore, COR-003 did not demonstrate a reduction in blood glucose levels in a small Phase 2 clinical trial in patients with type 2 diabetes mellitus, the original indication for which it was being developed. We may experience delays in our ongoing or future preclinical studies or clinical trials, and we do not know whether future preclinical studies or clinical trials will begin on time, need to be redesigned, enroll an adequate number of subjects or patients on time or be completed on schedule, if at all. Clinical trials may be delayed, suspended or terminated for a variety of reasons, including delay or failure to:

- obtain authorization from regulators or institutional review boards, or IRBs, to commence a clinical trial at a prospective clinical trial site;
- reach agreements 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 clinical trial sites;
- recruit and enroll a sufficient number of patients in clinical trials to ensure adequate statistical power to detect statistically significant treatment effects;
- address any noncompliance with regulatory requirements or safety concerns that arise during the course of a clinical trial;
- have patients complete clinical trials or return for post-treatment follow-up;
- have CROs or other third parties comply with regulatory requirements, adhere to the trial protocol or meet contractual obligations in a timely manner or at all;
- identify a sufficient number of clinical trial sites and initiate them within the planned timelines; and
- manufacture sufficient quantities of the product candidate to complete clinical trials.

Positive or timely results from preclinical or early stage clinical trials do not ensure positive or timely results in late stage clinical trials or regulatory approval by the FDA, EMA or any comparable foreign regulatory agency. 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. Preclinical and clinical data are often susceptible to varying interpretations and analyses. Many companies that believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain regulatory approval for the product candidates. The FDA, EMA and any comparable foreign regulatory agency have substantial discretion in the approval process and in determining when or whether regulatory approval will be obtained for any of our product candidates. 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, EMA or any comparable foreign regulatory agency.

In some instances, there can be significant variability in safety or efficacy results between different clinical trials of the same product candidate due to numerous factors, including changes in clinical trial procedures set forth in protocols, differences in the size and type of the patient populations, adherence to the administration regimen and other clinical trial protocols, and the rate of dropout among clinical trial participants. In the case of our late stage clinical product candidates, results may differ in general on the basis of the larger number of clinical trial sites and additional countries involved in Phase 3 clinical trials. Different countries have different standards of care and different levels of access to care for patients, which in part drives the heterogeneity of the patient populations that enroll in our studies.

We have met with the FDA regarding the development pathway of COR-003. The FDA recommended, but did not require, a control group in the clinical trial design. We concluded that it was not practical to use any approved drug to serve as an active control in our Phase 3 clinical trial of COR-003. We are using an open-label, single-arm design because in the past the FDA has deemed that the concurrent use of a placebo control as monotherapy is unethical for the treatment of active endogenous Cushing's syndrome due to the progressive and serious nature of the condition. In February 2016, however, a Phase 3 clinical trial was registered by another company with the FDA to evaluate their monotherapy product candidate against concurrent use of placebo control. In addition, based on our analysis and feedback from experts whom we have consulted, we concluded that it was not practical to use any approved drug to serve as an active control due to the unsuitable mode of action, route of administration and side effect profile of available approved therapies. Studies lacking an active control group are more likely to be subject to unanticipated variability in study results that can potentially lead to flawed conclusions because they do not allow for discrimination of patient outcomes. As a result, even if we achieve the clinical trial's end points, the FDA or other regulatory authorities could view our study results as potentially biased and may ultimately require that we conduct a randomized, controlled clinical trial of COR-003 in order to obtain approval for commercialization. Unfavorable data from our clinical trials may restrict the potential development and commercialization of COR-003 or lead to the termination of its development.

In June 2015, we acquired COR-005 and were not involved in and had no control over the preclinical and clinical development of this product candidate prior to such acquisition. As a result, we are dependent on the prior research and development of COR-005 having been conducted in accordance with the applicable protocol, legal, regulatory and scientific standards, the accuracy of reported results of all clinical trials conducted prior to our acquisition having been accurately reported and the correct interpretation of collected data from these clinical trials. These factors could result in increased costs and delays in the development of COR-005, which could hurt our ability to generate future revenues from this product candidate.

The regulatory approval process of the FDA, EMA or any comparable foreign regulatory agency may be lengthy, time consuming and unpredictable.

Our future success is dependent upon our ability to successfully develop, obtain regulatory approval for and then successfully commercialize one or more of our product candidates. Although certain of our employees have prior experience with submitting marketing applications to the FDA, EMA or any comparable foreign regulatory agency, we, as a company, have not submitted such applications for our product candidates. We cannot be certain that any of our product candidates will be successful in clinical trials or receive regulatory approval. Applications for any of our product candidates could fail to receive regulatory approval for many reasons, including, but not limited to, the following:

- the FDA, EMA or any comparable foreign regulatory agency may disagree with the design or implementation of our clinical trials or our interpretation of data from nonclinical trials or 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, including reliance on foreign clinical data;
- the data collected from clinical trials of our product candidates may not be sufficient to support a finding that has statistical significance or clinical meaningfulness or support the submission of a new drug application, or NDA, or other submission, or to obtain regulatory approval in the United States or elsewhere;
- we may be unable to demonstrate to the FDA, EMA or any comparable foreign regulatory agency that a product candidate's risk-benefit ratio for its proposed indication is acceptable;
- the FDA, EMA or any comparable foreign regulatory agency 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; and
- the approval policies or regulations of the FDA, EMA or any comparable foreign regulatory agency may significantly change in a manner rendering our clinical data insufficient for approval.

Any of our current or future product candidates could take a significantly longer time to gain regulatory approval than expected or may never gain regulatory approval. This could delay or eliminate any potential product revenue by delaying or terminating the potential commercialization of our product candidates. For example, although our Phase 3 clinical program for COR-003 has an open-label, single-arm design because a concurrent placebo control as monotherapy was deemed unethical, and an approved drug to serve as active control (monotherapy) or as background therapy (adjunctive therapy) suitable for an international study population was deemed impractical, the FDA has recommended the inclusion of a control group. In February 2016, a Phase 3 clinical trial was registered by another company with the FDA to evaluate their monotherapy product candidate against concurrent use of placebo control. Therefore, even if we achieve the clinical trial's endpoints, the FDA and other regulatory authorities may ultimately require that we conduct a randomized, controlled clinical trial of COR-003 in order to obtain approval for commercialization.

We intend to seek formal advice and guidance from the FDA and the EMA prior to advancing COR-005 into further studies and pivotal clinical trials. If the feedback we receive is different from what we currently anticipate, this could delay the development and regulatory approval process for this product candidate.

We generally plan to seek regulatory approval to commercialize our product candidates in the United States, the European Union and other key global markets. To obtain regulatory approval in other countries, we must comply with numerous and varying regulatory requirements of such other countries regarding safety, efficacy, chemistry, manufacturing and controls, clinical trials, commercial sales, pricing and distribution of our product candidates. Even if we are successful in obtaining approval in one jurisdiction, we cannot ensure that we will obtain approval in any other jurisdictions. Failure to obtain marketing authorization for our product candidates will result in our being unable to market and sell such products. If we fail to obtain approval in any jurisdiction, the geographic market for our product candidates could be limited. Similarly, regulatory agencies may not approve the labeling claims that are necessary or desirable for the successful commercialization of our product candidates.

If serious adverse, undesirable or unacceptable side effects are identified during the development of our product candidates or following regulatory approval, if any, we may need to abandon our development of such product candidates.

If our product candidates are associated with serious adverse, undesirable or unacceptable side effects, 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.

For example, in our clinical trials of COR-003 to date, adverse events have included headache, nausea, back pain, dizziness, diarrhea and liver enzyme elevations. For COR-005, which is given by subcutaneous injections, adverse events have included injection site reaction such as swelling, itching and pain. In addition, headache and gastrointestinal effects such as nausea and diarrhea were observed for COR-005. These adverse events can be dose-dependent and may increase in frequency and severity if we increase the dose to increase efficacy. Occurrence of serious treatment-related side effects could impede clinical trial enrollment, require us to halt the clinical trial, and prevent receipt of regulatory approval from the FDA, EMA or any comparable foreign regulatory agency. They could also adversely affect physician or patient acceptance of our product candidates.

Discovery of previously unknown problems, or increased focus on a known problem, with an approved product may result in restrictions on its permissible uses, including withdrawal of the medicine from the market. Currently, ketoconazole is required to include a “black box” warning on its label for use as an antifungal related to liver toxicity in the United States. Ketoconazole is the racemic mixture, meaning it contains both mirror image forms of the molecule in a 1:1 ratio, from which we draw our single enantiomer product candidate COR-003. If COR-003 is required to include a similar “black box” warning on its label, it may limit our ability to commercialize the product, if approved.

Additionally, if one or more of our product candidates receives regulatory approval, and we or others later identify undesirable side effects caused by such product(s), a number of potentially significant negative consequences could result, including, but not limited to:

- withdrawal by regulatory authorities of approvals of such product;
- seizure of the product by regulatory authorities;
- recall of the product;
- restrictions on the marketing of the product;
- requirement by regulatory authorities of additional warnings on the label, such as a black box warning;
- requirement that we create a medication guide outlining the risks of such side effects for distribution to patients;

- commitment to expensive additional safety studies prior to launch as a prerequisite of approval by regulatory authorities of such product;
- commitment to expensive post-marketing studies as a prerequisite of approval by regulatory authorities of such product;
- initiation of legal action against us claiming to hold us liable for harm caused to patients; and
- harm to our reputation and resulting harm to physician or patient acceptance of our products.

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, financial condition, and results of operations.

We may find it difficult to enroll patients in our clinical trials given the limited number of patients who have the diseases for the treatment of which our product candidates are being studied. Difficulty in enrolling patients in our clinical trials could delay or prevent clinical trials of our product candidates.

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

Because we are focused on addressing rare diseases, there are limited patient pools from which to draw in order to complete our clinical trials in a timely and cost-effective manner. 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, and delay or potentially jeopardize our ability to commence product sales and generate revenue. In addition, many of the factors that may 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.

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. We currently have no products that have been approved for commercial sale. However, 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, healthcare 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 compromise the market acceptance of our product candidates or any prospects for commercialization of our product candidates, if approved.

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 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 regulatory 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.

Risks Related to Commercialization of Our Product Candidates

We have never commercialized a product candidate and we may lack the necessary expertise, personnel and resources to successfully commercialize any of our products that receive regulatory approval on our own or together with suitable partners.

We have never commercialized a product candidate. Our operations to date have been limited to organizing and staffing our company, business planning, raising capital, in-licensing or acquiring our product candidates, identifying potential product candidates and undertaking preclinical studies and clinical trials of our product candidates. We currently have no sales force or marketing or distribution capabilities. To achieve commercial success of our product candidates, if approved, we will have to develop our own sales, marketing and supply capabilities 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 product candidates and other unforeseen costs associated with creating an independent sales and marketing organization. Developing a sales and marketing organization requires significant investment, is time consuming and could delay the launch of our product candidates. We may not be able to build an effective sales and marketing organization in the United States, the European Union or other key global markets. 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.

We operate in a highly competitive and rapidly changing industry, which may result in our competitors discovering, developing or commercializing competing products before or more successfully than we do, or our entering a market in which a competitor has commercialized an established competing product, and we may not be successful in competing with them.

The development and commercialization of new drug products is highly competitive and subject to significant and rapid technological change. Our success is highly dependent upon our ability to in-license, acquire, develop and obtain regulatory approval for new and innovative drug products on a cost-effective basis and to market them successfully. In doing so, we face and will continue to face intense competition from a variety of businesses, including large, fully integrated, well-established pharmaceutical companies who already possess a large share of the market, specialty pharmaceutical companies and biopharmaceutical companies, academic institutions, government agencies and other private and public research institutions in Europe, the United States and other jurisdictions.

We are currently aware of various companies that are marketing existing drugs that may compete with our product candidates such as Corcept Therapeutics and Novartis. Corcept Therapeutics markets Korlym (mifepristone) in the United States. Korlym is indicated for the control of hyperglycemia secondary to hypercortisolism in patients with endogenous Cushing's syndrome who have type 2 diabetes or glucose intolerance and have failed surgery or are not candidates for surgery. The product has already received regulatory approval from the FDA and was launched in the United States in April 2012. Similarly, Novartis markets Signifor (pasireotide), a somatostatin analog approved for the treatment of adults with Cushing's disease for whom pituitary surgery is not an option or has not been curative.

In 2012, Signifor was approved by the EMA for the treatment of Cushing's disease, and was approved by the FDA in December 2012. It is also an approved somatostatin analog (or SSA) therapy for the treatment of acromegaly. The product has been marketed in the United Kingdom, Germany and other European countries since 2012, and in the United States since the first half of 2013. Additionally, in 2014, the EMA approved ketoconazole for the treatment of endogenous Cushing's syndrome. Ketoconazole is the most commonly prescribed drug therapy for the treatment of endogenous Cushing's syndrome, even though it is not approved for this use in the United States. Regulatory approval of ketoconazole in the United States for the treatment of endogenous Cushing's syndrome could significantly increase competition for COR-003 due to their similar mechanisms of action.

Other companies acquiring and developing or marketing drug therapies or products for rare diseases include Ipsen, Pfizer, GP Pharma, Italfarmaco, HRA and Chiasma. We anticipate this competition to increase in the future as new companies enter the endocrinology and rare diseases markets. In addition, the health care industry is characterized by rapid technological change, and new product introductions or other technological advancements could make some or all of our products obsolete.

The highly competitive nature of and rapid technological changes in the biotechnology and pharmaceutical industries could render our product candidates or our technology obsolete or non-competitive. Our competitors may, among other things:

- have similar or better product candidates or technologies;
- possess greater financial and human resources as well as supporting clinical data;
- develop and commercialize products that are safer, more effective, less expensive, or more convenient or easier to administer;
- obtain regulatory approval more quickly;
- establish superior proprietary positions;
- have access to greater manufacturing capacity;
- seek patent protection that competes with our product candidates;
- implement more effective approaches to sales and marketing; or
- enter into more advantageous collaborative arrangements for research, development, manufacturing and marketing of products.

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

The successful commercialization of our product candidates, if approved, will depend, in part, on the extent to which coverage and reimbursement for our products or procedures using our products will be available from government and health administration authorities, private health insurers and other third-party payors. To manage healthcare costs, many governments and third-party payors increasingly scrutinize the pricing of new technologies and require greater levels of evidence of favorable clinical outcomes and cost-effectiveness before extending coverage and adequate reimbursement to such new technologies. In the United States, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, or the Medicare Modernization Act, changed the way Medicare covers and pays for pharmaceutical products. The legislation expanded Medicare coverage for drug purchases by the elderly under a new Part D and introduced a new reimbursement methodology based on average sale prices for physician-administered drugs. In addition, this legislation provided authority for limiting the number of drugs that will be covered in any therapeutic class. Cost-reduction initiatives and other provisions of this legislation could decrease the coverage and reimbursement that we receive for any approved products. While the Medicare Modernization Act applies only to drug benefits for Medicare beneficiaries, private payors often follow Medicare coverage policy and payment limitations in setting their own reimbursement rates. Therefore, any reduction in reimbursement that results from the Medicare Modernization Act may result in a similar reduction in payments from private payors. In light of such challenges to prices and increasing levels of evidence of the benefits and clinical outcomes of new technologies, we cannot be sure that coverage will be available for any product candidate that we commercialize, and, if available, that the reimbursement rates will be adequate. If we are unable to obtain adequate levels of coverage and reimbursement for our product candidates, our ability to generate revenue will be compromised.

Our potential customers, including hospitals, physicians and other healthcare providers that purchase certain injectable drugs administered during a procedure, such as our product candidates, generally rely on third-party payors to pay for all or part of the costs and fees associated with the drug and the procedures administering the drug. These third-party payors may pay separately for the drug or may bundle or otherwise include the costs of the drug in the payment for the procedure. We are unable to predict at this time whether our product candidates, if approved, will be eligible for such separate payments. To the extent there is no separate payment for our product candidates, there may be further uncertainty as to the adequacy of reimbursement amounts. Nor can we predict at this time the adequacy of payments, whether made separately for the drug and procedure or with a bundled or otherwise aggregate payment amount for the drug and procedure. In addition, obtaining and maintaining adequate coverage and reimbursement status is time consuming and costly.

Because each third-party payor individually approves coverage and reimbursement levels, obtaining coverage and adequate reimbursement is a time consuming, costly and sometimes unpredictable process. We may be required to provide scientific and clinical support, medical necessity or both for the use of any product to each third-party payor separately with no assurance that approval would be obtained, and we may need to conduct expensive pharmacoeconomic studies in order to demonstrate the cost-effectiveness, medical necessity or both of our products. This process could delay the market acceptance of any product and could have a negative effect on our future revenues and operating results.

Third-party payors may deny coverage and reimbursement status altogether of a given drug product, or cover the product, but may also establish prices at levels that are too low to enable us to realize an appropriate return on our investment in product development. Because the rules and regulations regarding coverage and reimbursement change frequently, in some cases on short notice, even when there is favorable coverage and reimbursement, future changes may occur that adversely impact such favorable coverage and reimbursement status. Further, the net reimbursement for drug products may be subject to additional reductions if there are changes to laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the United States.

The unavailability or inadequacy of third-party coverage and reimbursement could negatively affect 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 healthcare 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.

Our products may not gain market acceptance, in which case we may not be able to generate product revenues.

Even if the FDA, EMA or any comparable foreign regulatory agency approves the marketing of any product candidates that we develop, physicians, healthcare providers, patients or the medical community may not accept or use them. Efforts to educate the medical community and third-party payors on the benefits of our product candidates may require significant resources and may not be successful. If COR-003, COR-005 or any other product candidate that we develop does not achieve an adequate level of acceptance, we may not generate significant product revenues or any profits from operations. The degree of market acceptance of COR-003, COR-005 or any of our product candidates that are approved for commercial sale will depend on a variety of factors, including, but not limited to:

- whether clinicians and potential patients perceive our product candidates to have better efficacy, safety and tolerability profile, and ease of use compared with our competitors;
- the timing of market introduction;
- the number of competing products;
- our ability to provide acceptable evidence of safety and efficacy;
- the prevalence and severity of any side effects;
- relative convenience and ease of administration;
- cost-effectiveness;
- patient diagnostics and screening infrastructure in each market;
- marketing and distribution support; and
- availability of coverage, reimbursement and adequate payment from health maintenance organizations and other third-party payors, both public and private.

In addition, the potential market opportunity for COR-003, COR-005 or any other product candidate we may develop is difficult to estimate precisely. Our estimates of the potential market opportunity are predicated on several key assumptions such as industry knowledge and publications, third-party research reports and other surveys. While we believe that our internal assumptions are reasonable, these assumptions may be inaccurate. If any of the assumptions proves to be inaccurate, then the actual market for COR-003 or our other product candidates could be smaller than our estimates of the potential market opportunity. If the actual market for COR-003 or our other product candidates is smaller than we expect, or if the products fail to achieve an adequate level of acceptance by physicians, health care payors and patients, our product revenue may be limited and we may be unable to achieve or maintain profitability. Further, given the limited number of treating physicians, if we are unable to convince a significant number of such physicians of the value of our product candidates, we may be unable to achieve a sufficient market share to make our products, if approved, profitable.

Risks Related to Our Reliance on Third Parties

We rely on third parties to conduct our nonclinical and clinical trials and if these third parties perform in an unsatisfactory manner, our business could be substantially harmed.

We have relied upon and plan to continue to rely upon third-party CROs to conduct and monitor and manage data for our ongoing nonclinical and clinical programs, and may not currently have all of the necessary contractual relationships in place to do so. Once we have established contractual relationships with such third-party CROS, we will have only limited control over their actual performance of these activities. Nevertheless, we are responsible for ensuring that each of our trials is conducted in accordance with the applicable protocol, legal, regulatory, environmental and scientific standards and our reliance on the CROs does not relieve us of our regulatory responsibilities.

We and our CROs and other vendors are required to comply with current Good Manufacturing Practices, or cGMP, current Good Clinical Practices, or cGCP, and Good Laboratory Practice, or GLP, which are regulations and guidelines enforced by the FDA, the Competent Authorities of the Member States of the European Union and any comparable foreign regulatory agency for all of our product candidates in nonclinical and clinical development. Regulatory authorities enforce these regulations through periodic inspections of study 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, EMA or any comparable foreign regulatory agency 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 products 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.

Our business involves the controlled use of hazardous materials, chemicals, biologicals and radioactive compounds. Substantially all such use is outsourced to third-party CRO manufacturers and clinical sites. Although we believe that our third-party CROs safety procedures for handling and disposing of such materials comply with industry standards, there will always be a risk of accidental contamination or injury. By law, radioactive materials may only be disposed of at certain approved facilities. If liable for an accident, or if it suffers an extended facility shutdown, we or our CROs could incur significant costs, damages or penalties.

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 our 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. Our CROs may also generate higher costs than anticipated. 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.

If any of our relationships with these third-party CROs terminates, we may not be able to enter into arrangements with alternative CROs or to do so on commercially reasonable terms. If we are able to replace a CRO, switching or adding additional CROs involves additional cost and requires management time and focus and there is a natural transition period when a new CRO commences work. As a result, delays could occur, which could hurt 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.

The failure of our suppliers to supply us with the agreed upon drug substance or drug product could hurt our business.

We do not currently, and do not expect to in the future, independently conduct manufacturing activities for our product candidates. We expect to rely on third-party suppliers for the drug substance and drug product for our product candidates. The failure of these suppliers to perform as contracted, or the need to identify new suppliers, could result in a delay in the development of our product candidates. 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 hurt our business.

We and our collaborators and contract manufacturers are subject to significant regulation with respect to manufacturing our product candidates. The manufacturing facilities on which we rely may not continue to meet regulatory requirements or may not be able to meet supply demands.

All entities involved in the preparation of therapeutics for clinical trials or commercial sale, including our existing contract manufacturers for our product candidates, are subject to extensive regulation. Components of a finished therapeutic product approved for commercial sale or used in late-stage clinical trials must be manufactured in accordance with cGMP. These regulations govern manufacturing processes and procedures, including record keeping, and the implementation and operation of quality systems to control and assure the quality of investigational products and products approved for sale. Poor control of production processes can lead to the introduction of contaminants or to inadvertent changes in the properties or stability of our product candidates that may not be detectable in final product testing. We, our collaborators or our contract manufacturers must supply all necessary documentation in support of an NDA or foreign equivalent on a timely basis and must adhere to GLP and cGMP regulations enforced by the FDA and other regulatory agencies through their facilities inspection program. Some of our contract manufacturers have never produced a commercially approved pharmaceutical product and therefore have not obtained the requisite regulatory authority approvals to do so. The facilities and quality systems of some or all of our collaborators and third-party contractors must pass a pre-approval inspection for compliance with the applicable regulations as a condition of regulatory approval of our product candidates or any of our other potential products.

In addition, the regulatory authorities may, at any time, audit or inspect a manufacturing facility involved with the preparation of our product candidates or our other potential products or the associated quality systems for compliance with the regulations applicable to the activities being conducted. Although we oversee the contract manufacturers, we cannot control the manufacturing process of, and are completely dependent on, our contract manufacturing partners for compliance with the regulatory requirements. If these facilities do not pass a pre-approval plant inspection, regulatory approval of the products may not be granted or may be substantially delayed until any violations are corrected to the satisfaction of the regulatory authority, if ever.

The regulatory authorities also may, at any time following approval of a product for sale, audit the manufacturing facilities of our collaborators and third-party contractors. If any such inspection or audit identifies a failure to comply with applicable regulations or if a violation of our product specifications or applicable regulations occurs independent of such an inspection or audit, we or the relevant regulatory authority may require remedial measures that may be costly and/or time consuming for us or a third party to implement, and that may include the temporary or permanent suspension of a clinical trial or commercial sales or the temporary or permanent closure of a facility.

If we, our collaborators or any of our third-party manufacturers fail to maintain regulatory compliance, the FDA or another applicable regulatory authority could impose regulatory sanctions including, among other things, refusal to approve a pending application our product candidates, withdrawal of an approval or suspension of production.

Additionally, if the supply from one approved manufacturer is interrupted, an alternative manufacturer would need to be qualified through an NDA supplement or equivalent foreign regulatory filing, which could result in further delay. The regulatory agencies may also require additional studies if a new manufacturer is relied upon for commercial production. Switching manufacturers may involve substantial costs and is likely to result in a delay in our desired clinical and commercial timelines.

These factors could cause us to incur higher costs and could cause the delay or termination of clinical trials, regulatory submissions, required approvals or commercialization of our product candidates. Furthermore, if our suppliers fail to meet contractual requirements and we are unable to secure one or more replacement suppliers capable of production at a substantially equivalent cost, our clinical trials may be delayed or we could lose potential revenue.

Our reliance on third parties requires us to share our trade secrets, which increases the possibility that a competitor will discover them or that our trade secrets will be misappropriated or disclosed.

Because we rely on third parties to develop and manufacture our product candidates, we must, at times, share trade secrets with them. We seek to protect our proprietary technology in part by entering into confidentiality agreements and, if applicable, material transfer agreements, collaborative research agreements, consulting agreements or other similar agreements with our collaborators, advisors, employees, and consultants prior to beginning research or disclosing proprietary information. These agreements typically limit the rights of the third parties to use or disclose our confidential information, such as trade secrets. Despite the contractual provisions employed when working with third parties, the need to share trade secrets and other confidential information increases the risk that such trade secrets become known by our competitors, are inadvertently incorporated into the technology of others, or are disclosed or used in violation of these agreements. Given that our proprietary position is based, in part, on our know-how and trade secrets, a competitor’s discovery of our trade secrets or other unauthorized use or disclosure would impair our competitive position and may harm our business.

Risks Related to Our Intellectual Property

If we or our licensors are unable to obtain and maintain effective patent rights for our technologies, product candidates or any future product candidates, or if the scope of the patent rights obtained is not sufficiently broad, we may not be able to compete effectively in our markets.

In addition to the exclusivity provided for our product candidates with regulatory orphan drug status, we rely upon a combination of patents, trade secret protection and confidentiality agreements to protect the intellectual property related to our technologies and product candidates. Our success depends in large part on our and our licensors' ability to obtain and maintain patent and other intellectual property protection in the United States and in other countries with respect to our proprietary technology and product candidates.

We have sought to protect our proprietary position by filing patent applications in the United States and abroad related to our novel technologies and products that are important to our business. This 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, in a timely manner or in all jurisdictions. It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. Moreover, in some circumstances, we do not have the right to control the preparation, filing and prosecution of patent applications, or to maintain the patents, covering technology that we license from third parties. Therefore, these patents and applications may not be prosecuted and enforced in a manner consistent with the best interests of our business.

The patent position of biotechnology and pharmaceutical companies generally is highly uncertain and involves complex legal and factual questions for which legal principles remain unsolved. The patent applications that we own or in-license may fail to result in issued patents with claims that cover our product candidates in the United States or in foreign countries. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions remain confidential for a period of time after filing, and some remain so until issued. Therefore, we cannot be certain that we were the first to file any patent application related to our product candidates, or whether we were the first to make the inventions claimed in our owned patents or pending patent applications, nor can we know whether those from whom we license patents were the first to make the inventions claimed or were the first to file. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. There is no assurance that all potentially relevant prior art relating to our patents and patent applications has been found, which can invalidate a patent or prevent a patent from issuing from a pending patent application. Even if patents do successfully issue, and even if such patents cover our product candidates, third parties may challenge their validity, enforceability or scope, which may result in such patents being narrowed, found unenforceable or invalidated, which could allow third parties to commercialize our technology or products and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third-party patent rights. Furthermore, even if they are unchallenged, our patents and patent applications may not adequately protect our intellectual property, provide exclusivity for our product candidates, prevent others from designing around our claims or provide us with a competitive advantage. Any of these outcomes could impair our ability to prevent competition from third parties.

We and/or our licensors have filed several patent applications covering various aspects of our product candidates. We cannot offer any assurances about which, if any, patents will issue, the breadth of any such patent, or whether any issued patents will be found invalid and unenforceable or will be challenged by third parties. Any successful opposition to these patents or any other patents owned by or licensed to us after patent issuance could deprive us of rights necessary for the successful commercialization of any product candidates that we may develop. Further, if we encounter delays in regulatory approvals, the period of time during which we could market a product candidate under patent protection could be reduced.

We may not have sufficient patent terms to effectively protect our products and business.

Patents have a limited lifespan. In the United States, the natural expiration of a patent is generally 20 years after it is first filed. Although various extensions may be available, the life of a patent, and the protection it affords, is limited. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such product candidates are commercialized. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours or otherwise provide us with a competitive advantage. Even if patents covering our product candidates are obtained, once the patent life has expired for a product, we may be open to competition from generic medications.

While patent term extensions in the United States and under supplementary protection certificates in the European Union may be available to extend the patent exclusivity term for our product candidates, we cannot provide any assurances that any such patent term extension will be obtained and, if so, for how long.

Patent policy and rule changes could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents.

Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of our patents or narrow the scope of our patent protection. The laws of foreign countries may not protect our rights to the same extent as the laws of the United States. Assuming the other requirements for patentability are met, in the United States prior to March 15, 2013, the first to invent the claimed invention is entitled to the patent, while outside the United States, the first to file a patent application is entitled to the patent. After March 15, 2013, under the Leahy-Smith America Invents Act, or the AIA, enacted on September 16, 2011, the United States has moved to a first inventor to file system. The AIA also includes a number of significant changes that affect the way patent applications will be prosecuted and may also affect patent litigation. The effects of these changes are currently unclear as the United States Patent and Trademark Office, or the USPTO, is still implementing various regulations, the courts have yet to address many of these provisions and the applicability of the act and new regulations on specific patents discussed herein have not been determined and would need to be reviewed. In general, the AIA and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents. In addition, recent U.S. Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our 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 actions by the U.S. Congress, the federal courts and the USPTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future.

Third-party claims of intellectual property infringement may expose us to substantial liability or prevent or delay our development and commercialization efforts.

Our commercial success depends in part on our ability to develop, manufacture, market and sell our product candidates, if approved, and use our proprietary technology without alleged or actual infringement, misappropriation or other violation of the patents and proprietary rights of third parties. There have been many lawsuits and other proceedings involving patent and other intellectual property rights in the biotechnology and pharmaceutical industries, including patent infringement lawsuits, interferences, oppositions and reexamination proceedings before the USPTO, and corresponding foreign patent offices. Numerous U.S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are developing product candidates. Some claimants may have substantially greater resources than we do and may be able to sustain the costs of complex intellectual property litigation to a greater degree and for longer periods of time than we could. In addition, patent holding companies that focus solely on extracting royalties and settlements by enforcing patent rights may target us.

As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our product candidates may be subject to claims of infringement of the intellectual property rights of third parties.

Third parties may assert that we are employing their proprietary technology without authorization. There may be third-party patents or patent applications with claims to compositions, formulations, methods of manufacture or methods of treatment related to the use or manufacture of our product candidates. We cannot be sure that we know of each and every patent and pending application in the United States and abroad that is relevant or necessary to the commercialization of our product candidates. Because patent applications can take many years to issue, there may be currently pending patent applications that may later result in issued patents upon which our product candidates may infringe. In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents. If any third-party patents were held by a court of competent jurisdiction to cover the manufacturing process of any of our product candidates, any compositions formed during the manufacturing process or any final product itself, the holders of any such patents may be able to block our ability to commercialize such product candidate unless we obtained a license under the applicable patents, or until such patents expire or are finally determined to be invalid or unenforceable. Similarly, if any third-party patents were held by a court of competent jurisdiction to cover aspects of our compositions, formulations, or methods of treatment, prevention or use, the holders of any such patents may be able to block our ability to develop and commercialize the applicable product candidate unless we obtained a license or until such patent expires or is finally determined to be invalid or unenforceable. In either case, such a license may not be available on commercially reasonable terms, or at all. Even if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors access to the same technologies licensed to us.

Parties making claims against us may obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize one or more of our product candidates, if approved. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business. In the event of a successful claim of infringement against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, pay royalties, redesign our infringing products or obtain one or more licenses from third parties, which may be impossible or require substantial time and monetary expenditure.

Additional competitors could enter the market with generic versions of our products, which may result in a decline in sales of affected products.

Under the Hatch-Waxman Act, a pharmaceutical manufacturer may file an abbreviated new drug application, or ANDA, seeking approval of a generic copy of an approved innovator product. Under the Hatch-Waxman Act, a manufacturer may also submit an NDA under section 505(b)(2) that references the FDA's prior approval of the innovator product. A 505(b)(2) NDA product may be for a new or improved version of the original innovator product. Hatch-Waxman also provides for certain periods of regulatory exclusivity, which preclude FDA approval, or, in some circumstances, FDA filing and reviewing, of an ANDA or 505(b)(2) NDA. These include, subject to certain exceptions, the period during which an FDA-approved drug is subject to orphan drug exclusivity. Although COR-003 is being developed as a new chemical entity, or NCE, we intend to rely on orphan drug exclusivity rather than NCE exclusivity for nonpatent protection of COR-003. In addition to the benefits of regulatory exclusivity, an innovator NDA holder may have patents claiming the active ingredient, product formulation or an approved use of the drug, which would be listed with the product in the FDA publication, "Approved Drug Products with Therapeutic Equivalence Evaluations," known as the "Orange Book." If there are patents listed in the Orange Book, a generic or 505(b)(2) applicant that seeks to market its product before expiration of the patents must include in the ANDA what is known as a "Paragraph IV certification," challenging the validity or enforceability of, or claiming non-infringement of, the listed patent or patents. Notice of the certification must be given to the innovator, too, and if within 45 days of receiving notice the innovator sues to protect its patents, approval of the ANDA is stayed for 30 months, or as lengthened or shortened by the court.

Accordingly, if COR-003 or any of our other product candidates is approved, competitors could file ANDAs for generic versions of our product candidates, or 505(b)(2) NDAs that reference our product candidates, respectively. If there are patents listed for our product candidates in the Orange Book, those ANDAs and 505(b)(2) NDAs would be required to include a certification as to each listed patent indicating whether the ANDA applicant does or does not intend to challenge the patent. We cannot predict whether any patents issuing from our pending patent applications will be eligible for listing in the Orange Book, how any generic competitor would address such patents, whether we would sue on any such patents or the outcome of any such suit.

We may not be successful in securing or maintaining proprietary patent protection for products and technologies we develop or license. Moreover, if any patents that are granted and listed in the Orange Book are successfully challenged by way of a Paragraph IV certification and subsequent litigation, the affected product could immediately face generic competition and its sales would likely decline rapidly and materially. Should sales decline, we may have to write off a portion or all of the intangible assets associated with the affected product and our ability to generate revenue could be compromised.

Although we are not currently involved in any litigation, we may be involved in lawsuits to protect or enforce our patents or the patents of our licensors, which could be expensive, time consuming and unsuccessful.

Competitors may infringe upon our patents or the patents of our licensors. Although we are not currently involved in any litigation, if we or one of our licensing partners were to initiate legal proceedings against a third party to enforce a patent covering one of our product candidates, the defendant could counterclaim that the patent covering our product candidate is invalid and/or unenforceable, or request declaratory judgment that there is no infringement. In patent litigation in the United States, defendant counterclaims alleging invalidity, noninfringement and/or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, nonobviousness or non-lack of enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld material relevant information from the USPTO, or made a misleading statement, during prosecution. The outcome following legal assertions of invalidity and unenforceability is unpredictable.

Interference or derivation proceedings provoked by third parties or brought by us or declared by the USPTO may be necessary to determine the priority of inventions with respect to our patents or patent applications or those of our licensors. An unfavorable outcome could require us to cease using the related technology or to attempt to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms, or at all. Our defense of litigation or interference proceedings may fail and, even if successful, may result in substantial costs, and distract our management and other employees. In addition, the uncertainties associated with litigation could compromise our ability to raise the funds necessary to continue our clinical trials, continue our research programs, license necessary technology from third parties or enter into development partnerships that would help us bring our product candidates to market, if approved.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could hurt the market price of our ordinary shares.

We have not yet registered a trademark and failure to secure or maintain adequate protection for our trademarks could adversely affect our business.

We have filed a U.S., Canadian and International (Madrid Protocol) trademark application designating Australia, China, European Community, India, Israel, Japan, Mexico and Turkey for the mark, "Strongbridge Biopharma." If the U.S. or any foreign trademark offices raise any objections, we may be unable to overcome such objections. In addition, in the USPTO and in comparable agencies in many foreign jurisdictions, third parties are given an opportunity to oppose pending trademark applications and to seek to cancel registered trademarks. Oppositions or cancellation proceedings have been filed and may in the future be filed against our trademarks, and our trademarks may not survive such proceedings.

Furthermore, third parties may allege in the future, that a trademark or trade name that we elect to use for our product candidates may cause confusion in the marketplace. We evaluate such potential allegations in the course of our business, and such evaluations may cause us to change our commercialization or branding strategy for our product candidates, which may require us to incur additional costs. Moreover, any name we propose to use with our product candidate in the United States must be approved by the FDA, regardless of whether we have registered it, or applied to register it, as a trademark. The FDA typically conducts a review of proposed product names, including an evaluation of potential for confusion with other product names. If the FDA objects to any of our proposed proprietary product names, we may be required to expend significant additional resources in an effort to identify a suitable substitute name that would qualify under applicable trademark laws, not infringe the existing rights of third parties and be acceptable to the FDA.

At times, competitors may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. Over the long term, if we are unable to establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively and our business may be adversely affected. Our efforts to enforce or protect our proprietary rights related to trademarks, domain names or copyrights may be ineffective and could result in substantial costs and diversion of resources.

In addition, there could be potential trade name or trademark infringement claims brought by owners of other registered trademarks alleging that the use of a corporate name or logo, product names or other signs by which we distinguish our products and services are infringing their trademark rights. The outcome of such claims is uncertain and may adversely affect our freedom to use our corporate name or other relevant signs. If litigation arises in this area, it may lead to significant costs and diversion of management and employee attention.

We may be subject to claims that our employees, consultants or independent contractors have wrongfully used or disclosed confidential information of third parties or that our employees have wrongfully used or disclosed alleged trade secrets of their former employers.

We may employ individuals who were previously employed at universities or other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although we try to ensure that our employees, consultants and independent contractors do not use the proprietary information or know-how of others in their work for us, and we are not currently subject to any claims that our employees, consultants or independent contractors have wrongfully used or disclosed confidential information of third parties, we may in the future be subject to such claims. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

We may be subject to claims challenging the inventorship of our patents and other intellectual property.

Although we are not currently experiencing any claims challenging the inventorship of our patents or ownership of our intellectual property, we may in the future be subject to claims that former employees, collaborators or other third parties have an interest in our patents or other intellectual property as an inventor or co-inventor. For example, we may have inventorship disputes arise from conflicting obligations of consultants or others who are involved in developing our product candidates. Litigation may be necessary to defend against these and other claims challenging inventorship. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, valuable intellectual property. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

We may not be able to protect our intellectual property rights throughout the world.

Filing, prosecuting and defending patents on product candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States can be less extensive than those in the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. Further, licensing partners may not prosecute patents in certain jurisdictions in which we may obtain commercial rights, thereby precluding the possibility of later obtaining patent protection in these countries. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and may also export infringing products to territories where we have patent protection, but enforcement is not as strong as that in the United States. 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.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets and other intellectual property protection, particularly those relating to biotechnology products, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our patent rights in foreign jurisdictions, 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.

Risks Related to Government and Regulation

Even if one or more of our product candidates obtains regulatory approval, we will be subject to ongoing obligations and continued regulatory requirements, which may result in significant additional expense.

If regulatory approval is obtained for any of our product candidates, the product will remain subject to continual regulatory review. Any regulatory approvals that we receive for our product candidates may be subject to limitations on the approved indicated uses for which the product may be marketed or to the conditions of approval, or contain requirements for potentially costly post-marketing testing, including Phase 4 clinical trials and surveillance to monitor the safety and efficacy of the product candidate. In addition, if the FDA, the EMA or any comparable foreign regulatory authority approves any of our product candidates, we will be subject to ongoing regulatory obligations and oversight by regulatory authorities, including with respect to the manufacturing processes, labeling, packing, distribution, adverse event reporting, storage, advertising and marketing restrictions, and recordkeeping and, potentially, other post-marketing obligations, all of which 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-regulatory approval. Because our Phase 3 clinical trial of COR-003 will collect safety data for only 90 patients, we currently expect that we would be required by the FDA and the EMA to collect additional safety data post-approval.

In addition, approved products, manufacturers and manufacturers' facilities are subject to continual review and periodic inspections. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with our third-party manufacturers or manufacturing 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, disgorgement of profits or revenues, warning letters or holds on clinical trials;
- refusal by the FDA to approve pending applications or supplements to approved applications filed by us;
- suspension or revocation of product 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. The policies of the FDA, the EMA or any comparable foreign regulatory agency 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 regulatory approval that we may have obtained, which would compromise our ability to achieve or sustain profitability.

Although we have obtained orphan drug designation for our key product candidates from the FDA and EMA, orphan drug designation may not ensure that we will enjoy market exclusivity in a particular market, and if we fail to obtain or maintain orphan drug exclusivity for our product candidates, we may be subject to earlier competition and our potential revenue will be reduced.

Under the Orphan Drug Act of 1983, the FDA may designate a product as an orphan drug if it is intended to treat an orphan disease or condition, defined as a patient population of fewer than 200,000 in the United States, or a patient population greater than 200,000 in the United States where there is no reasonable expectation that the cost of developing the drug will be recovered from sales in the United States. In the European Union, the EMA's Committee for Orphan Medicinal Products grants orphan drug designation to promote the development of products that are intended for the diagnosis, prevention, or treatment of a life-threatening or chronically debilitating condition affecting not more than 5 in 10,000 persons in the European Union. Additionally, designation is granted for products intended for the diagnosis, prevention or treatment of a life-threatening, seriously debilitating or serious and chronic condition when, without incentives, it is unlikely that sales of the drug in the European Union would be sufficient to justify the necessary investment in developing the drug or biological product or where there is no satisfactory method of diagnosis, prevention or treatment, or, if such a method exists, the medicine must be of significant benefit to those affected by the condition.

In the United States, orphan drug designation entitles a party to financial incentives, such as opportunities for grant funding towards clinical trial costs, tax advantages and user-fee waivers. In addition, if a product receives the first FDA approval for the indication for which it has orphan drug designation, the product is entitled to orphan drug exclusivity, which means the FDA may not approve any other application to market the same drug for the same indication for a period of seven years, except in limited circumstances, such as a showing of clinical superiority over the product with orphan exclusivity or where the manufacturer is unable to assure sufficient product quantity. In the European Union, orphan drug designation entitles a party to financial incentives such as a reduction of fees or fee waivers and ten years of market exclusivity following drug or biological product approval. This period may be reduced to six years if 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.

COR-003 has been granted orphan drug designation for the treatment of endogenous Cushing's syndrome in the United States and Europe. COR-005 has been granted orphan drug designation for the treatment of acromegaly in the United States and in Europe. Even though we have obtained orphan drug designation for our key product candidates, we may not be the first to obtain regulatory approval for any particular orphan indication due to the uncertainties associated with developing biopharmaceutical products. For example, ketoconazole was granted orphan drug exclusivity in Europe and is now being marketed for the treatment of endogenous Cushing's syndrome. Therefore COR-003 will need to show significant benefit compared to ketoconazole in order to be marketed in Europe prior to the expiration of the ketoconazole orphan drug exclusivity. Further, even though we have obtained orphan drug designation for our key product candidates, that exclusivity may not effectively protect the product from competition because different drugs with different active moieties can be approved for the same condition. Orphan drug designation neither shortens the development time or regulatory review time of a drug nor gives the drug any advantage in the regulatory review or approval process.

Enacted and future legislation may increase the difficulty and cost for us to obtain regulatory approval of and commercialize our product candidates, and may affect the prices we may set.

In the United States and the European Union, there have been a number of legislative, regulatory and proposed changes regarding the healthcare system. These changes could prevent or delay regulatory approval of our product candidates, restrict or regulate post-approval activities, and affect our ability to sell profitably any products for which we obtain regulatory approval and begin to commercialize.

As a result of legislative proposals and the trend toward managed health care in the United States, third-party payors are increasingly attempting to contain healthcare costs by limiting both coverage and the level of reimbursement of new drugs. In the United States, the Medicare Modernization Act changed the way Medicare covers and pays for pharmaceutical products. The legislation expanded Medicare coverage for drug purchases by the elderly under a new Part D and introduced a new reimbursement methodology based on average sale prices for physician-administered drugs. In addition, this legislation provided authority for limiting the number of drugs that will be covered in any therapeutic class. Cost-reduction initiatives and other provisions of this legislation could decrease the coverage and reimbursement that we receive for any approved products. While the Medicare Modernization Act applies only to drug benefits for Medicare beneficiaries, private payors often follow the Medicare coverage policy and payment limitations in setting their own reimbursement rates. Therefore, any reduction in reimbursement that results from the Medicare Modernization Act may result in a similar reduction in payments from private payors.

In March 2010, President Obama signed into law the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or collectively, PPACA, a sweeping law intended, among other things, to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add new transparency requirements for health care and health insurance industries, impose new taxes and fees on the health industry, and impose additional health policy reforms. PPACA, among other things: increased the statutory minimum Medicaid rebates a manufacturer must pay under the Medicaid Drug Rebate Program; addressed a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected; and established a new Medicare Part D coverage gap discount program in which manufacturers must provide 50% point-of-sale discounts on negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period as a condition for the manufacturer's outpatient drugs to be covered under Part D and implemented payment system reforms, including a national pilot program on payment bundling to encourage hospitals, physicians and other providers to improve the coordination, quality and efficiency of certain healthcare services through bundled payment models. Further, the PPACA imposed a significant annual nondeductible fee on entities that manufacture or import specified branded prescription drug products and biologic agents, apportioned among these entities according to their market share in certain government healthcare programs. We expect that additional healthcare reform measures will likely be adopted in the future, any of which may increase our regulatory burdens and operating costs and limit the amounts that federal, state and foreign governments will reimburse for healthcare products and services, which could result in reduced demand for our products, if approved, or additional pricing pressures.

Moreover, other legislative changes have also been proposed and adopted in the United States since PPACA was enacted. On August 2, 2011, the Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction tasked with recommending a targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021 was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs. This includes aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, which went into effect on April 1, 2013 and will stay in effect through 2024 unless additional Congressional action is taken. On January 2, 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, which, among other things, further reduced Medicare payments to several providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. These new laws may result in additional reductions in Medicare and other health care funding, which could compromise the ability of patients and third-party payors to purchase our product candidates.

In the European Union, proposed new clinical trial regulations will centralize clinical trial approval, which eliminates redundancy, but in some cases this may extend timelines for clinical trial approvals due to potentially longer wait times. Proposals to require specific consents for use of data in research, among other measures, may increase the costs and timelines for our product development efforts. Austerity measures in certain European nations may also affect the prices we are able to seek if our products are approved, as discussed below.

Both in the United States and in the European Union, legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for pharmaceutical products. We do not know whether additional legislative changes will be enacted, whether the regulations, guidance or interpretations will be changed, or what the impact of such changes on the regulatory approvals of our product candidates, if any, may be.

Our relationships with customers, consultants and payors will be subject to applicable fraud and abuse, privacy and security, transparency and other healthcare laws and regulations, which, if violated, could expose us to criminal sanctions, civil penalties, exclusion from government healthcare programs, contractual damages, reputational harm and diminished profits and future earnings.

Healthcare providers, physicians and others play a primary role in the recommendation and prescription of any products for which we may in the future obtain regulatory approval and commercialize. Our current and future arrangements with third-party payors, consultants, customers, physicians and others may expose us to broadly applicable fraud and abuse and other healthcare federal and state laws and regulations, including in the United States, that may constrain the business or financial arrangements and relationships through which we market, sell and distribute our products for which we obtain regulatory approval. Potentially applicable healthcare laws and regulations include, but are not limited to, the following:

- the U.S. federal Anti-Kickback Statute, which prohibits, among other things, persons or entities from knowingly and willfully soliciting, offering, receiving or paying remuneration, directly or indirectly, overtly or covertly, in cash or in kind, to induce or in return for, purchasing, leasing, ordering, arranging for, or recommending the purchase, lease, or order of, any good, facility, item or service for which payment may be made under U.S. government healthcare programs such as Medicare and Medicaid;

- the federal civil and criminal false claims laws and civil monetary penalties laws, including civil whistleblower or qui tam actions, which prohibit, among other things, any person or entity from knowingly presenting, or causing to be presented, a false or fraudulent claim for payment or approval to the federal government or knowingly making, using or causing to be made or used a false record or statement material to a false or fraudulent claim to the federal government, or knowingly concealing or knowingly and improperly avoiding or decreasing an obligation to pay or transmit money or property to the federal government;

- though we are not currently regulated under the Privacy Rule or the Security Rule of the Health Insurance Portability and Accountability Act of 1996, or HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, and its implementing regulations, which impose various obligations with respect to safeguarding the privacy, security and transmission of individually identifiable health information, it may implicate certain aspects of our business relationships;

- the health care fraud provisions of HIPAA, which impose criminal liability for, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, including private third-party payors, or to obtain, by means of false or fraudulent pretenses, representations or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, and knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of, or payment for, healthcare benefits, items or services;

- the federal Physician Payments Sunshine Act under PPACA and its implementing regulations, which requires certain manufacturers of drugs, devices, biologics and medical supplies to annually report to the Centers for Medicare & Medicaid Services information related to payments and other transfers of value made by such manufacturers to physicians and teaching hospitals, and ownership and investment interests held by physicians or their immediate family members; and

- analogous laws and regulations, such as state anti-kickback and false claims laws, which may apply to sales or marketing arrangements, research, distribution and claims involving healthcare items or services reimbursed by state governmental and non-governmental third-party payors, including private insurers, state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government, and state requirements for manufacturers to report information related to payments to physicians and other health care providers or marketing expenditures and other restrictions on drug manufacturer marketing practices.

Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available under the U.S. federal Anti-Kickback Statute and analogous state laws, it is possible that some of our current and future business activities could be subject to challenge under one or more of such laws. In addition, recent health care reform legislation has strengthened these laws. For example, PPACA, among other things, amends the intent requirement of the U.S. federal Anti-Kickback Statute and criminal healthcare fraud statutes. A person or entity no longer needs to have actual knowledge of these statutes or specific intent to violate them in order to be in violation. Moreover, PPACA provides that the government may assert that a claim including items or services resulting from a violation of the U.S. 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 with third parties will comply with applicable healthcare 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, agency guidance or case law involving applicable healthcare 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, without limitation, significant civil, criminal and administrative penalties, damages, fines, exclusion from U.S. government funded healthcare programs, such as Medicare and Medicaid, imprisonment, disgorgement, enhanced government reporting and oversight, contractual damages, reputational harm, diminished profits and future earnings and/or the curtailment or restructuring of our operations. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses or divert our management's attention from the operations of our business. 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 similar penalties, including, without limitation, criminal, civil or administrative sanctions, including exclusions from government-funded healthcare programs.

We are subject to U.S. and certain foreign export and import controls, sanctions, embargoes, anti-corruption laws and anti-money laundering laws and regulations. Compliance with these legal standards could impair our ability to compete in domestic and international markets. We can face criminal liability and other serious consequences for violations which can harm our business.

We are subject to export control and import laws and regulations, including the U.S. Export Administration Regulations, U.S. Customs regulations, various economic and trade sanctions regulations administered by the U.S. Treasury Department's Office of Foreign Assets Controls, the U.S. Foreign Corrupt Practices Act of 1977, as amended, the U.S. domestic bribery statute contained in 18 U.S.C. § 201, the U.S. Travel Act, the USA PATRIOT Act and other state and national anti-bribery and anti-money laundering laws in the countries in which we conduct activities.

Anti-corruption laws are interpreted broadly and prohibit companies and their employees, agents, contractors and other partners from authorizing, promising, offering, or providing, directly or indirectly, improper payments or anything else of value to recipients in the public or private sector. We may engage third parties for clinical trials outside of the United States, to sell our products abroad once we enter a commercialization phase and/or to obtain necessary permits, licenses, patent registrations and other regulatory approvals. We have direct or indirect interactions with officials and employees of government agencies or government-affiliated hospitals, universities and other organizations. We can be held liable for the corrupt or other illegal activities of our employees, agents, contractors and other partners, even if we do not explicitly authorize or have actual knowledge of such activities. Any violations of the laws and regulations described above may result in substantial civil and criminal fines and penalties, imprisonment, the loss of export or import privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm and other consequences.

Risks Related to Our Ordinary Shares

The price of our ordinary shares may be volatile and may fluctuate due to factors beyond our control.

The market price of our ordinary shares may be volatile and subject to wide fluctuations in response to a variety of factors, many of which are beyond our control, including:

- positive or negative results of testing and clinical trials by us, strategic partners or competitors;
- delays in in-licensing or acquiring additional complementary product candidates;
- any delay in the commencement, enrollment and the ultimate completion of clinical trials;
- technological innovations or commercial product introductions by us or competitors;
- failure to successfully develop and commercialize any of our product candidates, if approved;
- changes in government regulations;
- developments concerning proprietary rights, including patents and litigation matters;
- public concern relating to the commercial value or safety of any of our product candidates;
- financing or other corporate transactions, or inability to obtain additional funding;
- failure to meet or exceed expectations of the investment community;
- announcements of significant licenses, acquisitions, strategic partnerships or joint ventures by us or our competitors;
- publication of research reports or comments by securities or industry analysts; or
- general market conditions in the pharmaceutical industry or in the economy as a whole.

The share price of publicly traded emerging biopharmaceutical and drug discovery and development companies has been highly volatile and is likely to remain highly volatile in the future. In addition, the stock market in general has experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of individual companies. Broad market and industry factors may hurt the market price of companies' stock, including ours, regardless of actual operating performance.

PRINCIPAL RISKS AND UNCERTAINTIES (CONTINUED)

An active market in our ordinary shares may not develop or be liquid enough for investors to resell our ordinary shares.

Prior to our initial public offering in October 2015, there was no U.S. public market for our ordinary shares. The listing of our common stock on the NASDAQ Global Select Market does not assure that a meaningful, consistent and liquid trading market exists. Although our ordinary shares are listed on the NASDAQ Global Select Market, trading volume in our ordinary shares has been limited and an active trading market for our shares may never develop or be sustained. If an active market for our ordinary shares does not develop, it may be difficult for investors to sell their shares without depressing the market price for the shares or at all.

Future sales, or the possibility of future sales, of a substantial number of our ordinary shares could adversely affect the price of our ordinary shares.

Future sales of a substantial number of our ordinary shares, or the perception that such sales will occur, could cause a decline in the market price of our ordinary shares. We currently have 21,205,382 ordinary shares outstanding. A significant portion of these ordinary shares are subject to lock-up agreements executed in connection with our initial public offering of ordinary shares in October 2015. These lock-up agreements expire in April 2016. If, after the end of such lock-up agreements, these shareholders sell substantial amounts of ordinary shares in the public market, or the market perceives that such sales may occur, the market price of our ordinary shares and our ability to raise capital through an issuance of equity securities in the future could be adversely affected. We also intend to register all ordinary shares that we may issue under our equity compensation plans. Once we register these ordinary shares, they can be freely sold in the public market upon issuance, subject to volume limitations applicable to affiliates and the lock-up agreements. If a large number of our ordinary shares or securities convertible into our ordinary shares are sold in the public market after they become eligible for sale, the sales could reduce the trading price of our ordinary shares and impede our ability to raise future capital.

We expect to be classified a passive foreign investment company for U.S. federal income tax purposes, which could result in adverse U.S. federal income tax consequences to U.S. Holders of our ordinary shares.

A non-U.S. corporation generally will be classified as a passive foreign investment company, or PFIC, for U.S. federal income tax purposes for any taxable year if either (1) 75% or more of its gross income for such year consists of certain types of "passive" income or (2) 50% or more of the value of its assets (determined on the basis of a quarterly average) during such year produce or are held for the production of passive income. For this purpose, "passive income" generally includes, among other items of income, dividends, interest, royalties, rents and gains from commodities and securities transactions and from the sale or exchange of property that gives rise to passive income, and a non-U.S. corporation is treated as owning a proportionate share of the assets and earning a proportionate share of the income of any other corporation in which such non-U.S. corporation owns, directly or indirectly, more than 25% of the value of such other corporation's stock. Based on our projected income, assets and activities, we expect that we will be treated as a PFIC for the current taxable year and for the foreseeable future. Accordingly, a U.S. Holder, would be subject to substantially increased U.S. federal income tax liability, including upon the receipt of any "excess distributions" from us and upon the sale or other disposition of our ordinary shares. Although certain elections may be available to mitigate the adverse impact of the PFIC rules, such elections may result in a current U.S. federal tax liability prior to any distribution on or disposition of our ordinary shares. Further, there can be no assurances that we will supply U.S. Holders with information that such U.S. Holders are required to report under the rules governing such elections. Accordingly, the acquisition of our ordinary shares may not be an appropriate investment for certain holders that are not tax-exempt organizations. U.S. Holders should consult their tax advisers regarding the application of the PFIC rules to an investment in our ordinary shares.

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

The trading market for our ordinary shares will depend in part on the research and reports that securities or industry analysts publish about us or our business. If no or too few securities or industry analysts commence or continue coverage of our company, the trading price for our ordinary shares would likely be negatively affected. In the event securities or industry analysts initiate coverage, if one or more of the analysts who cover us downgrade our ordinary shares or publish inaccurate or unfavorable research about our business, the price of our ordinary shares would likely decline. If one or more of these analysts cease coverage of our company or fail to publish reports on us regularly, demand for our ordinary shares could decrease, which might cause the price of our ordinary shares and trading volume to decline.

We have never paid cash dividends, do not expect to pay dividends in the foreseeable future and our ability to pay dividends, or repurchase or redeem our ordinary shares, is limited by law.

We have not paid any dividends since our inception and do not anticipate paying any dividends on our ordinary shares in the foreseeable future. Even if future operations lead to significant levels of distributable profits, we currently intend that any earnings will be reinvested in our business and that dividends will not be paid until we have an established revenue stream to support continuing dividends. The proposal to pay future dividends to shareholders will in addition effectively be at the sole discretion of our board of directors after taking into account various factors our board of directors deems relevant, including our business prospects, capital requirements, financial performance and new product development. In addition, payment of future dividends is subject to certain limitations under the Irish Companies Act 2014, or the Irish Companies Act. The Irish Companies Act, among other requirements, require Irish companies to have distributable reserves available for distribution equal to or greater than the amount of the proposed dividend. Accordingly, investors cannot rely on dividend income from our ordinary shares and any returns on an investment in our ordinary shares will likely depend entirely upon any future appreciation in the price of our ordinary shares.

We are a foreign private issuer and, as a result, we are not subject to U.S. proxy rules and are subject to Exchange Act reporting obligations that, to some extent, are more lenient and less frequent than those of a U.S. domestic public company.

We 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. Because we qualify as a foreign private issuer under the Exchange Act and although we are subject to Irish laws and regulations with regard to such matters and intend to furnish quarterly financial information to the Securities and Exchange Commission, we are exempt from certain provisions of the Exchange Act that are applicable to U.S. domestic public companies, including: (1) the sections of the Exchange Act regulating the solicitation of proxies, consents or authorizations with respect to a security registered under the Exchange Act; (2) 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 (3) the rules under the Exchange Act requiring the filing with the 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. In addition, foreign private issuers are not required to file their annual report on Form 20-F until four months after the end of each financial year, while U.S. domestic issuers that are accelerated filers are required to file their annual report on Form 10-K within 75 days after the end of each fiscal year. Foreign private issuers are also exempt from the Regulation Fair Disclosure, aimed at preventing issuers from making selective disclosures of material information. As a result of the above, you may not have the same protections afforded to shareholders of companies that are not foreign private issuers.

As a foreign private issuer and as permitted by the listing requirements of NASDAQ, we rely on certain home country governance practices rather than the corporate governance requirements of NASDAQ.

We are a foreign private issuer. As a result, in accordance with NASDAQ Listing Rule 5615(a)(3), we comply with home country governance requirements and certain exemptions thereunder rather than complying with certain of the corporate governance requirements of NASDAQ.

Irish law does not require that a majority of our board of directors consist of independent directors. Our board of directors therefore may include fewer independent directors than would be required if we were subject to NASDAQ Listing Rule 5605(b)(1). In addition, we are not subject to NASDAQ Listing Rule 5605(b)(2), which requires that independent directors must regularly have scheduled meetings at which only independent directors are present.

Our articles of association (hereinafter referred to as our Articles) provide that at any meeting of shareholders, a shareholder may designate another person to attend, speak and vote at the meeting on their behalf by proxy, but no such proxy shall be voted or acted upon at any subsequent meeting, unless the proxy expressly provides for this. Irish law does not require shareholder approval for the issuance of securities in connection with the establishment of or amendments to equity-based compensation plans for employees. To this extent, our practice varies from the requirements of NASDAQ Listing Rule 5635, which generally requires an issuer to obtain shareholder approval for the issuance of securities in connection with such events.

As a result of the above, you may not have the same protections afforded to shareholders of companies that are not foreign private issuers.

We may lose our foreign private issuer status, which would then require us to comply with the Exchange Act's domestic reporting regime and cause us to incur significant legal, accounting and other expenses.

We are a foreign private issuer and therefore we are not required to comply with all of the periodic disclosure and current reporting requirements of the Exchange Act applicable to U.S. domestic issuers. Losing our status as a foreign private issuer would require us to comply with all of the periodic disclosure and current reporting requirements of the Exchange Act applicable to U.S. domestic issuers. In order to maintain our current status as a foreign private issuer, either (1) a majority of our ordinary shares must be either directly or indirectly owned of record by non-residents of the United States or (2)(A) a majority of our executive officers or directors may not be United States citizens or residents, (B) more than 50% of our assets cannot be located in the United States and (C) our business must be administered principally outside the United States. If we lost this status, we would be required to comply with the Exchange Act reporting and other requirements applicable to U.S. domestic issuers, which are more detailed and extensive than the requirements for foreign private issuers. We may also be required to make changes in our corporate governance practices in accordance with various SEC and stock exchange rules. The regulatory and compliance costs to us under U.S. securities laws if we are required to comply with the reporting requirements applicable to a U.S. domestic issuer may be significantly higher than the cost we would incur as a foreign private issuer. As a result, we expect that a loss of foreign private issuer status would increase our legal and financial compliance costs and would make some activities highly time consuming and costly. We also expect that if we were required to comply with the rules and regulations applicable to U.S. domestic issuers, it would make it more difficult and expensive for us to obtain director and officer liability insurance, and we may be required to accept reduced coverage or incur substantially higher costs to obtain coverage. These rules and regulations could also make it more difficult for us to attract and retain qualified members of our board of directors.

Our shareholder's rights are governed by Irish law and differ from the rights of shareholders under U.S. law.

We are a public limited company incorporated under the laws of Ireland. Therefore, the rights of holders of ordinary shares are governed by Irish law and by our memorandum and articles of association. These rights differ from the typical rights of shareholders in U.S. corporations. In certain cases, facts that, under U.S. law, would entitle a shareholder in a U.S. corporation to claim damages may not give rise to a cause of action under Irish law entitling a shareholder in an Irish company to claim damages. For example, the rights of shareholders to bring proceedings against us or against our directors or officers in relation to public statements are more limited under Irish law than under the civil liability provisions of the U.S. securities laws.

Our shareholders may have difficulties enforcing, in actions brought in courts in jurisdictions located outside the United States, judgments obtained in the U.S. courts under the U.S. securities laws. In particular, if a shareholder sought to bring proceedings in Ireland based on U.S. securities laws, the Irish court might consider that:

- it did not have jurisdiction;
- it was not the appropriate forum for such proceedings;
- applying Irish conflict of laws rules, U.S. laws (including U.S. securities laws) did not apply to the relationship between you and us or our directors and officers; or
- the U.S. securities laws were of a penal nature or violated Irish public policy and should not be enforced by the Irish court.

Our shareholders should also be aware that Irish law does not allow for any form of legal proceedings directly equivalent to the class action available in the United States.

To the extent our financial statements will be audited by a registered public accounting firm in Ireland, because the PCAOB is not currently permitted to inspect registered public accounting firms in the Republic of Ireland, including our independent registered public accounting firm, you may not benefit from such inspections.

Auditors of U.S. public companies, including our independent registered public accounting firm, are required by the laws of the United States to undergo periodic PCAOB inspections to assess their compliance with U.S. law and professional standards in connection with performance of audits of financial statements filed with the SEC. The laws of certain European Union countries, including the Republic of Ireland, do not currently permit the PCAOB to conduct inspections of accounting firms established and operating in such European Union countries. Accordingly, to the extent our financial statements will be audited by a registered public accounting firm in Ireland, the PCAOB would be prevented from fully evaluating the effectiveness of our independent registered public accounting firm's audit procedures or quality control procedures. Unlike shareholders or potential shareholders of most U.S. public companies, our shareholders would be deprived of the possible benefits of such PCAOB inspections.

A future transfer of our ordinary shares, other than one effected by means of the transfer of book-entry interests in DTC, may be subject to Irish stamp duty.

The rate of stamp duty, when applicable, on the transfer of shares in an Irish-incorporated company is 1% of the price paid, or the market value of the shares acquired, whichever is greater. Payment of Irish stamp duty is generally a legal obligation of the transferee. We expect that most of our ordinary shares will be traded through the Depositary Trust Company, or DTC, or through brokers who hold such shares on behalf of customers through DTC. As such, the transfer of ordinary shares should be exempt from Irish stamp duty based on established practice of the Irish Revenue Commissioners.

We received written confirmation from the Irish Revenue Commissioners on June 22, 2015 that a transfer of our ordinary shares held through DTC and transferred by means of a book-entry interest would be exempt from Irish stamp duty. However, if you hold your ordinary shares directly of record, rather than beneficially through DTC, or through a broker that holds your ordinary shares through DTC, any transfer of your ordinary shares may be subject to Irish stamp duty. The potential for stamp duty to arise could adversely affect the price and liquidity of our ordinary shares. In addition, the terms of our eligibility agreement with DTC will require us to provide certain indemnities relating to Irish stamp duty to third parties. If liability were to arise as a result of the indemnities provided under the terms of the eligibility agreement, we may face significant unexpected costs.

The process to acquire full ownership of Cortendo AB is lengthy and may cause us to incur unanticipated costs. Any delay in our acquiring full ownership of Cortendo AB could result in increased administrative costs and burdens and could adversely affect our day-to-day operations.

As the holder of more than 90% of Cortendo AB's shares following the settlement of the Exchange Offer, we will pursue a squeeze-out process permitted under Swedish law, which will allow us to acquire the remaining shares of Cortendo AB that were not exchanged as part of the Exchange Offer. This process and any delays may cause us to incur unexpected costs or result in unanticipated structuring or tax costs. Further, the act of redomiciling may impair our ability to utilize our NOLs. This process will be conducted by arbitration proceedings. The final arbitration award in which the squeeze-out price is determined will likely not be rendered until 12 to 18 months or more from initiation of the proceedings. We will have the possibility to request advance title to the remaining Cortendo AB shares before such time, which normally can be obtained within six to nine months from initiation of the proceedings, provided that we provide sufficient security for the final squeeze-out price and interest thereon. In such case, we would receive title to such shares and would also be required to pay a preliminary per-share squeeze-out price for the remaining Cortendo AB shares that corresponds to the value of the per-share Exchange Offer consideration, together with interest thereon. Until advance title is granted, Cortendo AB shareholders who did not participate in the Exchange Offer will hold a minority interest in Cortendo AB. After advance title has been granted, the former Cortendo AB shareholders will merely have a claim for the final squeeze-out price, reduced by the preliminary amount we paid in connection with the advance title.

The existence of minority shareholders in Cortendo AB may, among other things, make it more difficult or delay our ability to implement changes to our legal structure and interfere with our day-to-day business operations and corporate governance. For example, intra-group transfers of entities and transactions between us and our subsidiaries and affiliates, or among our subsidiaries and affiliates, will need to be carried out on market terms and on an arm's-length basis, which may impair the efficiency of our day-to-day operations. As a matter of Swedish law, minority Cortendo AB shareholders will also have the ability to request special investigations, convene general meetings of shareholders and propose agenda items for our annual general meetings. Each of these circumstances, along with other measures we may need to take to recognize the continuing legal rights of the remaining minority Cortendo AB shareholders, may result in increased costs and administrative burden.

In addition, holders of Cortendo AB shares who have chosen not to exchange their shares pursuant to the Exchange Offer will have a pro rata claim upon any dividends or other distributions payable by Cortendo AB and will be entitled to receive a proportionate share of any dividend payments or other distributions made by Cortendo AB, consequently reducing the amount of any dividend payments or other distributions that we might make to holders of our shares.

We expect to expend cash in connection with the squeeze-out proceedings.

The actual price per share purchased pursuant to the Swedish squeeze-out proceedings will be determined by the arbitration tribunal. As a result of the squeeze-out proceedings, we may ultimately have to pay, in the aggregate, a higher price per share in order to purchase the remaining 78,621 Cortendo AB shares that are outstanding following the completion of the Exchange Offer. Such price will also under Swedish law have to be paid in cash, which will have an impact on our liquidity and cash reserves, and therefore may have an adverse effect on our financial and operational flexibility.

Anti-takeover provisions in our Articles and under Irish law could make an acquisition of us more difficult, limit attempts by our shareholders to replace or remove our current directors and management team, and limit the market price of our ordinary shares.

Our Articles contain provisions that may delay or prevent a change of control, discourage bids at a premium over the market price of our ordinary shares and adversely affect the market price of our ordinary shares and the voting and other rights of the holders of our ordinary shares. These provisions include:

- dividing our board of directors into three classes, with each class serving a staggered three-year term;
- permitting our board of directors to issue preference shares without shareholder approval, with such rights, preferences and privileges as they may designate;
- provisions which allow our board of directors to adopt a shareholder rights plan upon such terms and conditions as it deems expedient and in our best interests;
- establishing an advance notice procedure for shareholder proposals to be brought before an annual meeting, including proposed nominations of persons for election to our board of directors; and
- the ability of our board of directors to fill vacancies on our board in certain circumstances.

These provisions do not make us immune from takeovers. However, these provisions will apply even if the offer may be considered beneficial by some shareholders. In addition, these provisions may frustrate or prevent any attempts by our shareholders to replace or remove our current management team by making it more difficult for shareholders to replace members of our board of directors, which is responsible for appointing the members of our management.

Irish law differs from the laws in effect in the United States with respect to defending unwanted takeover proposals and may give our board of directors less ability to control negotiations with hostile offerors.

We are subject to the Irish Takeover Rules. Under the Irish Takeover Rules, our board of directors is not permitted to take any action that might frustrate an offer for our ordinary shares once our board of directors has received an approach that may lead to an offer or has reason to believe that such an offer is or may be imminent, subject to certain exceptions. Potentially frustrating actions such as (1) the issue of shares, options, restricted share units or convertible securities, (2) material acquisitions or disposals, (3) entering into contracts other than in the ordinary course of business or (4) any action, other than seeking alternative offers, which may result in frustration of an offer, are prohibited during the course of an offer or at any earlier time during which our board of directors has reason to believe an offer is or may be imminent. These provisions may give our board of directors less ability to control negotiations with hostile offerors than would be the case for a corporation incorporated in the United States.

PRINCIPAL RISKS AND UNCERTAINTIES (CONTINUED)

We are an "emerging growth company," and we cannot be certain if the reduced reporting requirements applicable to "emerging growth companies" will make our ordinary shares less attractive to investors.

We are an "emerging growth company," as defined in 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 not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act exemptions from the requirements to provide certain executive compensation disclosures, exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and shareholder approval of any golden parachute payments not previously approved. As an "emerging growth company," in our initial registration statement, we were required to report only two years of financial results and selected financial data compared to three and five years, respectively, for comparable data reported by other public companies. We could be an "emerging growth company" for up to five years, although circumstances could cause us to lose that status earlier, including if the market value of our ordinary shares held by non-affiliates exceeds $700 million as of any June 30 before that time, in which case we would no longer be an "emerging growth company" as of the following December 31, our fiscal year end. We cannot predict if investors will find our ordinary shares less attractive because we may rely on these exemptions. If some investors find our ordinary shares less attractive as a result, there may be a less active trading market for our ordinary shares and the price of our ordinary shares may be more volatile.

RESULTS AND DIVIDENDS

The result for the year and the Company's financial position at the end of the year are disclosed on pages 53 - 54. The following table sets forth our results of operations for the years ended December 31, 2014 and 2015.

	Year Ended December 31, 2015 $'000	Year Ended December 31, 2014 $'000	Change $'000
Operating expenses:			
Research and development	20,135	5,844	14,291
General and administrative	22,719	4,588	18,131
Total operating expenses	42,854	10,432	32,422
Operating loss	(42,854)	(10,432)	(32,422)
Other (expense) income, net	(1,229)	282	(1,511)
Loss before taxes	(44,083)	(10,150)	(33,933)
Tax benefit	450	480	(30)
Net loss	(43,633)	(9,670)	(33,963)
Net loss attributable to minority interest	53	—	53
Net loss attributable to ordinary shareholders	(43,580)	(9,670)	(33,910)

Revenues

We have not generated any revenue during the periods presented. Our ability to generate product revenue and become profitable depends upon our ability to obtain regulatory approval for and to successfully commercialize our product candidates.

RESULTS AND DIVIDENDS (CONTINUED)

Research and Development Expenses

The following table summarizes our research and development expenses during the years ended December 31, 2014 and 2015:

	Year Ended December 31, 2015	Year Ended December 31, 2014	Change
	$ '000	$ '000	$ '000
Clinical development and supporting activities	12,697	4,518	8,179
Antisense Therapeutics license fee	3,899	—	3,899
Compensation and related personnel costs	1,744	164	1,580
Travel, entertainment and other costs	162	—	162
Preclinical development	840	894	(54)
Stock-based compensation expense	793	268	525
Total research and development expenses	20,135	5,844	14,291

Research and development expenses were $20.1 million for the year ended December 31, 2015, an increase of $14.3 million compared to the year ended December 31, 2014. The $8.2 million increase in clinical development was primarily attributed to a $4.8 million increase due to the ongoing clinical trials for COR-003, and a $3.4 million increase due to the initiation of the development activity for COR-004 and COR-005. Research and development expenses for the year ended December 31, 2015 included $3.9 million of the $5.0 million in aggregate cash paid to Antisense Therapeutics upon entering into a license agreement in May 2015, with the remaining $1.1 million of cash paid recorded as the initial carrying value of our investment in the equity of Antisense Therapeutics. Compensation and related costs increased by $1.7 million, and non-cash stock-based compensation increased $0.5 million, for the year ended December 31, 2015 as compared to the same period in 2014 due to increased headcount of research and development personnel during the 2015 period.

General and Administrative Expenses

The following table summarizes our general and administrative expenses during the years ended December 31, 2014 and 2015:

	Year Ended December 31, 2015	Year Ended December 31, 2014	Change
	$'000	$'000	$'000
Outside professional services	8,054	3,335	4,719
Re-domiciliation and IPO preparation costs	4,007	—	4,007
Corporate development and licensing transaction costs	3,390	—	3,390
Compensation and related personnel costs	3,305	710	2,595
Travel, entertainment and other costs	478	455	23
Stock-based compensation expense	3,147	(17)	3,164
Facility costs	338	105	233
Total general and administrative expenses	22,719	4,588	18,131

RESULTS AND DIVIDENDS (CONTINUED)

General and Administrative Expenses (continued)

General and administrative expenses were $22.7 million for the year ended December 31, 2015, an increase of $18.1 million compared to the year ended December 31, 2014. The $4.7 million increase in outside professional and consulting services was primarily due to increased legal fees in support of general corporate matters, employee recruiting fees, audit fees, market analysis costs, and consulting fees for business development efforts. General and administrative expenses for the year ended December 31, 2015 also included $4.0 million of legal and accounting fees related to the re-domiciliation of the Company from Sweden to Ireland completed in September 2015 and the indirect activities necessary to prepare the Company's financial records for the U.S. initial public offering completed in October 2015. General and administrative expenses for the year ended December 31, 2015 also included $3.4 million of transaction fees and expenses related to the acquisition of COR-005 from Aspireo Pharmaceuticals, the license of COR-004 from Antisense Therapeutics, and other business development activities. Compensation and related personnel costs increased by $2.6 million, and non-cash stock-based compensation by $3.2 million, during the year ended December 31, 2015 due to increased headcount of administrative personnel during the 2015 period. Facility costs increased by $0.2 million primarily as a result of entering into a lease for our Trevose, Pennsylvania office space in April 2015.

Other Income (Expense), Net

The following table summarizes our other income (expense), net, during the years ended December 31, 2014 and 2015:

	Year Ended December 31, 2015	Year Ended December 31, 2014	Change
	$'000	$'000	$'000
Foreign exchange loss	(124)	(204)	80
Other income	28	208	(180)
Other expense	(1,133)	278	(1,411)
Total other income (expense), net	(1,229)	282	(1,511)

Other income (expense), net, changed from income of $0.3 million in 2014 to expense of $1.2 million in 2015. The change was primarily due to the charges related to the wind down of our previous foreign currency hedging program, and the write down of our investment in Antisense equity to market value.

Income Tax Benefit

We recorded income tax benefit of $0.5 million for the years ended December 31, 2014 and 2015, due to the generation of U.S. state and federal net operating loss carry forwards and federal tax credit carry forwards. The income tax benefit for U.S. state and federal net operating loss carry forwards and the federal tax credit carry forwards has been recognized to the extent it is supported by the deferred tax liabilities recorded in connection with the acquisition of BioPancreate.

Net Loss Attributable to Minority Interest

We recorded a net loss attributable to minority interest of $53,000 for the year ended December 31, 2015. The minority interest results from the 0.418% of Cortendo AB shares not acquired by Strongbridge Biopharma plc pursuant to the exchange offer that expired September 3, 2015.

RESULTS AND DIVIDENDS (CONTINUED)

Liquidity and Capital Resources

We do not expect to generate significant revenue from product sales unless and until we obtain regulatory approval of and commercialize our current or any future product candidates. We anticipate that we will continue to generate losses for the foreseeable future, and we expect the losses to increase as we continue the development of and seek regulatory approvals for our product candidates and begin to commercialize any approved products. We are subject to all of the risks applicable to the development of new products, and we may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may harm our business. We also expect to incur additional costs associated with operating as a public company and we anticipate that we will need substantial additional funding in connection with our continuing operations.

Our operations have been financed primarily by net proceeds from the issuance of ordinary shares. Our primary uses of capital are, and we expect will continue to be, third-party expenses associated with the planning and conduct of clinical trials, costs of process development services and manufacturing of our product candidates, and compensation-related expenses. We also expect our cash needs to increase to fund potential in-licenses, acquisitions or similar transactions as we pursue our strategy.

Cash used to fund operating expenses is affected by the timing of when we pay expenses, as reflected in the change in our outstanding accounts payable and accrued expenses. We believe that our existing cash and cash equivalents will be sufficient to fund planned operations into the fourth quarter of 2017, which is after the expected receipt of data from the COR-003 SONICS trial.

Our future funding requirements will depend on many factors, including the following:

- the scope, rate of progress, results and cost of our preclinical studies and clinical trials and other related activities;
- the cost of formulation, development, manufacturing of clinical supplies and establishing commercial supplies of our product candidates and any other product candidates that we may develop, in-license or acquire;
- the cost, timing and outcomes of pursuing regulatory approvals;
- the cost and timing of establishing administrative, sales, marketing and distribution capabilities;
- the terms and timing of any collaborative, licensing and other arrangements that we may establish, including any required milestone and royalty payments thereunder; and
- the emergence of competing technologies and their achieving commercial success before we do or other adverse market developments.

We expect to continue to incur losses. Our ability to achieve and maintain profitability is dependent upon the successful development, regulatory approval and commercialization of our product candidates and achieving a level of revenues adequate to support our cost structure. We may never achieve profitability, and unless and until we do, we will continue to need to raise additional capital. If we need to raise additional capital to fund our operations and complete our ongoing and planned clinical trials, funding may not be available to us on acceptable terms, or at all.

Liquidity and Capital Resources (continued)

We plan to continue to fund our operations and capital funding needs through equity or debt financing. The sale of additional equity would result in additional dilution to our shareholders. The incurrence of debt financing would result in debt service obligations and the instruments governing such debt could provide for operating and financing covenants that would restrict our operations. If we are not able to secure adequate additional funding, we may be forced to make reductions in spending, extend payment terms with suppliers, liquidate assets where possible or suspend or curtail planned programs. In addition, lack of funding would limit any strategic initiatives to in-license or acquire additional product candidates or programs.

Cash Flows

Comparison for the Years Ended December 31, 2015 and 2014

	Year Ended December 31, 2015	Year Ended December 31, 2014
	$'000	$'000
Net cash (used in) provided by:		
Operating activities	(37,360)	(9,504)
Investing activities	(4,294)	(24)
Financing activities	77,404	10,193
	35,750	665
Effect of exchange rate changes on cash and cash equivalents	241	70
Net increase in cash and cash equivalents	35,991	735

Operating Activities

Net cash used in operating activities was $37.4 million for the year ended December 31, 2015, compared to $9.5 million for the year ended December 31, 2014. The increase in net cash used was primarily due to increased operating expenses due to additional headcount, increased clinical trial activities and other research activities, re-domiciliation of the Company from Sweden to Ireland, and transaction fees and expenses related to the acquisition of COR-005 from Aspireo Pharmaceuticals, the license of COR-004 from Antisense Therapeutics, and other business development activities.

Investing Activities

Net cash used in investing activities for 2015 was $3.2 million due to the Aspireo asset purchase, the result of the purchase of office equipment and furniture and the investment in Antisense.

Financing Activities

Net cash provided by financing activities was $77.4 million for the year ended December 31, 2015, compared to $10.2 million for the year ended December 31, 2014, which in both years was the result of private placement equity financings and an IPO in October of 2015.

DIRECTORS AND COMPANY SECRETARIES

The directors and the company secretaries who served during the year are listed on page 2.

No director, secretary or any member of their immediate families had any interest in shares or debentures of any subsidiary. Directors' remuneration is set forth in Note 20 of the Consolidated Financial Statements. The interest of the directors in ordinary share capital of the Company at December 31, 2015 and December 31, 2014 (or date of appointment if later) are as follows:

	As at December 31, 2015		As at December 31, 2014 or Date of Appointment if later	
	Ordinary shares	Stock Options	Ordinary shares	Stock Options
Name	No of shares	No of shares	No of shares	No of shares
John H. Johnson	—	67,767	—	—
Richard S. Kollender	—	37,188	—	—
Garheng Kong, M.D., Ph.D.	—	34,385	—	—
Mårten Steen, M.D., Ph.D.	—	34,918	—	—
Hilde H. Steineger, Ph.D.	—	34,918	—	—
Matthew Pauls	4,215	681,817	4,215	681,817

The Company Secretary held ordinary shares of 1,718 as at December 31, 2015 and at date of appointment. Stock options held by the Company Secretary amounted to 187,908 as at December 31, 2015 and at date of appointment.

RELATED PARTY DISCLOSURES

TMF Administration Services Limited ('TMF') provides accounting and corporate administration services to the Company at arm's length commercial rates. Kevin Butler and Atif Kamal, directors of the Company during the year, were also directors of TMF during the year and in that capacity had a material interest in transactions conducted with the Company.

The following is a description of transactions since January 1, 2013 to which we have been a party, in which the amount involved exceeded or will exceed $120,000, and in which any of our executive officers, directors, or holders of more than 5% of any class of our voting securities, or an affiliate or immediate family member thereof, had or will have a direct or indirect material interest, other than compensation, termination and change in control arrangements, which are described under "Executive Compensation." We believe the terms obtained or consideration that we paid or received, as applicable, in connection with the transactions described below were comparable to terms available or the amounts that would be paid or received, as applicable, in arm's-length transactions with unrelated third parties.

RELATED PARTY DISCLOSURES (CONTINUED)

Certain of our existing shareholders that beneficially own more than 5% of our ordinary shares and/or their affiliates purchased our ordinary shares in our initial U.S. public offering of 2,500,000 ordinary shares in October 2015. These 5% shareholders included New Enterprise Associates, RA Capital Management, LLC, Kristianro A/S (wholly owned by Eigil Stray Spetalen), Broadfin Capital, LLC and HealthCap VI, LP, of which Mr. Steen, one of our directors, is a Partner.

On May 14, 2015, we entered into a Share Purchase Agreement to sell $33.2 million of our shares in a private placement (2,284,414 shares at a subscription price of $14.54 per share). Certain of our 5% shareholders participated in this transaction, including New Enterprise Associates, RA Capital Management, LLC and HealthCap VI, LP, of which Mr. Steen, one of our directors, is a Partner. This transaction closed on June 29, 2015 and June 30, 2015 following shareholder approval and other specified conditions.

There were no other contracts of any significance in relation to the business of the Company in which the directors had any interest, as defined in the Companies Act 2014, at any time during the year.

POWERS OF DIRECTORS

The Board is responsible for managing the business affairs of the Company in accordance with the Constitution of the Company, which allow them to enter into contracts and perform all tasks necessary to conduct the business of the Company. The Board may delegate certain functions to other parties, subject to supervision and direction by the directors. The Board consists of six directors.

SHAREHOLDER MEETINGS

The shareholders' rights and operations of shareholders meetings are defined in the Constitution and comply with the Companies Act 2014. The Company will hold a general meeting each year as its annual general meeting in addition to any other meeting in that year. The annual general meeting date and agenda is specified in the notice sent out for the meeting.

FINANCIAL RISK MANAGEMENT

The operations of the Company are subject to various risks. Information about the capital and financial risk management objectives and policies of the Company, along with exposure of the Company to the relevant financial risks, are disclosed on pages 35 to 42 of this report and in note 14 to the consolidated financial statements.

POLITICAL DONATIONS

No political contributions that require disclosure under Irish law were made during the year.

DIVIDENDS

No dividends were paid in either 2014 or 2015, nor are expected to be paid in the foreseeable future.

FUTURE DEVELOPMENTS

The Company will continue to focus on developing treatments for rare diseases. We intend to independently commercialize our rare disease product candidates, if approved, in the United States and the European Union, and selectively in other key global markets. We intend to expand our portfolio through a disciplined in-licensing and acquisition strategy. We plan to source new product candidates by in-licensing or acquiring them. We intend to build our company by creating franchises in areas where there is a significant commercial opportunity. We seek to in-license and acquire products and product candidates that target rare diseases in therapeutically aligned franchises. We believe that complementary products and product candidates will allow us to significantly leverage our expertise as well as our development and commercial infrastructure. For example, our product candidates for the treatment of endogenous Cushing's syndrome and acromegaly, if approved, will serve as the basis for our rare endocrine franchise. In addition to identifying products and product candidates that can form the basis of new rare disease franchises, we also intend to leverage opportunities to develop potential products and product candidates for additional indications within their respective therapeutic franchises.

GOING CONCERN

The directors have a reasonable expectation that the Company has adequate resources to continue in operational existence for the foreseeable future. Accordingly, they have chosen to adopt the going concern basis in preparing the financial statements.

SIGNIFICANT SUBSEQUENT EVENTS

There were no significant subsequent events after the year-end until the date of approval of these financial statements that would require adjustment to or disclosure in the financial statements. Key subsequent events arising are disclosed in note 11 of the consolidated financial statements.

ACCOUNTING RECORDS

The directors are responsible for ensuring that adequate accounting records, as outlined in Section 281 to 285 of the Companies Act 2014, are kept by the Company and its subsidiaries. The measures taken by directors to ensure compliance with the Company's obligation to keep adequate accounting records are the use of appropriate systems and procedures and by ensuring that a competent service provider is responsible for the preparation and maintenance of the accounting records. The accounting records of the Company are kept at 3rd Floor, Kilmore House, Park Lane, Spencer Dock, Dublin 1, Ireland.

INDEPENDENT AUDITORS

Ernst & Young, Chartered Accountants, who were appointed during the period, have expressed their willingness to continue in office in accordance with Section 383(2) of the Companies Act 2014.

The report was approved on April 12, 2016 by the Board and authorised for issue by:

/s/ Matthew Pauls	/s/ Richard Kollender
Matthew Pauls	Richard Kollender
Director	Director

STATEMENT OF DIRECTORS' RESPONSIBILITIES

Company law in the Republic of Ireland requires the Directors to prepare financial statements for each financial year which give a true and fair view of the state of the assets, liabilities and financial position of the Parent Company and of the Group and of the profit or loss of the Group for that period.

In preparing the financial statements of the Group, the Directors are required to:

- select suitable accounting policies and then apply them consistently;
- make judgments and estimates that are reasonable and prudent;
- comply with applicable US generally accepted accounting principles to the extent that the use of US generally accepted accounting principles does not contravene any provision of the Companies Act 2014, subject to any material departures disclosed and explained in the financial statements; and
- prepare the financial statements on the going concern basis unless it is inappropriate to presume that the Group will continue in business

The considerations set out above for the Group are also required to be addressed by the Directors in preparing the financial statements of the Parent Company (which are set out on pages 83 to 93), in respect of which the applicable accounting standards are those which are generally accepted in the Republic of Ireland.

The directors have elected to prepare the Parent Company's financial statements in accordance with accounting standards issued by the Financial Reporting Council and promulgated by the Institute of Chartered Accountants in Ireland, including FRS 102 The Financial Reporting Standard applicable in the UK and Republic of Ireland (Generally Accepted Accounting Practice in Ireland).

Under company law the directors must not approve the financial statements unless they are satisfied that they give a true and fair view of the assets, liabilities and financial position, of the group and parent company as at the end of the financial year, and the profit or loss for the group for the financial year, and otherwise comply with the Companies Act 2014.

The Directors are responsible for keeping accounting records which disclose with reasonable accuracy the assets, liabilities, financial position and profit and loss of the Parent Company and which enable them to ensure that the financial statements of the Group are prepared in accordance with applicable US generally accepted accounting principles and comply with the provisions of the Companies Acts 2014. They are also responsible for safeguarding the assets of the Group and hence for taking reasonable steps for the prevention and detection of fraud and other irregularities.

The report was approved on April 12,, 2016 by the Board and authorised for issue by:

/s/ Matthew Pauls	/s/ Richard Kollender
Matthew Pauls	Richard Kollender
Director	Director

INDEPENDENT AUDITOR'S REPORT

We have audited the financial statements of Strongbridge Biopharma plc for the period ended 31 December 2015 which comprise the Consolidated Profit and Loss Account, the Consolidated Balance Sheet, the Consolidated Statement of Changes in Equity, the Consolidated Statement of Cash Flows, the Parent Company Balance Sheet, the Parent Company Statement of Changes in Equity, the related notes 1 to 22 in respect of the group financial statements and the related notes 1 to 14 in respect to the parent company financial statements. The financial reporting framework that has been applied in the preparation of the group financial statements is Irish law and U.S. Generally Accepted Accounting Principles (U.S. GAAP), as defined in section 279 of Part 6 of the Companies Act 2014, to the extent that the use of those principles in the preparation of the financial statements does not contravene any provision of that Part of the Companies Act 2014 and for the preparation of the parent company financial statements in accordance with Irish law and accounting standards issued by the Financial Reporting Council and promulgated by the Institute of Chartered Accountants in Ireland, including FRS 102 *The Financial Reporting Standard applicable in the UK and Republic of Ireland* (Generally Accepted Accounting Practice in Ireland).

This report is made solely to the company's members, as a body, in accordance with section 391 of the Companies Act 2014. Our audit work has been undertaken so that we might state to the company's members those matters we are required to state to them in an auditor's report and for no other purpose. To the fullest extent permitted by law, we do not accept or assume responsibility to anyone other than the company and the company's members as a body, for our audit work, for this report, or for the opinions we have formed.

Respective responsibilities of directors and auditors

As explained more fully in the Statement of Directors' Responsibilities set out on page 50, the directors are responsible for the preparation of the financial statements and for being satisfied that they give a true and fair view and otherwise comply with the Companies Act 2014. Our responsibility is to audit the financial statements in accordance with applicable law and International Standards on Auditing (UK and Ireland). These standards require us to comply with the Auditing Practices Board's (APB's) Ethical Standards for Auditors.

Scope of the audit of the financial statements

An audit involves obtaining evidence about the amounts and disclosures in the financial statements sufficient to give reasonable assurance that the financial statements are free from material misstatement, whether caused by fraud or error. This includes an assessment of: whether the accounting policies are appropriate to the group's and parent company's circumstances and have been consistently applied and adequately disclosed; the reasonableness of significant accounting estimates made by the directors; and the overall presentation of the financial statements. In addition, we read all the financial and non-financial information in the directors' report to identify material inconsistencies with the audited financial statements and to identify any information that is apparently materially incorrect or materially inconsistent with the knowledge acquired by us in the course of performing the audit. If we become aware of any apparent material misstatements or inconsistencies we consider the implications for our report.

Opinion on financial statements

In our opinion:

- the group financial statements give a true and fair view in accordance with U.S. Generally Accepted Accounting Principles (U.S. GAAP), as defined in section 279 of Part 6 of the Companies Act 2014, to the extent that the use of those principles in the preparation of the financial statements does not contravene any provision of that Part of the Companies Act 2014, of the assets, liabilities and financial position of the Group as at 31 December 2015 and of the loss for the Group for the year then ended;
- the parent company statement of financial position gives a true and fair view of the assets, liabilities and financial position of the parent company as at 31 December 2015 and has been properly prepared in accordance with FRS 102 The Financial Reporting Standard applicable in the UK and Republic of Ireland; and
- the financial statements have been properly prepared in accordance with the requirements of the Companies Act 2014.

Matters on which we are required to report by the Companies Act 2014

- We have obtained all the information and explanations which we consider necessary for the purposes of our audit.
- In our opinion the accounting records of the company were sufficient to permit the parent company financial statements to be readily and properly audited.
- The parent company balance sheet is in agreement with the accounting records.
- In our opinion the information given in the directors' report is consistent with the financial statements.

Matters on which we are required to report by exception

We have nothing to report in respect of Sections 305 to 312 of the Companies Act 2014 which require us to report to you if, in our opinion, the disclosures of directors' remuneration and transactions specified by law are not made.

Breffni Maguire
For and on behalf of Ernst & Young
Chartered Accountants and Statutory Audit Firm
Dublin

X April 2016

STRONGBRIDGE BIOPHARMA plc

CONSOLIDATED PROFIT AND LOSS ACCOUNT

	Notes	December 31, 2015 $'000	December 31, 2014 $'000
Operating expenses			
Research and development	3	20,135	5,844
General and administrative	4	22,719	4,588
Total operating expenses		42,854	10,432
Operating loss		(42,854)	(10,432)
Other (expense)/income, net:			
Foreign exchange loss		(124)	(204)
Other income	5	28	208
Other expense	5	(1,133)	278
Total other (expense)/income, net		(1,229)	282
Loss before taxes		(44,083)	(10,150)
Tax benefit	16	450	480
Net loss		(43,633)	(9,670)
Net loss attributable to minority interest		(53)	—
Net loss attributable to ordinary shareholders of the Company		(43,580)	(9,670)
Net loss attributable to ordinary shareholders:			
Basic and diluted		(43,580)	(9,670)
Net loss per share attributable to ordinary shareholders:			
Basic and diluted		(2.62)	(1.20)
Weighted-average shares used in computing net loss per share attributable to ordinary shareholders:			
Basic and diluted		16,606,669	8,043,175

The accompanying notes are an integral part of the Consolidated Financial Statements.

CONSOLIDATED BALANCE SHEET

	Notes	As at December 31, 2015 $'000	As at December 31, 2014 $'000
ASSETS			
Fixed assets			
Tangible assets - Property and equipment, net	7	35	21
Intangible assets - In-process research and development	8	36,551	5,228
Intangible Assets - Goodwill	8	7,256	2,200
Investments and other assets	9	612	10
Current assets			
Debtors (falling due within one year) - Prepayments and other current assets		1,253	598
Cash at bank and in hand	6	51,623	15,632
Total assets		97,330	23,689
LIABILITIES AND SHAREHOLDERS' EQUITY			
Shareholders' equity			
Share capital	15	256	97
Share premium		165,719	55,467
Other reserves		5,191	480
Profit and loss account		(80,803)	(37,223)
Attributable to Shareholders in the Company		90,363	18,821
Minority interest	15	564	—
Total Shareholders' equity		90,927	18,821
Provisions for liabilities			
Stock-based liability awards		—	1,183
Deferred tax liabilities	16	926	1,376
Creditors - amounts falling due within one year			
Accounts payable		2,792	887
Accrued liabilities	10	2,685	1,422
Total liabilities		6,403	4,868
Total liabilities and Shareholders' equity		97,330	23,689

The accompanying notes are an integral part of the Consolidated Financial Statements.

The Consolidated Financial Statements were approved and signed on behalf of the Board of Directors on April 12, 2016:

/s/ Matthew Pauls	/s/ Richard Kollender
Matthew Pauls	Richard Kollender
Director	Director

CONSOLIDATED STATEMENT OF CASH FLOWS

	Year ended December 31, 2015 $'000	Year ended December 31, 2014 $'000
Cash flows from Operating Activities		
Net loss	(43,633)	(9,670)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	11	9
Stock-based compensation	3,940	251
Deferred income tax benefit	(450)	(480)
Impairment on investment in Antisense Therapeutics	551	—
Change in fair value of foreign currency forward contracts	438	(279)
Changes in working capital:		
- Accounts payable	1,737	236
- Accrued liabilities	1,263	736
- Other assets	(52)	2
- Prepaid expenses and other current assets	(1,165)	(309)
Net cash used in operating activities	(37,360)	(9,504)
Cash flows from Investing Activities		
Payments for acquisitions (Note 12)	(3,168)	—
Investment in Antisense Therapeutics	(1,101)	—
Purchase of equipment	(25)	(24)
Net cash used in investing activities	(4,294)	(24)
Cash flows from Financing Activities		
Proceeds from Initial Public Offering, net	19,475	—
Proceeds from issuance of ordinary shares	58,341	10,193
U.S. non-accredited shares repurchased	(412)	—
Net cash provided by financing activities	77,404	10,193
Effect of exchange rate changes on cash and cash equivalents	241	70
Net increase in cash and cash equivalents	35,991	735
Cash and cash equivalents—beginning of period	15,632	14,897
Cash and cash equivalents—end of period	51,623	15,632

The accompanying notes are an integral part of the Consolidated Financial Statements.

CONSOLIDATED STATEMENT OF CHANGES IN EQUITY
(In thousands except share amounts)

	Called up share capital Shares	Called up share capital Amount	Share Premium	Other Reserves	Profit and loss account	Minority Interest	Total Equity
		$'000	$'000	$'000	$'000	$'000	$'000
Balance at January 1, 2014	7,939,608	79	45,273	—	(27,553)	24	17,823
Net loss	—	—	—	—	(9,670)	—	(9,670)
Shares exchanged for BioPancreate minority interest	5,272	—	19	—	—	(24)	(5)
Stock-based compensation	—	—	—	480	—	—	480
Issuance of shares	1,755,909	18	10,175	—	—	—	10,193
Balance at December 31, 2014	9,700,789	97	55,467	480	(37,223)	—	18,821

	Called up share capital Shares	Called up share capital Amount	Share Premium	Other Reserves	Profit and loss account	Minority Interest	Total Equity
		$'000	$'000	$'000	$'000	$'000	$'000
Balance at January 1, 2015	9,700,789	97	55,467	480	(37,223)	—	18,821
Net loss	—	—	—	—	(43,580)	(53)	(43,633)
Stock-based compensation	—	—	—	3,581	—	—	3,581
Reclassification of stock-based liability award to equity	—	—	—	1,542	—	—	1,542
Issuance of Shares	9,108,169	91	91,418	—	—	—	91,509
US Non Accredited Shares Repurchased	(24,955)	—	—	(412)	—	—	(412)
Issuance of shares in initial public offering, net	2,500,000	25	19,450	—	—	—	19,475
Minority interest resulting from exchange offer	(78,621)	(1)	(616)	—	—	617	—
Euro Beneficial shares issued	40,000	44	—	—	—	—	44
Balance at December 31, 2015	21,245,382	256	165,719	5,191	(80,803)	564	90,927

The accompanying notes are an integral part of the Consolidated Financial Statements.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

1. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

a. General Information

The Company was incorporated under the laws of Ireland on May 26, 2015 with registered number 562659 as a public limited company under the Companies Act 2014 and is domiciled in Ireland. The Company is a continuation of Cortendo AB, the predecessor, and the consolidated financial statements represent the assets, liabilities and results of operations of Cortendo AB, for all periods presented.

The Company is a biopharmaceutical entity focused on the development, in-licensing, acquisition and eventual commercialisation of multiple complementary products and product candidates within franchises that target rare diseases.

The consolidated financial statements of the Company have been prepared in accordance with Section 279 of Part 6 of the Companies Act 2014, which provides that a true and fair view of the state of affairs and profit or loss may be given by preparing the financial statements in accordance with generally accepted accounting principles in the United States (U.S. GAAP), as defined in Section 279(1) of Part 6 of the Companies Act 2014, to the extent that the use of those principles in the preparation of the consolidated financial statements does not contravene any provision of that part of the Companies Act 2014.

These consolidated financial statements were prepared in accordance with Irish Company Law, to present to the shareholders of the Company and file with the Companies Registration Office in Ireland. Accordingly, these consolidated financial statements include presentation and additional disclosures required by the Republic of Ireland's Companies Act 2014 in addition to those disclosures required under U.S. GAAP.

Terminology typically utilised in a set of U.S. GAAP financial statements has been retained for the benefit of those users of these financial statements who also have access to our form 20-F U.S. GAAP financial statements, rather than defaulting to the terminology set out under Irish Company Law. Accordingly, references to other income, other expense, tax benefit and net loss have the same meaning as references to other interest receivable and similar income, interest payable and similar charges, tax on profit or loss on ordinary activities, loss on ordinary activities after taxation under Irish Company Law.

The consolidated financial statements include the accounts of the Company, BioPancreate Inc. (Trevose, Pennsylvania, United States), Cortendo Invest AB (Gothenburg, Sweden) and Cortendo Caymans (Georgetown, Cayman Islands). All intercompany transactions and balances have been eliminated in consolidation.

The preparation of consolidated financial statements requires management to make estimates and assumptions, which affect the reported earnings, financial position and various disclosures. Although the estimates are considered reasonable, actual results could differ from the estimates.

The Company's functional currency is United States Dollars (USD). Transactions in foreign currencies are translated into the functional currency at the rate of exchange prevailing at the date of the transaction. Any monetary assets and liabilities arising from these transactions are translated into the functional currency at exchange rates prevailing at the balance sheet date or on settlement. Resulting gains and losses are recorded in foreign exchange loss in the consolidated statement of comprehensive income.

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (CONTINUED)

b. Reconciliation to amounts reported in the Company's annual report on Form 20-F filed with the United States Securities and Exchange Commission ("the U.S. SEC")

These consolidated financial statements are prepared using U.S. GAAP to the extent that the use of such principles does not contravene Irish Company Law. The consolidated financial statements included in the annual report on Form 20-F as filed on March 24, 2016 with the U.S. SEC are prepared using U.S. GAAP. The primary differences between these statutory financial statements and the Consolidated Financial Statements included on Form 20-F is the presentation format of the income statement and balance sheet and the inclusion of certain additional disclosures.

It is noted that there are no material differences to be reconciled between the two financial statements.

c. Cash at bank and in hand

Cash and cash equivalents consist of account balances at banks and money market accounts, respectively. We consider all short-term highly liquid investments with an original maturity at the date of purchase of three months or less to be cash equivalents. The carrying amount of cash approximates its fair value.

d. Fixed Assets

Property and equipment, net, consists of computer and related IT equipment. Computers and related IT equipment are depreciated over their useful life of 2 to 5 years. Depreciation expense for the years ended December 31, 2014 and 2015 was not significant.

e. Goodwill

Irish Company law requires that goodwill is written off over a period of time which does not exceed its useful economic life. However, the Company does not believe this gives a true and fair view as not all goodwill and intangible assets decline in value. In addition, since goodwill that does decline in value rarely does so on a straight-line basis, straight-line amortization of goodwill over an arbitrary period does not reflect the economic reality. Consistent with U.S. GAAP, Strongbridge considers goodwill an indefinite-lived intangible asset that is not amortized over an arbitrary period. Rather, the Company accounts for goodwill in accordance with US GAAP. Therefore in order to present a true and fair view of the economic reality, goodwill is considered indefinite-lived and is not amortized. The Company is not able to reliably estimate the impact on the financial statements of the true and fair override on the basis that the useful economic of goodwill cannot be predicted with a satisfactory level of reliability nor can the pattern in which goodwill diminishes be known.

Goodwill represents the cost of acquired companies in excess of the fair value of the net assets of such companies at the acquisition date. Goodwill is tested for impairment annually in the Company's fourth quarter, or more frequently if changes in circumstances or the occurrence of events suggest impairment exists. The test for impairment requires the Company to make several estimates about fair value, most of which are based on projected future cash flows and market valuation multiples. The estimates associated with the goodwill impairment tests are considered critical due to the judgments required in determining fair value amounts, including projected discounted future cash flows. Changes in these estimates may result in the recognition of an impairment loss.

The Group test goodwill for impairment on an annual basis or whenever events occur that may indicate possible impairment. This analysis requires us to make a series of critical assumptions to (1) evaluate whether any impairment exists and (2) measure the amount of impairment.

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (CONTINUED)

e. Goodwill (continued)

Because we have one operating segment, when testing for a potential impairment of goodwill, we are required to estimate the fair value of our business and determine the carrying value. If the estimated fair value is less than the carrying value of our business, then we are required to estimate the fair value of all identifiable assets and liabilities in a manner similar to a purchase price allocation for an acquired business. Only after this process is completed can the goodwill impairment be determined, if any.

To estimate the fair value of the business, primarily a market-based approach is applied, utilizing our public market value. We did not record a charge for impairment for the years ended December 31, 2014 and 2015

f. In-process research and development

Purchased identifiable intangible assets with indefinite lives, such as our in-process research and development, are evaluated for impairment annually in accordance with our policy and whenever events or changes in circumstances indicate that it is more likely than not that the fair value of these assets may not be recovered.

To test these assets for impairment, we compare the fair value of the asset to its carrying value. The method we use to estimate the fair value measurements of indefinite-lived intangible assets is based on the income approach. For the impairment analysis for the year ended December 31, 2015, significant unobservable inputs used in the income approach valuation method including a discount rates, royalty rates and probabilities of product candidate advancement from one clinical trial phase to the next. The determination of fair value of indefinite lived assets is considered Level 3 for fair value measurement.

g. Share-Based Awards

We account for stock-based compensation awards in accordance with FASB ASC Topic 718, Compensation—Stock Compensation (ASC 718). ASC 718 requires all stock-based payments including grants of stock options and restricted stock and modifications to existing stock options, to be recognized in the consolidated statements of operations based on their fair values.

Our stock-based awards are subject to either service-based or performance-based vesting conditions. Vesting of certain awards could also be accelerated upon achievement of defined market-based vesting conditions. Certain awards also contain a combination of service and market conditions or performance and market conditions.

We account for employee stock-based awards at grant-date fair value. If we issue awards with an exercise price denominated in a currency other than our functional currency, trading currency or the currency for which we compensate our employee, we account for these as liabilities. We account for non-employee and liability-classified stock-based awards based on the then-current fair values at each financial reporting date until the performance is complete for non-employee awards, or until the award is settled (exercised) for liability-classified awards. Changes in the amounts attributed to these awards between the reporting dates are included in stock-based compensation expense (credit) in our statements of operations. We include liability-classified stock options in non-current liabilities in our balance sheets as their settlement (exercise) does not require use of cash, cash equivalents or other current assets.

We record compensation expense for service-based awards over the vesting period of the award on a straight-line basis. Compensation expense related to awards with performance-based vesting conditions is recognized over the requisite service period using the accelerated attribution method to the extent achievement of the performance condition is probable. For those awards in which the performance condition was the completion of our IPO, we did not recognize compensation expense until the close of the IPO as we did not deem the IPO probable until it occurred.

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (CONTINUED)

g. Share-Based Awards (continued)

Compensation expense for awards with service and market-based vesting conditions is recognized using the accelerated attribution method over the shorter of the requisite service period or the implied period associated with achievement of the market-based vesting provisions.

We estimate the fair value of our awards with service conditions or a combination of service and market conditions using the Black-Scholes option pricing model, which requires the input of subjective assumptions, including (i) the expected stock price volatility, (ii) the expected term of the award, (iii) the risk-free interest rate and (iv) expected dividends. Due to the lack of historical and implied volatility data of our common stock, we based our estimate of expected volatility on the historical volatility of a group of similar companies that are publicly traded. We selected companies with comparable characteristics to us, including enterprise value, risk profiles and position within the industry, and with historical share price information sufficient to meet the expected term of the stock-based awards. We compute historical volatility data using the daily closing prices for the selected companies' shares during the equivalent period of the calculated expected term of the stock-based awards.

We estimate the fair value of our awards with market conditions using a Monte Carlo simulation to determine the probability of satisfying the market condition. We make this estimate using the conditions that exist at the grant-date. The derived service period, which may be the requisite service period, is also determined at this time. Compensation cost for our awards with a market condition is recognized ratably using the accelerated attribution method if the award is subject to graded vesting over the requisite service period. The compensation cost for our awards with a market condition is not reversed if the market condition is not satisfied.

We have estimated the expected term of employee service-based stock options using the "simplified" method, whereby the expected term equals the arithmetic average of the vesting term and the original contractual term of the option, due to our lack of sufficient historical data. We have estimated the expected term of employee awards with service and market conditions using a Monte-Carlo simulation model. This approach involves generating random stock-price paths through a lattice-type structure. Each path results in a certain financial outcome, such as accelerated vesting or specific option payout. We have estimated the expected term of nonemployee service- and performance-based awards based on the remaining contractual term of such awards.

The risk-free interest rates for periods within the expected term of the option are based on the Swedish Government Bond rate or the U.S. Treasury Bond rate with a maturity date commensurate with the expected term of the associated award. The Group have never paid dividends, and do not expect to pay dividends in the foreseeable future.

The Group are also required to estimate forfeitures at the time of grant, and revise those estimates in subsequent periods if actual forfeitures differ from estimates. We record stock-based compensation expense only for those awards that are expected to vest. To the extent that actual forfeitures differ from our estimates, the differences are recorded as a cumulative adjustment in the period the estimates were revised. Historical forfeitures have been insignificant.

h. Taxes

We use the asset and liability method of accounting for taxes in accordance with FASB ASC Topic 740, Income Taxes (ASC 740). Under this method, tax expense is recognized for the amount of (1) taxes payable or refundable for the current year and (2) deferred tax consequences of temporary differences resulting from matters that have been recognized in an entity's financial statements or tax returns.

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (CONTINUED)

h. Taxes (continued)

Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in the results of operations in the period that includes the enactment date. A valuation allowance is provided to reduce the deferred tax assets reported if, based on the weight of the available positive and negative evidence, it is more likely than not some portion or all of the deferred tax assets will not be realized.

ASC Topic 740 clarifies the accounting for uncertainty in taxes recognized in an enterprise's financial statements and prescribes a recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. ASC Topic 740.10.40 provides guidance on de-recognition, classification, interest and penalties, accounting in interim periods, disclosure and transition. The Group have no material uncertain tax positions for any of the reporting periods presented.

We recognize interest and penalties related to uncertain tax positions in tax expense. As of December 31, 2014 and 2015, the Group had no accrued interest or penalties related to uncertain tax positions and no amounts have been recognized in our statements of operations.

i. Research and Development

Research and development costs are expensed as incurred. Research and development expenses consist of internal and external expenses. Internal expenses include compensation and related expenses. External expenses include development, clinical trials, report writing and regulatory compliance costs incurred with clinical research organizations and other third-party vendors. At the end of the reporting period, we compare payments made to third-party service providers to the estimated progress toward completion of the research or development objectives. Such estimates are subject to change as additional information becomes available. Depending on the timing of payments to the service providers and the progress that we estimate has been made as a result of the service provided, we may record net prepaid or accrued expense relating to these costs. Upfront and milestone payments made to third parties who perform research and development services on our behalf are expensed as services are rendered.

j. Earnings per Share ("EPS")

Basic EPS is calculated using the weighted average number of shares of common stock outstanding during each period. It excludes both the dilutive effects of additional common shares that would have been outstanding if the shares issued under stock incentive plans had been exercised and the dilutive effects of restricted shares and restricted share units, to the extent those shares and units have not vested. Diluted EPS is calculated including the effects of shares and potential shares issued under stock incentive plans, following the treasury stock method.

3. RESEARCH AND DEVELOPMENT

Research and development costs are expensed as incurred. Research and development expenses consist of internal and external expenses. Internal expenses include compensation and related expenses. External expenses include development, clinical trials, report writing and regulatory compliance costs incurred with clinical research organisations and other third-party vendors.

3. RESEARCH AND DEVELOPMENT (CONTINUED)

The Group incurred research and development expenses of $5.8 million and $20.1 million for the years ended December 31, 2014 and 2015, respectively as summarised as follows:

	Year Ended December 31, 2015	Year Ended December 31, 2014
	$'000	$'000
Clinical development and supporting activities	12,697	4,518
Antisense Therapeutics license fee	3,899	—
Compensation and related personnel costs	1,744	164
Travel, entertainment and other costs	162	—
Preclinical development	840	894
Stock-based compensation expense	793	268
Total research and development expenses	20,135	5,844

4. GENERAL AND ADMINISTRATION

General and administration expenses for the years ended December 31, 2015 and 2014 are summarised as follows (in thousands):

	Year Ended December 31, 2015	Year Ended December 31, 2014
	$'000	$'000
Outside professional services	8,054	3,335
Re-domiciliation and IPO preparation costs	4,007	—
Corporate development and licensing transaction costs	3,390	—
Compensation and related personnel costs	3,305	710
Travel, entertainment and other costs	478	455
Stock-based compensation expense	3,147	(17)
Facility costs	338	105
Total general and administrative expenses	22,719	4,588

5. OTHER INCOME (EXPENSE), NET

Other income for the years ended December 31, 2015 and 2014 are summarised as follows (in thousands):

	Year Ended December 31, 2015	Year Ended December 31, 2014
	$'000	$'000
Interest income	$ 25	$ 208
Dividend income	$ 3	—
Total income	$ 28	$ 208

Other expense for the years ended December 31, 2015 and 2014 are summarised as follows (in thousands):

	Year Ended December 31, 2015	Year Ended December 31, 2014
	$'000	$'000
Impairment loss on Antisense Therapeutics	$ (550)	—
Realised (loss)/gain on financial derivatives	$ (438)	$ 278
Lease expense	$ (141)	—
Interest expense	$ (3)	—
Other expense	$ (1)	—
Total expense	$ (1,133)	$ 278

6. CASH AND CASH EQUIVALENTS

Cash at bank and in hand includes cash in hand, deposits held at call with banks, other short term highly liquid investments with original maturity of three months or less. The total amount of cash and cash equivalents held at 31 December 2015 in thousands was $51,623 (2014: $15,632).

7. PROPERTY AND EQUIPMENT, NET

Property and equipment, net relates to computers and related IT equipment can be summarized as follows:

	Year Ended December 31, 2015		Year Ended December 31, 2014	
	Computer & related IT Equipment	Total	Computer & related IT Equipment	Total
	$'000	$'000	$'000	$'000
Cost				
At beginning of the year	$ 112	$ 112	$ 88	$ 88
Additions	$ 25	$ 25	$ 24	$ 24
At end of the year	$ 137	$ 137	$ 112	$ 112
Accumulated depreciation				
At beginning of the year	$ (91)	$ (91)	$ (82)	$ (82)
Depreciation charge for the year	$ (11)	$ (11)	$ (9)	$ (9)
At end of the year	$ (102)	$ (102)	$ (91)	$ (91)
Net Book Value				
At beginning of the year	$ 21	$ 21	$ 6	$ 6
At end of the year	$ 35	$ 35	$ 21	$ 21

8. GOODWILL AND IN-PROCESS RESEARCH AND DEVELOPMENT

The following table presents in-process research and development and goodwill as of and during the years ended December 31, 2015 and December 31, 2014 (in thousands):

	As of December 31, 2015			
	Cost	Additions	Disposals	Total
In-process research and development	$ 5,228	$ 31,323	—	$ 36,551
Goodwill (note 12)	$ 2,200	$ 5,056	—	$ 7,256
Total	$ 7,428	$ 36,379	—	$ 43,807

	As of December 31, 2014			
	Cost	Additions	Disposals	Total
In-process research and development	$ 5,228	—	—	$ 5,228
Goodwill	$ 2,200	—	—	$ 2,200
Total	$ 7,428	—	—	$ 7,428

Goodwill and in-process research and development as of December 31, 2014 and 2015 resulted from our acquisition of BioPancreate in 2014 and our acquisition of product candidate COR-005 from Aspireo Pharmaceuticals, Ltd in 2015.

In-process research and development is initially measured at its fair value and is not amortized until commercialization. Once commercialization occurs, in-process research and development will be amortized over its estimated useful life.

We did not identify any indicators of impairment of our in-process research and development or goodwill as of December 31, 2015.

9. INVESTMENTS AND OTHER ASSETS

Other assets as at year ended December 31, 2015 and December 31, 2014 relate to following (in thousands):

	Year Ended December 31, 2015	Year Ended December 31, 2014
	$'000	$'000
Antisense Stock Investment*	$ 550	—
Deposits on leased facilities	$ 62	—
Other	—	$ 10
Total Fees	$ 612	$ 10

*In May 2015, the Group entered into an exclusive license agreement, or the Antisense License Agreement, with Antisense Therapeutics. Refer to Note 11 of Consolidated Financial Statements for further details.

10. ACCRUED LIABILITIES

Accrued liabilities as at year ended December 31, 2015 and December 31, 2014 consist of the following (in thousands):

	Year Ended December 31, 2015	Year Ended December 31, 2014
	$'000	$'000
Consulting and professional fees	$ 1,288	$ 516
Employee compensation	$ 1,172	$ 804
Payroll liabilities	—	—
Other	$ 225	$ 102
	$ 2,685	$ 1,422

11. COMMITMENTS AND CONTINGENCIES

(a) Lease

On April 22, 2014, we entered into a 48-month building lease for approximately 3,000 square feet of space in Radnor, Pennsylvania. The lease has annual rent escalations. We obtained access to the newly leased space on August 1, 2014, and this was considered the lease commencement date for accounting purposes. Thus, rent expense began on this date and is recognized on a straight-line basis over the term of the lease.

In March 2015, the Company entered into a 52-month building sublease agreement for 14,743 square feet of office space in Trevose, Pennsylvania. The lease has annual rent escalations and is recognized on a straight-line basis over the term of the lease. As a result of this lease, we vacated the previously leased Radnor, Pennsylvania facility as of April 13, 2015 and determined that the Radnor, Pennsylvania facility was not likely to be utilized during the remaining lease term and as such we commenced efforts to sublease the facility. The Company recorded a liability as of the April 13, 2015 cease-use date of $0.1 million for the estimated fair value of its obligations under the lease. The most significant assumptions used in determining the amount of the estimated liability are the potential sublease revenues and the credit-adjusted risk-free rate utilized to discount the estimated future cash flows.

As of December 31, 2015 and 2014, future minimum commitments under facility operating leases were as follows:

	As at December 31, 2015	As at December 31, 2014
	$'000	$'000
2015	—	$ 111
2016	$ 227	$ 114
2017	$ 311	$ 118
2018	$ 319	$ 121
2019	$ 184	—
Total minimum lease payments	$ 1,041	$ 464

Rent expense recognised under the operating lease, including additional rent charges for utilities, parking, maintenance and real estate taxes, for the year ended 31 December 2015 amounted to (in thousands) $254 (2014: $83).

11. COMMITMENTS AND CONTINGENCIES (CONTINUED)

(b) License Agreements

Cornell Center for Technology Enterprise and Commercialization

In 2011, a license agreement was executed between BioPancreate and the Cornell Center for Technology Enterprise and Commercialization (CCTEC). Under the terms of the license agreement, BioPancreate obtained certain rights from the CCTEC for commercial development, use and sale of products that use the technology associated with the license. We are obligated to make milestone payments upon the achievement of certain regulatory and clinical milestones up to $2.6 million in the aggregate. For years in which licensed products are sold, we are required to pay a royalty based on a low single-digit percentage of net sales. The minimum annual royalty in such years is $100,000. In the event the product is sublicensed, up to $3.5 million of certain fees we receive that are not earned royalties or reimbursements for direct costs are due to CCTEC upon achievement of certain regulatory and clinical milestones.

Antisense Therapeutics

In May 2015, we entered into an exclusive license agreement, or the Antisense License Agreement, with Antisense Therapeutics that provided us with development and commercialization rights to Antisense Therapeutics' product candidate, ATL1103, for endocrinology applications (specifically excluding the treatment of any form of cancer and the treatment of any complications of diabetes). We refer to this product candidate as COR-004. Under the terms of the Antisense License Agreement, we paid Antisense Therapeutics an initial upfront license fee of $3.0 million in cash which was recorded as research and development expenses. We also invested $2.0 million in Antisense Therapeutics equity which was initially recorded as a non-current other asset for $1.1 million with the difference constituting the cost of the license which was recorded as research and development expense. The terms of the Antisense License Agreement provided that we could terminate the Antisense License Agreement upon 90 days' prior written notice to Antisense Therapeutics if we believed the further development and commercialization of COR-004 was no longer feasible due to a material change that was beyond our control. If, however, it is determined that we terminated the Antisense License Agreement for convenience, we would be required to pay Antisense Therapeutics a $2.0 million termination fee. On March 7, 2016, we provided a notice to Antisense Therapeutics of our intent to terminate the Antisense License Agreement effective June 7, 2016 because we believe the further development and commercialization of COR-004 is no longer feasible due to material changes that were beyond our control.

We have received a reply from Antisense Therapeutics objecting to our termination notice and to our assertion that the further development and commercialization of COR-004 was no longer feasible due to material changes that were beyond our control. The reply also requests that the parties appoint an independent expert to resolve this dispute in accordance with the terms of the Antisense License Agreement.

(c) Other Commitments

In 2012, we entered into consulting agreements with two individuals to serve as Chief Executive Officer and Chief Operating Officer, respectively. In connection with those agreements, each individual is entitled to a payment in the event of the sale or license by us prior to December 31, 2016 of BioPancreate or major assets derived from the BioPancreate technology. The payment amounts are based on a percentage of the acquisition price or up-front license fee, as applicable. The maximum amount payable per individual in the event of a sale or license is $1.25 million or $2.5 million in total. Each individual is entitled to such payments even though each is no longer serving in their respective officer roles.

12. ACQUISITIONS

Acquisitions have been accounted for under the acquisition method of accounting, and the related assets acquired and liabilities assumed were recorded at fair value as of the acquisition date.

On June 30, 2015, we acquired from Aspireo Pharmaceuticals Ltd. (Aspireo), an Israeli company, its product candidate, DG3173, and the rights and obligations to the on-going research and development contracts, the combination of which represented "substantially all" of the Aspireo business. We refer to this product candidate as COR-005. Under the terms of the acquisition agreement, we issued to Aspireo 2,062,677 common shares, which had a value of $33.2 million on June 30, 2015. In connection with this acquisition, we also made a payment to the Office of the Chief Scientist of the Israeli Ministry of Economy, or OCS, in the amount of $3.0 million, which represents the repayment of amounts granted by the OCS to Aspireo, plus interest, that were used in support of research and development conducted by Aspireo for the development of DG3173.

The acquisition was accounted for using the acquisition method of accounting for business combinations. The total consideration transferred was allocated to the assets acquired and liabilities assumed based on their respective fair values. The fair value of $16.10 per ordinary share of the 2,062,677 ordinary shares issued was determined based on the closing market price on the NOTC of our ordinary shares on the acquisition date. To determine the fair value of the acquired in-process research and development intangible asset, we applied the income approach using the multi-period excess earnings method.

The following table summarizes the estimated fair values of the assets acquired and liabilities assumed (in thousands):

In process research and development	$	31,323
Liabilities assumed:		
Other liabilities (net)	$	(195)
OCS liability	$	(2,973)
Total fair values of assets and liabilities	$	28,155
Fair value of total consideration transferred	$	(33,211)
Goodwill	$	(5,056)

The excess of the consideration transferred over net assets acquired was assigned to goodwill in an amount of $5.1 million and is primarily related to expected synergies. A deferred tax liability was not recorded for the difference between the book and cost basis of the in-process research and development intangible asset because the asset is domiciled in the Cayman Islands and therefore we do not expect to pay income tax. The goodwill is not deductible for income tax purposes.

We incurred $2.2 million in acquisition-related transaction costs for the period ended December 31, 2015, which is included as general and administration expense.

13. FAIR VALUE MEASUREMENTS

Fair value accounting is applied for all financial assets and liabilities and non-financial assets and liabilities that are recognized or disclosed at fair value in the financial statements on a recurring basis (at least annually).

We are required to disclose information on all assets and liabilities reported at fair value that enables an assessment of the inputs used in determining the reported fair values. FASB ASC Topic 820, Fair Value Measurements and Disclosures (ASC 820), establishes a hierarchy of inputs used in measuring fair value that maximizes the use of observable inputs and minimizes the use of unobservable inputs by requiring that the observable inputs be used when available.

13. FAIR VALUE MEASUREMENTS (CONTINUED)

Observable inputs are inputs that market participants would use in pricing the asset or liability based on market data obtained from sources independent of us. Unobservable inputs are inputs that reflect our assumptions about the inputs that market participants would use in pricing the asset or liability, and are developed based on the best information available in the circumstances. The fair value hierarchy applies only to the valuation inputs used in determining the reported fair value of the investments and is not a measure of the investment credit quality. The three levels of the fair value hierarchy are described as follows:

Level 1: Valuations based on unadjusted quoted prices in active markets for identical assets or liabilities that we have the ability to access at the measurement date.

Level 2: Valuations based on quoted prices for similar assets or liabilities, or quoted prices in markets that are not active, and for which all significant inputs are observable, either directly or indirectly.

Level 3: Valuations that require inputs that reflect our own assumptions that are both significant to the fair value measurement and unobservable. To the extent that valuation is based on models or inputs that are less observable or unobservable in the market, the determination of fair value requires more judgment. Accordingly, the degree of judgment we exercise in determining fair value is greatest for instruments categorized in Level 3. A financial instrument's level within the fair value hierarchy is based on the lowest level of any input that is significant to the fair value measurement.

The following tables summarise the valuation of the Company's financial instruments carried at fair value by the above pricing categories as of December 31, 2015 and December 31, 2014 (in thousands):

	As of December 31, 2015			
	Level I	Level II	Level III	Total
Financial assets:				
Cash and cash equivalents	$ 45,296	—	—	$ 45,296
Non-current assets	—	$ 550	—	$ 550
Total financial assets	$ 45,296	$ 550	—	$ 45,846

	As of December 31, 2014			
	Level I	Level II	Level III	Total
Financial assets:				
Foreign currency forward contracts	—	$ 438	—	$ 438
Total financial assets	$ 0	$ 438	—	$ 438

Our foreign currency forward contracts are classified within Level II because of the use of observable inputs for similar derivative instruments in active markets, or quoted prices for identical or similar instruments in markets that are not active, and are directly or indirectly observable, and are classified as prepaid expenses and other current assets. The noncurrent asset comprising of our investment in ATL common stock is classified as Level II as we discounted the active market quoted price of the security to reflect our contractual restriction on selling the investment.

Because of their short term nature, the amounts reported in the balance sheet for cash and cash equivalents, and accounts payable approximate fair value.

14. DERIVATIVE INSTRUMENTS AND HEDGING ACTIVITIES

The Company enters into certain derivative financial instruments, when available on a cost-effective basis, to mitigate its risk associated with changes foreign currency exchange rates.

To reduce our currency exposure, we used a hedging program from the fourth quarter of 2013 through the second quarter of 2015. The foreign currency forward contracts used in our hedging program were not entered into for speculative purposes and, although we believe they served as effective economic hedges, we did not seek to qualify for hedging accounting. In 2014, our operations continued to shift to the United States, but a large portion of our cash and cash equivalents were still held in foreign currencies. In the first half of 2015, all of our forward contracts expired.

15. SHAREHOLDERS' EQUITY

The issued share capital for the Company during the year ended December 31, 2015 and December 31, 2014 can be summarised as follows:

	Ordinary shares with par value of €1.00 each	Ordinary shares with par value of $0.01 each	Issued Share Capital at par
	No of shares	No of shares	$'000
Opening Balance as at 1 January 2014	—	7,939,608	79
In January 2014, shares exchanged for BioPancreate minority interest	—	5,272	—
In December 2014, private placement of 1,755,909 shares issued, par value $0.01	—	1,755,909	18
Opening Balance as at 31 December 2014	—	9,700,789	97
Opening Balance as at 1 January 2015	—	9,700,789	97
In February 2015, private placement of 4,761,078 shares issued, par value $0.01	—	4,761,078	48
On May 26, 2015, 40,000 deferred ordinary shares issued, par value €1.00	40,000	—	44
On June 29,and 30, 2015, private placement of 2,284,414 shares issued, par value $0.01	—	2,284,414	23
On June 30, 2015 private placement of 2,062,677 shares issued, par value $0.01	—	2,062,677	21
US Non Accredited Shares Repurchases	—	(24,955)	—
Reallocation of ordinary shares not tendered	—	(78,621)	(1)
On October 22, 2015 issued 2,500,000 ordinary shares, par value $0.01 by Initial Public Offering	—	2,500,000	25
Opening Balance as at 31 December 2015	40,000	21,205,382	256

15. SHAREHOLDERS' EQUITY (CONTINUED)

On February 10, 2015, following shareholder approval the Company entered into a share purchase agreement with investors and issued 4,761,078 ordinary shares for $26.4 million. Issuance costs amounted to $605,000.

On May 26, 2015, Strongbridge Biopharma plc (then named Cortendo plc), was incorporated under the laws of Ireland and issued 40,000 ordinary shares issued, par value €1.00.

On June 29 and 30, 2015, the Company raised $33.2 million in aggregate gross proceeds in a private placement of common shares. Issuance costs amount to $662,000 The subscription price was $14.54 per share and the Company issued 2,284,414 new shares to the investors.

On June 30, 2015, the Company acquired from Aspireo Pharmaceuticals Ltd., an Israeli company, its product candidate, DG3173. Under the terms of the acquisition agreement, the Company issued to Aspireo Pharmaceuticals 2,062,677 ordinary shares, which had a value of $33.2 million. In connection with this acquisition, we made a payment to the Office of the Chief Scientist of the Israeli Ministry of Economy, or OCS, in the amount of $3.0 million, which represents the repayment of amounts previously granted by OCS to Aspireo Pharmaceuticals, plus interest, that were used in support of research and development conducted by Aspireo Pharmaceuticals for the development of DG3173.

On August 7, 2015, Strongbridge Biopharma plc initiated an exchange offer for the outstanding shares of Cortendo AB. The exchange offer was structured as a one-for-one exchange offer in which shareholders of Cortendo AB exchanged their common shares, with a par value of $0.15, for beneficial interests in ordinary shares of Strongbridge Biopharma plc, with a par value of $0.01, in the form of Norwegian depositary receipts and, as the case may be, Swedish depositary receipts (except for non-accredited investors who hold Cortendo AB shares located in the United States, who were offered cash in an amount equivalent to the value of the Strongbridge Biopharma plc shares such investors would otherwise receive for their Cortendo AB shares exchanged). The exchange offer was settled on September 8, 2015, and Cortendo AB became a subsidiary with 99.582% of its shares being owned by Strongbridge Biopharma plc.

On September 8, 2015, Strongbridge Biopharma plc effected a 1 for 11 reverse stock split of its ordinary shares. With affect from September 8, 2015, the 0.418% of Cortendo AB not owned by Strongbridge Biopharma plc, is accounted for as a minority interest.

On October 15, 2015, a registration statement was declared effective by the U.S. Securities and Exchange Commission and on October 16, 2015 the Company initiated an initial U.S. public offering (IPO) of 2,500,000 ordinary shares at a price of $10.00 per share. The aggregate net proceeds received by us from the IPO were $19.5 million. The shares began trading on The NASDAQ Global Select Market under the symbol "SBBP". On October 20, 2015, trading ceased on the Norwegian Over-The-Counter Market, or NOTC.

Voting Rights and Privileges

As of December 31, 2015, the authorized share capital of the Company is €40,000 and $7,000,000 divided into 40,000 deferred ordinary shares of €1.00 each, 600,000,000 ordinary shares of $0.01 each, par value and 100,000,000 preferred shares of $0.01 each, par value.

As of December 31, 2015, there were 40,000 authorized deferred ordinary shares of €1.00 each and 21,205,382 ordinary shares of $0.01 each outstanding, respectively.

The holders of ordinary shares are entitled to one vote for each ordinary share held at all general meetings of shareholders without limitation. The holders are entitled to receive dividends if and when declared by the Board of Directors or by the Company in general meeting, provided no dividend shall exceed the amount recommended by the Board of Directors.

15. SHAREHOLDERS' EQUITY (CONTINUED)

Voting Rights and Privileges (continued)

No dividends have been declared or paid since inception. The holders are entitled to share rateably in the assets available for distribution to shareholders, in the event of any voluntary or involuntary liquidation.

The deferred ordinary shares are issued in order to satisfy an Irish legislative requirement to maintain a minimum level of issued share capital denominated in euro. The deferred ordinary shares carry no voting rights and are not entitled to any dividend or distribution.

Equity Financings

In December 2014, we issued 1,755,909 shares of common stock for $10.2 million, net of transaction costs. The subscription price was $6.17 per share.

On February 10, 2015, we issued 4,761,078 shares of our common stock for $25.8 million, net of transaction costs. The subscription price was $5.54 per share.

On June 29 and 30, 2015, following shareholder approval of the share purchase agreement which the Company entered into on May 14, 2015, 2,284,414 new shares was issued to the investors. The subscription price was $14.54 per share and proceeds net of transaction costs were $32.6 million.

On October 21, 2015, we closed on our initial U.S. public offering of 2,500,000 ordinary shares at a price to the public of $10.00 per ordinary share for aggregate gross proceeds of $25 million, before deducting the underwriting commission and estimated offering expenses of $5.5 million.

The Company is listed on The NASDAQ Global Select Market under the symbol "SBBP". A registration statement relating to these securities was declared effective by the U.S. Securities and Exchange Commission on October 15, 2015.

Shares Reserved for Issuance

There were 925,077 shares of common stock in Cortendo AB and 2,591,520 ordinary share in the Company reserved for future issuance upon exercise of stock options as of December 31, 2014 and 2015, respectively.

Stock-based Compensation

The Board of Directors approve the granting of awards to our officers, directors, employees and third party-consultants. Under these grants, the beneficiaries are given the right to acquire new shares of common stock at a pre-determined option price. The purpose of the grants is to assist us in attracting, retaining and motivating officers, employees, directors and consultants. In addition, these awards provide us with the ability to provide incentives that are directly linked to the performance of our business and the related increase in shareholder value.

Our awards have terms that range from five to ten years. As determined by our Board of Directors, our awards vest over service periods ranging up to four years or upon achievement of defined performance or market criteria such as the vesting of certain awards upon our IPO or awards that are accelerated when the fair value of our stock price reaches defined targets.

The exercise price for each stock option is determined by the Board of Directors based upon considerations such as the fair value of the underlying ordinary shares and certain market conditions. For options granted prior to our October 21, 2015, IPO, the determination of the fair value of our common stock takes into account the price at which our shares were being quoted on the NOTC, recent equity financings and our valuations calculated with the assistance of third-parties.

15. SHAREHOLDERS' EQUITY (CONTINUED)

Stock-based Compensation (continued)

On July 21, 2015, we cancelled 465,262 of our options for certain employees that were not vested and for which service was expected to be rendered and concurrently replaced these with 586,710 options. We accounted for the cancellation and replacement as a modification whereby we determined value of the original options based on current assumptions, without regard to the assumptions made on the grant date. We then compared the fair value of the modified award to the fair value of the original options immediately before the terms were modified, measured based on the share price and other pertinent factors on the date of the modification The incremental value of $468,000 was recorded over the remaining requisite service periods as these awards are expected to vest.

On September 8, 2015, we effected a 1-for-11 reverse stock split of our ordinary shares. In conjunction with the reverse stock split, we adjusted our outstanding stock options by the same ratio.

On October 21, 2015, we converted all of our Cortendo AB awards which were previously denominated in Swedish Krona (SEK) and Norwegian Kroner (NOK), into awards to acquire shares in Strongbridge Biopharma plc which were denominated in U.S. dollars. For the stock options denominated in NOK, the calculation was based on 8.1935 NOK per U.S. dollars. Due to the effects of foreign exchange related to the exercise price, we accounted for the conversion as a modification whereby we determined value of the original options based on current assumptions, without regard to the assumptions made on the grant date. We then compared the fair value of the modified award to the fair value of the original options immediately before the terms were modified, measured based on the share price and other pertinent factors on the date of the modification. Because the effected options were vested, the incremental value of $325,000 was recorded as expense during the period ended December 31, 2015.

For the awards denominated in SEK which were classified as liability awards, we accounted for the conversion as a modification whereby we determined the value of the original options based on current assumptions, without regard to the assumptions made on the grant date. We then compared the fair value of the modified award to the fair value of the original options immediately before the terms were modified, measured based on the share price and other pertinent factors on the date of the modification. The incremental value was recorded as expense in the statement of operations. The liability awards were fully vested as of October 22, 2015 and therefore the resulting liability after modification of $1.5 million was reclassified from liability to additional paid-in capital on the October 22, 2015. As these stock options are now equity-classified and fully vested, we will not remeasure these stock options in the future.

15. SHAREHOLDERS' EQUITY (CONTINUED)

A summary of the outstanding stock options as of December 31, 2015 is as follows:

	Options Outstanding			
	Number of Shares	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value
				$'000
Outstanding-January 1, 2014	465,540	$ 4.63	3.76	1,182
Granted	504,990	$ 11.18		
Forfeited	(45,453)	$ 8.64		
Exercised	—			
Outstanding-December 31, 2014 and January 1, 2015	925,077	$ 8.01	3.72	1,011
Granted	1,710,530	$ 16.87		
Forfeited and cancelled	(44,087)	$ 7.60		
Exercised	—			
Outstanding-December 31, 2015	2,591,520	$ 13.59	5.97	1,844
Vested and exercisable-December 31, 2015	727,280	$ 6.53	3.12	1,844
Vested and expected to vest-December 31, 2015	2,591,520	$ 13.59	5.97	1,844

Included in the stock options outstanding at December 31, 2015, are unvested stock options to purchase 143,302 shares at a weighted average exercise $18.80 per share for which the vesting of certain tranches will accelerate if the fair value per share of our stock reaches $16.11, $31.46 or $37.62 for the respective grantee. In addition, the options outstanding include 106,738 shares that vest upon a market appreciation event so long as it occurs prior to May 26, 2019 of which all were unvested as of December 31, 2015 and 106,738 shares that will vest upon the one year anniversary of the market appreciation event of which all were unvested as of December 31, 2015. The market appreciation event is defined as the last trading day in the period in which the closing stock price on each of 20 consecutive trading days reported on NASDAQ has been at least $30.14 or $33.66 for the respective grantee.

The aggregate intrinsic values of options outstanding, vested and exercisable, and vested and expected to vest were calculated as the difference between the exercise price of the options and the estimated fair value of our common stock as of December 31, 2014 and 2015, respectively.

15. SHAREHOLDERS' EQUITY (CONTINUED)

Stock-based compensation expense

We recognized stock-based compensation expense for employees and non-employees in the accompanying consolidated statements of comprehensive income as follows (in thousands):

	Year Ended December 31, 2015	Year Ended December 31, 2014
Research and development	$ 793	$ 268
General and administrative	$ 3,147	$ (17)
Total stock-based compensation	$ 3,940	$ 251

Included in these amounts was stock compensation expense (credit) attributed to liability-classified awards of $(229,000) and $359,000, for the years ended December 31, 2014 and 2015, respectively.

As of December 31, 2015, the total unrecognized compensation expense related to unvested options, net of estimated forfeitures, was $9.9 million, which we expect to recognize over an estimated weighted-average period of 1.73 years.

In determining the estimated fair value of the stock-based awards, we use the Black-Scholes option-pricing model and assumptions discussed below. Each of these inputs is subjective and generally requires significant judgment.

The fair value of stock option awards was estimated with the following assumptions:

	Year Ended December 31, 2014	Year Ended December 31, 2015
Expected term (in years)	3.23	3.23
Risk-free interest rate	0.0% - 0.6%	0.0% - 0.6%
Expected volatility	68.3% - 80.7%	79.0% - 83.1%
Dividend rate	—%	—%

15. SHAREHOLDERS' EQUITY (CONTINUED)

Capital & Reserves

	Issued Share Capital at par	Share Premium	Other Reserves	Minority interest	Retained Earnings
	$'000	$'000	$'000	$'000	$'000
Opening Balance as at January 1, 2015	97	55,467	480	(54)	(37,223)
On February 10, 2015, private placement of 4,761,078 shares issued, par value $0.01	48	25,726	—	—	—
On May 26, 2015, 40,000 deferred ordinary shares issued, par value €1.00/$1.098	44	0	—	—	—
In June 2015, private placement of 2,284,414 shares issued, par value $0.01	23	32,540	—	—	—
On June 30, 2015 private placement of 2,062,677 shares issued, par value $0.01	21	33,152	—	—	—
US Non Accredited Shares Repurchases	—	(412)	—	—	—
Reallocation of ordinary shares not tendered	(2)	(616)	—	617	—
On October 22, 2015 issued 2,500,000 ordinary shares, par value $0.01 by Initial Public Offering	25	19,450	—	—	—
Stock based compensation	—	—	5,123	—	—
Net loss for the year	—	—	—	—	(43,580)
Opening Balance as at December 31, 2015	256	165,307	5,603	564	(80,803)

On February 10, 2015, following shareholder approval the Company entered into a share purchase agreement with investors and issued 4,761,078 ordinary shares for $26.4 million. Issuance costs amounted to $605,000.

On June 29 and 30, 2015, the Company raised $33.2 million in aggregate gross proceeds in a private placement of common shares. Issuance costs amount to $662,000. The subscription price was $16.10 per share and the Company issued 2,284,414 new shares to the investors.

On June 30, 2015, the Company acquired from Aspireo Pharmaceuticals Ltd., an Israeli company, its product candidate, DG3173. Under the terms of the acquisition agreement, the Company issued to Aspireo Pharmaceuticals 2,062,677 ordinary shares, which had a value of $33.2 million. In connection with this acquisition, we made a payment to the Office of the Chief Scientist of the Israeli Ministry of Economy, or OCS, in the amount of $3.0 million, which represents the repayment of amounts previously granted by OCS to Aspireo Pharmaceuticals, plus interest, that were used in support of research and development conducted by Aspireo Pharmaceuticals for the development of DG3173.

15. SHAREHOLDERS' EQUITY (CONTINUED)

Capital & Reserves (continued)

In order to effect a corporate reorganization, on September 8, 2015 the Company settled an exchange offer, pursuant to which holders of 99.449% of the outstanding shares of Cortendo AB exchanged their shares for beneficial interests in ordinary shares of Strongbridge Biopharma plc in the form of depositary receipts on a 1-for-1 basis. Non-accredited holders of Cortendo AB shares located within the United States, representing 0.133% of the outstanding shares of Cortendo AB, agreed to exchange their shares for cash, which cash settlement occurred on September 14, 2015. Non-accredited U.S. holders of ordinary shares of Cortendo AB received cash in an amount equivalent to the value of one ordinary share of Strongbridge Biopharma plc for each share of Cortendo AB validly exchanged. Pursuant to individual agreements with the holders of options to purchase shares of Cortendo AB, the outstanding options of Cortendo AB were converted to options to purchase an equivalent number of ordinary shares of Strongbridge Biopharma plc.

On May 26, 2015, Strongbridge Biopharma plc (then named Cortendo plc), was incorporated under the laws of Ireland and issued 40,000 ordinary shares issued, par value €1.00/$1.098. The ordinary shares of €1.00 each were redesignated into deferred ordinary shares of €1.00 each, par value, on August 7, 2015 and carry no voting rights and are not entitled to any dividend or distribution.

On October 15, 2015, a registration statement was declared effective by the U.S. Securities and Exchange Commission and on October 16, 2015 the Company initiated an initial U.S. public offering (IPO) of 2,500,000 ordinary shares at a price of $10.00 per share. The aggregate net proceeds received from the IPO were $19.5 million. The shares began trading on The NASDAQ Global Select Market under the symbol "SBBP". On October 20, 2015, trading ceased on the Norwegian Over-The-Counter Market, or NOTC.

16. TAXES

The reconciliation from tax loss to tax benefit for the year ended December 31, 2015 can be summarized as follows:

	Year Ended December 31, 2015
	$'000
Loss before taxes	$ (44,083)
Effective rate of tax of 1.0%	$ 450
Tax benefit	$ 450

For the years ended December 31, 2015 and 2014, the components of loss before taxes were as follows (in thousands):

	Year Ended December 31, 2015	Year Ended December 31, 2014
	$'000	$'000
Sweden	$ (33,960)	$ (9,165)
Ireland	$ (191)	—
Cayman Islands	$ (8,722)	—
U.S.	$ (1,210)	$ (985)
Total	$ (44,083)	$ (10,150)

16. TAXES (CONTINUED)

The components of tax for the years ended December 31, 2015 and 2014 were as follows (in thousands):

	Year Ended December 31, 2015	Year Ended December 31, 2014
Current tax expense (benefit):		
Sweden	—	—
Ireland	—	—
U.S. Federal	—	—
U.S. State	—	—
Total	—	—
Deferred tax expense (benefit):		
Sweden	$ 212	$ (648)
Ireland	$ (24)	—
U.S. Federal	$ (17,543)	$ (2,433)
U.S. State	$ (1,233)	$ (720)
Change in valuation allowance	$ 18,138	$ 3,321
Total	$ (450)	$ (480)

We recorded tax benefits for the federal and state net operating loss carry forwards and federal tax credit carryforwards attributable to BioPancreate. These deferred benefits are realizable as they offset the non-current deferred tax liability recorded in connection with the acquisition of BioPancreate. We have incurred net operating losses since inception. We have not reflected any benefit of net operating loss carryforwards (NOLs), other than those attributable to BioPancreate, in the accompanying financial statements. We have established a valuation allowance against the remaining deferred tax assets due to the uncertainty surrounding the realization of such assets.

Deferred taxes are recognized for temporary differences between the bases of assets and liabilities for financial statement and tax purposes. The tax effect of temporary differences that give rise to significant portions of the deferred tax assets are as follows (in thousands):

	Year Ended December 31, 2015	Year Ended December 31, 2014
Deferred tax assets:		
Net operating loss carryforwards	$ 22,039	$ 8,775
Tax credits	$ 9,135	$ 3,811
Capitalized research and development costs	$ 161	$ 161
Total deferred tax assets	$ 31,335	$ 12,747
Valuation allowance	$ (30,150)	$ (12,012)
Deferred tax assets recognized	$ 1,185	$ 735
Deferred tax liabilities:		
Acquired intangible assets	$ (2,111)	$ (2,111)
Total deferred tax liabilities	$ (2,111)	$ (2,111)
Net deferred tax liabilities	$ (926)	$ (1,376)

16. TAXES (CONTINUED)

We have evaluated the positive and negative evidence bearing upon the realizability of our deferred tax assets. Based on our history of operating losses, we have concluded that it is more likely than not that the benefit of our deferred tax assets, other than those attributable to BioPancreate, will not be realized. Accordingly, we have provided a full valuation allowance for the remaining deferred tax assets as of December 31, 2014 and 2015. The valuation allowance increased by approximately $3.3 million and $18.1 million during the year ended December 31, 2014 and 2015, respectively, due primarily to net operating losses.

The Company's effective income tax rate differs from the ultimate parent company, Strongbridge Biopharma plc's, Irish domestic statutory rate of 12.5% for the year ended December 31, 2015. With respect to the prior periods, the effective income tax rate differs from previous ultimate parent company, Cortendo AB's, Swedish domestic tax rate of 22% as follows:

	Year Ended December 31, 2015	Year Ended December 31, 2014
Ireland statutory income tax rate	12.50%	—
Swedish statutory income tax rate	—	22.00%
Foreign tax differential between Sweden, U.S., Cayman Island and Ireland	15.70%	(4.60)%
Federal tax credits	12.10%	20.90%
Change in valuation allowance	(41.20)%	(32.70)%
Other	1.90%	(0.90)%
Effective income tax rate	1.00%	4.70%

At December 31, 2015, we had approximately $66.6 million of Swedish NOLs and approximately $0.2 million of Ireland NOLs, which have an indefinite life, and approximately $37.1 million of U.S. federal and $37.0 million of state NOLs, which begin to expire in 2031. We operate through a permanent establishment in the United States. Income from the permanent establishment is taxed in both Sweden and the United States. Relief is granted by way of crediting the U.S. tax against the Swedish tax. This tax credit can never exceed the Swedish tax on the income. Since the tax rate is higher in the United States than in Sweden, the Swedish taxable carryforward losses of $66.6 million can only generate a tax benefit if income is derived from sources other than the permanent establishment in the United States.

At December 31, 2015, we had $8.9 million of U.S. federal orphan drug tax credit carryforwards, which begin to expire in 2032, and $167,000 of U.S. federal research and development tax credit carryforwards, which begin to expire in 2031.

Utilization of the NOLs may be subject to limitations under Swedish tax regulations or U.S. Internal Revenue Code Section 382 if there is a greater than 50% ownership change as determined under applicable regulations.

17. SEGMENT INFORMATION

Operating segments are identified as components of an enterprise about which separate discrete financial information is available for evaluation by the chief operating decision maker, or decision making group, in making decisions on how to allocate resources and assess performance. We view our operations and manage our business in one operating segment. Our material long-lived assets, which primarily consist of in-process research and development, reside in the United States, Sweden and Cayman Islands.

18. SUBSIDIARY INFORMATION

Cortendo AB has three wholly owned subsidiaries, Cortendo Invest AB, a company organized under the laws of Sweden, BioPancreate Inc., a Delaware corporation, and Cortendo Cayman Ltd., an exempted company incorporated in the Cayman Islands.

In order to effect a corporate reorganization, on September 8, 2015 we settled an exchange offer, which we refer to as the Exchange Offer, pursuant to which holders of 99.449% of the outstanding shares of Cortendo AB exchanged their shares for beneficial interests in ordinary shares of Strongbridge Biopharma plc in the form of depositary receipts on a 1-for-1 basis and non-accredited holders of Cortendo AB shares located within the United States, representing 0.133% of the outstanding shares of Cortendo AB, agreed to exchange their shares for cash, which cash settlement occurred on September 14, 2015. Non-accredited U.S. holders of ordinary shares of Cortendo AB received cash in an amount equivalent to the value of one ordinary share of Strongbridge Biopharma plc for each share of Cortendo AB validly exchanged. Pursuant to individual agreements with the holders of options to purchase shares of Cortendo AB, the outstanding options of Cortendo AB were converted to options to purchase an equivalent number of ordinary shares of Strongbridge Biopharma plc.

We intend to acquire the remaining 0.418% of the outstanding shares of Cortendo AB held by shareholders who declined to participate in the Exchange Offer, pursuant to a process permitted by Swedish law.

Following the settlement of the Exchange Offer, Strongbridge Biopharma plc became the parent of Cortendo AB and its subsidiaries. As a result of the settlement of the Exchange Offer, the historical financial statements of Cortendo AB became, for financial reporting purposes, the historical consolidated financial statements of Strongbridge Biopharma plc and its subsidiaries as a continuation of the predecessor.

As of March 1, 2016, the Company had the following subsidiaries:

Name	Nature of Business	Group Share %	Registered Office and Country of Incorporation
BioPancreate Inc.	Operating	100%	900 Northbrook Drive Suite 200 Trevose Pennsylvania 19053
Cortendo AB (publ)	Operating	99.582%	Box 47 433 21 Partille Gothenburg Sweden
Cortendo Cayman Ltd	Operating	100%	Maples Corporate Services PO Box 309 Ugland House Grand Cayman KY1-1104
Cortendo Invest AB	Holding	100%	Box 47 433 21 Partille Gothenburg Sweden
Strongbridge U.S. Inc.	Operating	100%	Corporate Trust Center Lmt 1209 Orange Street Wilmington, Delaware 19801

19. EMPLOYEES

As of December 31, 2015, the Company had 25 full-time employees including 24 working in the United States and one employee working in Sweden. Of these full-time employees, 11 were engaged in research and development and 14 were engaged in general and administrative activities.

19. EMPLOYEES (CONTINUED)

As of December 31, 2014, the Company had 6 full-time employees including 5 working in the United States and one employee working in Sweden. Of these full-time employees, 2 were engaged in research and development and 4 were engaged in general and administrative activities.

The employee costs for the year ended December 2015 and 2014 can be summarised as follows:

	Year Ended December 31, 2015 $'000	Year Ended December 31, 2014 $'000
Wages, salaries, bonuses and fringe benefits	4,758	807
Pension benefits	—	4
Payroll taxes	291	63
Stock-based compensation expense	3,940	251
	8,989	1,125

20. DIRECTORS' REMUNERATION

Name	Year	Fees earned or paid in cash $(1)
John H. Johnson	2015	65,050
	2014	—
Richard S. Kollender	2015	33,126
	2014	—
Garheng Kong, M.D., Ph.D.	2015	12,934
	2014	—
Mårten Steen, M.D., Ph.D.	2015	35,833
	2014	2,266
Hilde H. Steineger, Ph.D.	2015	35,833
	2014	26,441
H. Joseph Reiser(2)	2015	18,749
	2014	16,660
Espen Tidemann Jørgensen(2)	2015	14,348
	2014	26,441
Ernest Eichenberg III(2)	2015	10,938
	2014	15,390
Joseph M. Mahady(2)	2015	22,029
	2014	15,390
Eigil Stray Spetalen(2)	2015	21,349
	2014	19,774

20. DIRECTORS' REMUNERATION (CONTINUED)

(1) The board fees paid to our directors during 2014 were denominated in Norwegian Kroner (NOK). For the purposes of presentation, we have converted the board fees into U.S. dollars utilizing the exchange rates as of December 31, 2014.

(2) Messrs. Reiser, Eichenberg, Jørgensen, Spetalen and Mahady resigned from the board of directors of Cortendo AB in 2015.

In addition to directors' fees detailed above, directors' remuneration in relation to salaries and bonuses for year ended December 31, 2015 amounted to $223,301 (2014: $273,287). Stock based compensation expense for directors amounted to$2,193,859 for year ended December 31, 2015 (2014: ($63,000)). No pension payments or other benefits were payable.

21. AUDITOR'S REMUNERATION

Fee Category	Year Ended December 31, 2015 $'000	Year Ended December 31, 2014 $'000
Audit Fees	1,309	179
Audit-Related Fees	70	24
Tax Advisory Fees(1)	71	7
Other non-audit Fees(2)	365	14
Reimbursement of auditor's expenses	5	2
Total Fees	1,820	226

(1) Tax fees consists of fees incurred for tax compliance, tax advice and tax planning and includes fees for tax return preparation and tax consulting.

(2) Other non-audit fees consist of fees incurred for the Irish re-domicile and other services.

All such accountant services and fees were pre-approved by our audit committee in accordance with the "Pre-Approval Policies and Procedures".

The fees paid to Ernst & Young Ireland in respect of the audit of the group accounts were $180,000 in 2015 (2014: $Nil). In addition, Ernst & Young Ireland received fees of $Nil for other assurance services in 2015 (2014: $Nil). Ernst & Young Ireland did not receive any fees for other assurance services, tax advisory fees or other non-audit services in 2015 or 2014.

21. SUBSEQUENT EVENTS

There were no significant subsequent events from the end of the year until the date of signing of this report that would require an adjustment to or disclosure in the financial statements.

22. APPROVAL OF FINANCIAL STATEMENTS

The financial statements were approved and authorised for issue by the Board of Directors and signed on April 12, 2016.

STRONGBRIDGE BIOPHARMA plc

COMPANY BALANCE SHEET

	Notes	As at December 31, 2015 $ '000
ASSETS		
Fixed assets		
Financial assets	3	142,418
Current assets		
Debtors — amounts falling due within one year	5	260
Cash at bank and in hand	4	21,782
Total assets		164,460
LIABILITIES AND SHAREHOLDERS' EQUITY		
Capital and reserves		
Called up share capital - equity	7	256
Share premium account	8	326,031
Other reserves	8	2,489
Profit and loss account		(167,615)
Total Shareholders' equity		161,161
Creditors		
Creditors — amounts due within one year	6	3,299
Total liabilities		3,299
Capital and reserves and liabilities		164,460

The Company Balance Sheet was approved and signed on behalf by the Board of Directors on April 12, 2016:

/s/ Matthew Pauls	/s/ Richard Kollender
Matthew Pauls	Richard Kollender
Director	Director

COMPANY STATEMENT OF CHANGES IN EQUITY
(In thousands except share amounts)

	Called up share capital amount	Share premium	Other reserves	Profit and loss account	Total equity
	$'000	$'000	$'000	$'000	$'000
Balance at incorporation (May 26, 2015)	—	—	—	—	—
Net loss for the period	—	—	—	(167,615)	(167,615)
Share-based payment expense for the period	—	—	618	—	618
Issuance of deferred ordinary shares	44	—	—	—	44
Issuance of shares on exchange	2,058	306,581	—	—	308,639
Reverse stock split of 1-11 ordinary shares	(1,871)	—	1,871	—	—
Issuance of shares in initial public offering, net	25	19,450	—	—	19,475
Balance at December 31, 2015	256	326,031	2,489	(167,615)	161,161

The accompanying notes are an integral part of the Company Financial Statements.

NOTES TO COMPANY BALANCE SHEET

1. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

a. Basis of preparation

The financial statements of Strongbridge Biopharma plc (formerly known as Cortendo plc) ("Strongbridge" or the "Company"), have been prepared under the historical cost convention in accordance with FRS 102 - The Financial Reporting Standard applicable in the UK and Republic of Ireland ("FRS 102"), comprising applicable company law and the accounting standards issued by the Financial Reporting Council and promulgated by the Institute of Chartered Accountants in Ireland (Generally Accepted Accounting Practice in Ireland). The accompanying Balance Sheet of the Company is presented on a stand-alone basis, including related party transactions.

The financial statements of the Company have been prepared on the going concern basis. The directors have taken into account all relevant information covering a period of at least twelve months from the date of approval of the financial statements. The directors believe that the Company is well placed to manage its business risks successfully despite the current uncertain economic outlook. After making enquiries, the directors have a reasonable expectation that the Company has access to adequate resources to continue in operational existence for the foreseeable future. On that basis, the directors consider it appropriate to continue the use of the going concern assumption.

Strongbridge Biopharma plc is availing of the reduced disclosure framework under FRS 102 on the basis that Strongbridge Biopharma plc itself meets the definition of a qualifying entity, being a member of a group that prepare publicly available financial statements which give a true and fair view, and in which Strongbridge Biopharma plc is consolidated. The consolidated financial statements, in which these Company financial statements are included are available to the public at its registered office.

Strongbridge Biopharma plc has taken advantage of the following disclosure exemptions under FRS 102:

a. the requirements of section 4 Statement of Financial Position- Paragraph 4.12 (a) (iv).

b. the requirements of section 7 Statement of Cash Flows and Section 3 Financial Statement Presentation paragraph 3.17(d).

c. the requirements of Section 26 Share based Payment: paragraph 26.18 (b), 26.19 to 26.21 and 26.23.

d. requirements of Section 33 Related Party Disclosures, paragraph 33.7.

The accounting policies which follow set out those policies which apply in preparing the financial statements for the year ended 31 December 2015.

b. Judgements and key sources of estimation uncertainty

The preparation of financial statements requires management to make judgements, estimates and assumptions that affect the amounts reported for assets and liabilities as at the statement of financial position date and the amounts reported for revenues and expenses during the year. However, the nature of estimation means that actual outcomes could differ from those estimates.

The following judgements have the most significant effect on amounts recognised in the financial statements.

Taxation

Management estimation is required to determine the amount of deferred tax assets that can be recognised based upon likely timing and level of future taxable profits together with assessment of the effect of future tax planning strategies.

NOTES TO COMPANY BALANCE SHEET

1. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

b. Judgements and key sources of estimation uncertainty (continued)

Impairment of investments in group undertakings

Where there are indicators of impairment of investments in group undertakings, the Company performs impairment tests based on fair value less costs to sell or a value in use calculation. The fair value less costs to sell calculation is based on available data from binding sales transactions in an arm's length transaction on similar assets or observable market prices less incremental costs for disposing of the asset.

c. Functional currency

Items included in these financial statements are measured using the currency of the primary economic environment in which the Company operates (the "functional currency"). The financial statements are presented in the United States Dollars ("$"), which is the Company's functional and presentation currency.

Transactions during the period denominated in foreign currencies have been translated at the rates of exchange ruling at the dates of the transactions. Monetary assets and liabilities denominated in foreign currencies are translated to US$ at the rate of exchange ruling at the balance sheet date. The resulting profits or losses are dealt with in the profit and loss account.

d. Investment in group companies

Investments in subsidiaries are recognised at cost less impairment.

The Company assesses at each reporting date whether investments in group undertakings may be impaired. If any such indication exists the Company estimates the recoverable amount of investments. If it is not possible to estimate the recoverable amount of the individual investments, the Company estimates, the recoverable amount of the cash generating unit to which the investments belongs. The recoverable amount of an investment or cash-generating unit is the higher of its fair value less costs to sell and its value in use. If the recoverable amount is less than its carrying amount, the carrying amount of the investment is impaired and it is reduced to its recoverable amount through an impairment in the income statement unless the investment is carried at a revalued amount where the impairment loss of a revalued asset is a revaluation decrease.

An impairment loss recognised for investments in group undertakings is reversed in a subsequent period if and only if the reasons for the impairment loss have ceased to apply.

e. Dividends

Dividends on Ordinary shares are recognised as a liability in the period in which they are declared by the Company.

NOTES TO COMPANY BALANCE SHEET

1. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

f. Financial instruments

Cash at bank and in hand

Cash and cash equivalents in the Statement of Financial Position comprise cash at bank and in hand and short term deposits with an original maturity date of three months or less.

Short-term debtors and creditors

Debtors and creditors with no stated interest rate and receivable or payable within one year are recorded at transaction price. Any losses arising from impairment are recognised in the income statement in operating expenses.

g. Profit and loss account

In accordance with Section 304 of the Companies Act 2014 the Company is availing of the exemption from presenting the individual profit and loss account. The Company's loss for the period from May 26, 2015 (date of incorporation) to December 31, 2015 was $167,615 thousand.

h. Taxation

Deferred taxation is accounted for in respect of all timing differences at tax rates enacted or substantively enacted at the balance sheet date. Timing differences arise from the inclusion of items of income and expenditure in tax computations in periods different from those in which they are included in the financial statements. A deferred tax asset is only recognised when it is more likely than not the asset will be recoverable in the foreseeable future out of suitable taxable profits from which the underlying timing differences can be recovered.

i. Share based payments

The Company and its subsidiaries operate various share based payment plans. The Company issues Ordinary shares related to these employee equity share programs at various subsidiaries.

The share based payment expense associated with the share plans is recognised as an expense by the entity which receives services in exchange for the share based compensation. In these Company only accounts, the expense related to the options vested are recorded in other reserves and charged to the appropriate entity that receives services.

2. HISTORY AND DESCRIPTION OF THE COMPANY

Strongbridge Biopharma plc (formerly known as Cortendo plc) ("Strongbridge" or "the Company"), was incorporated under the laws of Ireland on May 26, 2015 with registered number 562659 as a public limited company under the Companies Act 2014 and is domiciled in Ireland.

The Company is a biopharmaceutical entity focused on the development, in-licensing, acquisition and eventual commercialisation of multiple complementary products and product candidates within franchises that target rare diseases. The primary focus to date has been to build the rare endocrine franchise, which includes product candidates for the treatment of Cushing's syndrome and acromegaly, two rare diseases with a high unmet need for innovative treatment options. The Company intends to identify and in-license or acquire products or product candidates that will be complementary to the existing rare endocrine franchise or that would form the basis for new rare disease franchises.

NOTES TO COMPANY BALANCE SHEET

2. HISTORY AND DESCRIPTION OF THE COMPANY (CONTINUED)

On August 7, 2015, the Company initiated an exchange offer for the outstanding shares of Cortendo AB. Cortendo AB shares were quoted on NOTC-A list. However, on October 15, 2015, a registration statement was declared effective by the U.S. Securities and Exchange Commission and on October 16, 2015 the initial U.S. public offering of 2,500,000 ordinary shares at a price to the public became effective commencing the listing and trading on the NASDAQ Global Select Market under the symbol "SBBP". As a result of the above, on October 20, 2015, trading ceased on the NOTC-A list.

The exchange offer was structured as a one-for-one exchange offer in which shareholders of Cortendo AB exchanged their common shares, with a par value of $0.15, for beneficial interests in ordinary shares of Strongbridge, with a par value of SEK 1, in the form of Norwegian depositary receipts and, as the case may be, Swedish depositary receipts (except for non-accredited investors who hold Cortendo AB shares located in the United States, who were offered cash in an amount equivalent to the value of the Strongbridge shares such investors would otherwise receive for their Cortendo AB shares exchanged).

The exchange offer was settled on September 8, 2015, and Cortendo AB became a subsidiary with 99.582% of its shares being owned by Strongbridge. Accordingly, On September 8, 2015, Strongbridge affected a 1-for-11 reverse stock split of its ordinary shares

3. FINANCIAL FIXED ASSETS

As at December 31, 2015 the Company had one subsidiary, Cortendo AB.

	Cortendo AB $'000
Arising on exchange offer as at September 8, 2015 on allotment of shares	308,639
Share based payments during the period	618
Impairment at year end	(166,839)
Balance as at December 31, 2015	142,418

In order to effect a corporate reorganization, on September 8, 2015 we settled an exchange offer, which we refer to as the Exchange Offer, pursuant to which holders of 99.449% of the outstanding shares of Cortendo AB exchanged their shares for beneficial interests in ordinary shares of Strongbridge Biopharma plc in the form of depositary receipts on a 1-for-1 basis and non-accredited holders of Cortendo AB shares located within the United States, representing 0.133% of the outstanding shares of Cortendo AB, agreed to exchange their shares for cash, which cash settlement occurred on September 14, 2015. Non-accredited U.S. holders of ordinary shares of Cortendo AB received cash in an amount equivalent to the value of one ordinary share of Strongbridge Biopharma plc for each share of Cortendo AB validly exchanged. Pursuant to individual agreements with the holders of options to purchase shares of Cortendo AB, the outstanding options of Cortendo AB were converted to options to purchase an equivalent number of ordinary shares of Strongbridge Biopharma plc.

We intend to acquire the remaining 0.418% of the outstanding shares of Cortendo AB held by shareholders who declined to participate in the Exchange Offer, pursuant to a process permitted by Swedish law.

Following the settlement of the Exchange Offer, Strongbridge Biopharma plc became the parent of Cortendo AB and its subsidiaries.

NOTES TO COMPANY BALANCE SHEET

3. FINANCIAL FIXED ASSETS (CONTINUED)

Impairment of financial fixed assets

The Financial Fixed Asset initially recorded on the Company's balance sheet of approximately $308.6 million reflected a $16.50 per share value placed on the shares issued upon the closing of the exchange offer. On December 31, 2015, the closing share price was $7.60, resulting in the market value of the Company's assets being considerably lower than the carrying value of the financial fixed assets at that date. Accordingly, the Company recorded an impairment charge in the profit and loss account of $166.8 million.

4. CASH AND CASH EQUIVALENTS

Cash at bank and in hand includes cash in hand, deposits held at call with banks, other short term highly liquid investments with original maturity of three months or less. The total amount of cash and cash equivalents held at 31 December 2015 in thousands was $21,782. Cash is maintained in two accounts with Bank of America.

At 31 December 2015, Bank of America had a credit rating of A1 (Moody's Investor Services Limited).

5. DEBTORS

Prepaid expenses and other current assets as at 31 December 2015 can be summarised as follows:

	$'000
Prepaid insurance	245
Other prepayments	15
Total	260

6. CREDITORS

Creditors (amounts due within one year) as at 31 December 2015 can be summarised as follows:

	$'000
Amounts due to subsidiary undertaking	3,040
Professional fees	173
Accrued director fees	78
Other	8
Total	3,299

7. SHARE CAPITAL

Ordinary shares

Voting rights and privileges

As of December 31, 2015, the authorised share capital of the Company is €40,000 and $7,000,000 divided into 40,000 deferred ordinary shares of €1.00 each, 600,000,000 ordinary shares of $0.01 each, par value and 100,000,000 preferred shares of $0.01 each, par value.

7. SHARE CAPITAL (CONTINUED)

As of December 31, 2015, there were 40,000 deferred ordinary shares of €1.00 each and 21,205,382 ordinary shares of $0.01 each outstanding, respectively.

The holders of ordinary shares are entitled to one vote for each ordinary share held at all general meetings of shareholders without limitation. The holders are entitled to receive dividends if and when declared by the Board of Directors or by the Company in general meeting, provided no dividend shall exceed the amount recommended by the Board of Directors. No dividends have been declared or paid since inception. The holders are entitled to share rateably in the assets available for distribution to shareholders, in the event of any voluntary or involuntary liquidation.

The deferred ordinary shares are issued in order to satisfy an Irish legislative requirement to maintain a minimum level of issued share capital denominated in euro. The deferred ordinary shares carry no voting rights and are not entitled to any dividend or distribution.

The authorised share capital for the Company for the period ended 31 December 2015 can be summarised as follows:

	Deferred ordinary shares with par value of €1.00 each No of shares	Ordinary shares with par value of $0.01 each No of shares	Preferred shares with par value of $0.01 each No of shares
Incorporated on May 26, 2015 with authorised share capital of 1,000,000 ordinary shares of €1.00 each	1,000,000		
On August 7, 2015 reduction of 960,000 ordinary shares of €1.00 each	(960,000)		
On August 7, 2015 authorisation of 600,000,000 ordinary shares of $0.01 each		600,000,000	
On August 7, 2015 authorisation of 100,000,000 preferred shares of $0.01 each			100,000,000
	40,000	600,000,000	100,000,000

In May 26, 2015, Strongbridge Biopharma plc (then named Cortendo plc), was incorporated under the laws of Ireland and issued 40,000 ordinary shares issued, par value €1.00. These shares were subsequently re-designated as deferred ordinary shares.

On August 7, 2015, the authorised share capital of the Company was amended by the reduction of 960,000 ordinary shares with a par value of €1.00 per share.

On August 7, 2015 authorised share capital was increased by 600,000,000 ordinary shares of $0.01 each and 100,000,000 preferred shares of $0.01 each.

7. SHARE CAPITAL (CONTINUED)

The issued share capital for the Company for the period ended 31 December 2015 can be summarised as follows:

	Deferred ordinary shares with par value of €1.00 each No of shares	Ordinary shares with par value of $0.01 each No of shares	Issued Share Capital at par €1.00/$0.01 $'000
On May 26, 2015, 40,000 ordinary shares issued, par value €1.00	40,000		44
On September 8, 2015 allotment of 205,759,204 ordinary shared issued, par value $0.01		205,759,204	2,058
On September 8, 2015 reverse stock split of 1-11 on ordinary shares, par value $0.01		(187,053,822)	(1,871)
On October 22, 2015 issued 2,500,000 ordinary shares, par value $0.01 by Initial Public Offering		2,500,000	25
	40,000	21,205,382	256

8. CAPITAL & RESERVES

	Share Premium $'000	Other Reserves $'000	Retained Earnings $'000
On May 26, 2015, 40,000 deferred ordinary shares issued, par value €1.00	—	—	—
On September 8, 2015 allotment of 205,759,204 ordinary shared issued, par value $0.01	306,581	—	—
On September 8, 2015 reverse stock split of 1-11 on ordinary shares, par value $0.01	—	1,871	—
On October 16, 2015 issued 2,500,000 ordinary shares, par value $0.01 by Initial Public Offering	19,450	—	—
Share based payment (see Note 10)	—	618	—
Net loss for the period	—	—	(167,615)
	326,031	2,489	(167,615)

NOTES TO COMPANY BALANCE SHEET

8. CAPITAL & RESERVES (CONTINUED)

On August 7, 2015, Strongbridge Biopharma plc initiated an exchange offer for the outstanding shares of Cortendo AB. The exchange offer was structured as a one-for-one exchange offer in which shareholders of Cortendo AB exchanged their common shares, with a par value of $0.15, for beneficial interests in ordinary shares of Strongbridge Biopharma plc, with a par value of $0.01, in the form of Norwegian depositary receipts and, as the case may be, Swedish depositary receipts (except for non-accredited investors who hold Cortendo AB shares located in the United States, who were offered cash in an amount equivalent to the value of the Strongbridge Biopharma plc shares such investors would otherwise receive for their Cortendo AB shares exchanged).

The exchange offer was settled on September 8, 2015, and Cortendo AB became a subsidiary with 99.582% of its shares being owned by Strongbridge Biopharma plc. The value of the consideration of the exchange amounted to NOK2,551,414,130 or $308,638,806 being the market capitalisation of Cortendo AB at that date.

On September 8, 2015, Strongbridge Biopharma plc effected a 1 for 11 reverse stock split of its ordinary shares through the purchase of 187,053,822 shares in the Company for $Nil consideration. These shares were subsequently cancelled by the Company resulting in the Capital Redemption Reserve at 31 December 2015.

On October 15, 2015, a registration statement was declared effective by the U.S. Securities and Exchange Commission and on October 16, 2015 the Company initiated an initial U.S. public offering (IPO) of 2,500,000 ordinary shares at a price of $10.00 per share. The aggregate net proceeds received by us from the IPO were $19.5 million net of costs of $5.5 million. The shares began trading on The NASDAQ Global Select Market under the symbol "SBBP". On October 20, 2015, trading ceased on the Norwegian Over-The-Counter Market, or NOTC.

Share premium account

This reserve records the amount above the nominal value received for shares sold, less transaction costs.

Other reserves

Other reserves include $1,870,538 in relation to the Capital Redemption Reserve described above and $617,745 in relation to the Share Based Payment Reserve at 31 December 2015. This Share Based Payment Reserve is used to recognise the value of equity-settled share-based payments provided to employees of the group as part of their remuneration.

9. SHARE BASED PAYMENTS

Share based payment charges of $617,745 has been included in Other Reserves and Financial Fixed Assets. See notes to the Consolidated Financial Statements for full details on share based payment arrangements. This charge related to share based payment charges incurred subsequent to the exchange offer completion on September 8, 2015.

10. RELATED PARTY TRANSACTIONS

The Profit and Loss account includes $78,312 of directors' fees for the period ended 31 December 2015 being the full amount of directors' remuneration in the period.

There were no contracts of any significance in relation to the business of the Company in which the directors had any interest, as defined in the Companies Act, 2014, at any time during the year or at the end of the financial year.

NOTES TO COMPANY BALANCE SHEET

10. RELATED PARTY TRANSACTIONS (CONTINUED)

In accordance with section 33 paragraph 1A of FRS 102, disclosures need not be given of transactions entered into between two or more members of a group, provided that any subsidiary which is a party to the transaction is wholly owned by such a member. The Company has availed of this exemption.

11. AUDITOR'S REMUNERATION

The fees paid to Ernst & Young Ireland with respect to the audit of the Company individual accounts were $63,000 excluding VAT in the period ended 31 December 2015. In addition, Ernst & Young Ireland received fees for other assurance services of $117,000 in 2015. Ernst & Young did not receive any fees for non-audit services or tax compliance and advisory services in 2015. The notes to the Consolidated Financial Statements provide additional information regarding auditor remuneration.

12. TAXATION

The company has incurred tax losses in the year that are available indefinitely for offset against future taxable profits. A deferred tax asset has not been recognised in respect to these losses as it is not probable that they will be recovered against future taxable profits.

13. SUBSEQUENT EVENTS

There were no significant subsequent events from the end of the year until the date of signing of this report that would require an adjustment to or disclosure in the financial statements.

14. APPROVAL OF THE FINANCIAL STATEMENTS

The Financial Statements were approved and authorised for issue by the Board of Directors on April 12, 2016.

STRONGBRIDGE BIOPHARMA

IMPORTANT ANNUAL GENERAL MEETING INFORMATION

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Electronic Voting Instructions

Available 24 hours a day, 7 days a week!

Instead of mailing your proxy, you may choose one of the voting methods outlined below to vote your proxy.

VALIDATION DETAILS ARE LOCATED BELOW IN THE TITLE BAR.

Proxies submitted by the Internet or telephone must be received by 5:00 p.m., Eastern Time, on May 9, 2016.

Vote by Internet

- Go to **www.envisionreports.com/SBBP**
- Or scan the QR code with your smartphone
- Follow the steps outlined on the secure website

Submit your proxy by telephone

- Call toll free 1-800-652-VOTE (8683) within the USA, US territories & Canada on a touch tone telephone
- Follow the instructions provided by the recorded message

Using a **black ink** pen, mark your votes with an **X** as shown in this example. Please do not write outside the designated areas. [X]

Annual General Meeting Proxy Card

1234 5678 9012 345

▼ IF YOU HAVE NOT VOTED VIA THE INTERNET OR SUBMITTED YOUR PROXY BY TELEPHONE, FOLD ALONG THE PERFORATION, DETACH AND RETURN THE BOTTOM PORTION IN THE ENCLOSED ENVELOPE TO BE RECEIVED BY 5:00 P.M. EASTERN TIME ON MAY 9, 2016. ▼

A Proposals — The Board of Directors recommends a vote FOR all the nominees listed and FOR Proposal 2.

1. To re-elect, by separate resolutions, the following individuals who retire as Directors in accordance with the Articles of Association of the Company and, being eligible, offer themselves for re-election as Class I directors:

	For	Against	Abstain
1.1 - Hilde Steineger, Ph.D.	☐	☐	☐
1.2 - Mårten Steen, M.D., Ph.D.	☐	☐	☐

	For	Against	Abstain
2. To authorise the Board of Directors, acting through its Audit Committee, to determine the remuneration of the auditors.	☐	☐	☐

B Non-Voting Items

Change of Address — Please print your new address below.

Comments — Please print your comments below.

Meeting Attendance
Mark the box to the right if you plan to attend the Annual General Meeting. ☐

C Authorized Signatures — This section must be completed for your vote to be counted. — Date and Sign Below

Please sign exactly as name(s) appears hereon. Joint owners should each sign. When signing as attorney, executor, administrator, corporate officer, trustee, guardian, or custodian, please give full title.

Date (mm/dd/yyyy) — Please print date below. / /

Signature 1 — Please keep signature within the box.

Signature 2 — Please keep signature within the box.

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2016 Annual General Meeting Admission Ticket

2016 Annual General Meeting of
Strongbridge Biopharma plc Shareholders

Thursday, May 12, 2016 at 10:00 a.m. Dublin Time
Offices of Arthur Cox
Earlsfort Terrace
Dublin, D02 CK83, Ireland

Upon arrival, please present this admission ticket and photo identification at the registration desk.

▼ IF YOU HAVE NOT VOTED VIA THE INTERNET OR SUBMITTED YOUR PROXY BY TELEPHONE, FOLD ALONG THE PERFORATION, DETACH AND RETURN THE BOTTOM PORTION IN THE ENCLOSED ENVELOPE. ▼

STRONGBRIDGE BIOPHARMA

Proxy — Strongbridge Biopharma plc

Notice of 2016 Annual General Meeting of Shareholders

Offices of Arthur Cox, Earlsfort Terrace, Dublin, D02 CK83, Ireland
Proxy Solicited by Board of Directors for Annual General Meeting — May 12, 2016

A. Brian Davis and Stephen J. Long, or any of them, each with the power of substitution, are hereby authorized to represent and vote the shares of the undersigned, with all the powers which the undersigned would possess if personally present, at the Annual General Meeting of Shareholders of Strongbridge Biopharma plc to be held on May 12, 2016 or at any postponement or adjournment thereof.

Shares represented by this proxy will be voted as instructed by the shareholder. If no such instructions are indicated, the Proxies will have authority to vote FOR Proposals 1.1 and 1.2 (the re-elections of Hilde Steineger, Ph.D. and Mårten Steen, M.D., Ph.D. as Class I directors) and **FOR Proposal 2** (to authorise the Board of Directors, acting through its Audit Committee, to determine the remuneration of the auditors).

In their discretion, the Proxies are authorized to vote upon such other business as may properly come before the meeting.

(Items to be voted appear on reverse side.)