

NOVO NORDISK A S
Form 6-K
March 04, 2016

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 6-K

REPORT OF FOREIGN PRIVATE ISSUER

Pursuant to Rule 13a-16 or 15d-16
of the Securities Exchange Act of 1934

March 4, 2016

NOVO NORDISK A/S

(Exact name of Registrant as specified in its charter)

Novo Allé

DK- 2880, Bagsvaerd

Denmark

(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 whether the registrant by furnishing the information contained in this Form is also thereby furnishing the information to the Commission pursuant to Rule 12g3-2(b) under the Securities Exchange Act of 1934.

Yes No

If “Yes” is marked, indicate below the file number assigned to the registrant in connection with Rule 12g-32(b):82-_____

Victoza® significantly reduces the risk of major adverse cardiovascular events in the LEADER trial

Bagsværd, Denmark, 4 March 2016 - Novo Nordisk today announced the top-line results from the LEADER trial, which investigated the cardiovascular safety of Victoza® (liraglutide) over a period of up to 5 years in more than 9,000 adults with type 2 diabetes at high risk of major adverse cardiovascular events. The trial compared the addition of either Victoza® or placebo to standard of care and met the primary endpoint of showing non-inferiority as well as demonstrating superiority, with a statistically significant reduction in cardiovascular risk. The primary endpoint of the study was defined as the composite outcome of the first occurrence of cardiovascular death, non-fatal myocardial infarction or non-fatal stroke. The superior reduction of major adverse cardiovascular events demonstrated by Victoza® was derived from all three components of the endpoint.

The safety profile of Victoza® in LEADER was generally consistent with previous liraglutide clinical studies.

“People with type 2 diabetes generally have a higher risk of experiencing major adverse cardiovascular events. That’s why we are very excited about the results from LEADER, which showed that Victoza®, in addition to helping people with type 2 diabetes control their blood sugar levels, also reduces their risk of major adverse cardiovascular events”, said Mads Krogsgaard Thomsen, executive vice president and chief science officer of Novo Nordisk. “LEADER is the largest and longest Novo Nordisk clinical trial to report to date, and we look forward to sharing the detailed results with the medical community and submitting the findings to the regulatory authorities.”

The detailed results are planned to be presented at the 76th Scientific Sessions of the American Diabetes Association in June 2016.

Conference call

On 4 March 2016 at 2.00 pm CET, corresponding to 8.00 am EST, a conference call for investors will be held. Investors will be able to listen in via a link on the investor section of novonordisk.com.

About LEADER

LEADER was a multicentre, international, randomised, double-blind, placebo-controlled trial investigating the long-term effects of Victoza® (1.2 and 1.8 mg) compared to placebo, both in addition to standard of care, in people with type 2 diabetes at high risk of cardiovascular events. The trial was initiated in September 2010 and randomised 9,340 people with type 2 diabetes from 32 countries that were followed for 3.5–5 years. The primary endpoint was the first occurrence of a composite cardiovascular outcome comprising cardiovascular death, non-fatal myocardial infarction or non-fatal stroke.

About Victoza®

Victoza® (liraglutide) is a human glucagon-like peptide-1 (GLP-1) analogue with an amino acid sequence 97% similar to endogenous human GLP-1.

Victoza® was launched in the EU in 2009 and is commercially available in more than 80 countries with more than 3 million patient years of use in people with type 2 diabetes globally. In Europe, Victoza® is indicated for treatment of adults with type 2 diabetes to achieve glycaemic control in combination with oral glucose-lowering medicinal products and/or basal insulin when these, together with diet and exercise, do not provide adequate glycaemic control. Victoza® was approved by the U.S. Food and Drug Administration in 2010, as an adjunct to diet and exercise to improve glycaemic control in adults with type 2 diabetes.

Novo Nordisk is a global healthcare company with more than 90 years of innovation and leadership in diabetes care. This heritage has given us experience and capabilities that also enable us to help people defeat other serious chronic conditions: haemophilia, growth disorders and obesity. Headquartered in Denmark, Novo Nordisk employs approximately 41,000 people in 75 countries and markets its products in more than 180 countries. Novo Nordisk's B shares are listed on Nasdaq Copenhagen (Novo-B). Its ADRs are listed on the New York Stock Exchange (NVO). For more information, visit novonordisk.com, Facebook, Twitter, LinkedIn, YouTube

Further information

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CVR no:
24 25 67 90
Company announcement No 20 / 2016

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 of the undersigned, thereunto duly authorized.

Date: March 4, 2016

NOVO NORDISK A/S

Lars Rebien Sørensen

Chief Executive Officer

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\$844(2)

- (1) Pursuant to Rule 416 under the Securities Act of 1933, this Registration Statement includes an indeterminate number of additional shares as may be issuable as a result of a stock split, stock dividend or similar adjustment of the outstanding shares of the common stock of First PacTrust Bancorp, Inc.
- (2) Calculated in accordance with Rule 457 under the Securities Act of 1933, based on: (i) with respect to the 605,000 shares being registered which are issuable upon exercise of the stock options referred to herein, the respective exercise prices of such options; and (ii) with respect to the 21,500 shares awarded as restricted stock as described herein, the average of the high and low sale prices per share of the common stock on the NASDAQ Stock Market on February 25, 2011 of \$15.79.

PART I
INFORMATION REQUIRED IN THE SECTION 10(a) PROSPECTUS

As an inducement material to their entering into employment with First PacTrust Bancorp, Inc. (the “Company”), the Company made equity compensation grants to the following individuals:

- (i) Gregory A. Mitchell, President and Chief Executive Officer of the Company: grant of an option to purchase 300,000 shares of the Company’s voting common stock, par value \$0.01 per share (the “Common Stock”), at an exercise price of \$11.35 per share;
- (ii) Richard Herrin, Executive Vice President and Chief Administrative Officer of Pacific Trust Bank (the “Bank”), a wholly owned subsidiary of the Company: grant of an option to purchase 65,000 shares of Common Stock at an exercise price of \$11.60 per share and grant of 4,200 shares of restricted stock;
- (iii) Matthew Bonaccorso, Executive Vice President and Chief Credit Officer of the Bank: grant of an option to purchase 100,000 shares of Common Stock at an exercise price of \$11.36 and grant of 5,000 shares of restricted stock;
- (iv) Gaylin Anderson, Executive Vice President and Chief Retail Banking Officer of the Bank; grant of an option to purchase 60,000 shares of Common Stock at an exercise price of \$11.36 and grant of 5,000 shares of restricted stock;
- (v) Joseph Abraham, Senior Vice President and Director of Credit Services of the Bank; grant of an option to purchase 30,000 shares of Common Stock at an exercise price of \$11.78 and grant of 3,000 shares of restricted stock; and
- (vi) Chang Liu, Executive Vice President and Chief Lending Officer of the Bank; grant of an option to purchase 50,000 shares of Common Stock at an exercise price of \$11.88 and grant of 4,300 shares of restricted stock.

The foregoing grants were approved by the Compensation Committee of the Company’s Board of Directors in reliance on NASDAQ Listing Rule 5635(c)(4), which exempts employment inducement grants from the general requirement of the NASDAQ Listing Rules that equity-based compensation plans and arrangements be approved by stockholders. This Registration Statement registers the shares of Common Stock issuable upon exercise of the options granted and the shares of Common Stock issued in connection with the restricted stock grants.

The document(s) containing the information specified in Part I of Form S-8 will be sent or given to the recipients of the foregoing grants, as required by Rule 428(b)(1) promulgated by the Securities and Exchange Commission (the “Commission”) under the Securities Act of 1933, as amended (the “Securities Act”).

Such document(s) are not being filed with the Commission, but constitute (along with the documents incorporated by reference into the Registration Statement pursuant to Item 3 of Part II hereof) a prospectus that meets the requirements of Section 10(a) of the Securities Act.

PART II
INFORMATION NOT REQUIRED IN PROSPECTUS

Item 3. Incorporation of Certain Documents by Reference.

The following documents previously or concurrently filed by the Company with the Commission (File No. 000-49806) (excluding any portion of such documents that has been furnished to and deemed not to be filed with the Commission) are hereby incorporated by reference into this Registration Statement and the Prospectus to which this Registration Statement relates (the "Prospectus"):

- (a) the Company's Annual Report on Form 10-K for the year ended December 31, 2010;
- (b) the Company's Current Reports on Form 8-K filed on January 5, 2011, January 27, 2011, February 24, 2011, February 25, 2011 and February 28, 2011; and
- (c) the description of the Common Stock contained in the Company's Registration Statement on Form 8-A filed on May 8, 2002, and all amendments or reports filed for the purpose of updating such description.

All documents filed by the Company with the Commission pursuant to Sections 13(a), 13(c), 14, or 15(d) of the Securities Exchange Act of 1934, as amended (the "Exchange Act") (excluding any document or portion thereof that has been furnished to and deemed not to be filed with the Commission), after the filing of this Registration Statement, and prior to the filing of a post-effective amendment which indicates that all securities offered hereby have been sold or which deregisters all securities then remaining unsold, shall be deemed incorporated by reference into this Registration Statement and the Prospectus and to be a part hereof and thereof from the date of the filing of such documents. Any statement contained in the documents incorporated, or deemed to be incorporated, by reference herein or therein shall be deemed to be modified or superseded for purposes of this Registration Statement and the Prospectus to the extent that a statement contained herein or therein or in any other subsequently filed document which also is, or is deemed to be, incorporated by reference herein or therein modifies or supersedes such statement. Any such statement so modified or superseded shall not be deemed, except as so modified or superseded, to constitute a part of this Registration Statement and the Prospectus.

The Company shall furnish without charge to each person to whom the Prospectus is delivered, on the written or oral request of such person, a copy of any or all of the documents incorporated by reference, other than exhibits to such documents (unless such exhibits are specifically incorporated by reference to the information that is incorporated). Requests should be directed to: Investor Relations, First PacTrust Bancorp, Inc., 610 Bay Boulevard, Chula Vista, California 91910, telephone: (619) 691-1519.

All information appearing in this Registration Statement and the Prospectus is qualified in its entirety by the detailed information, including financial statements, appearing in the documents incorporated herein or therein by reference.

Item 4. Description of Securities.

Not Applicable.

Item 5. Interests of Named Experts and Counsel.

Not Applicable.

Item 6. Indemnification of Directors and Officers.

Section 2-405.2 of the Maryland General Corporation Law permits a Maryland corporation to include in its charter a provision limiting the liability of its directors and officers to the corporation and its stockholders for monetary damages except: (1) to the extent it is proven that the director or officer actually received an improper benefit or profit, for the amount of the improper benefit or profit; or (2) to the extent a final judgment or adjudication against the director or officer is based on a determination that the director's or officer's act or failure to act was the result of active and deliberate dishonesty and was material to the cause of action against the director or officer. The

Company's charter contains such a provision, thereby limiting the liability of its directors and officers to the maximum extent permitted by Maryland law.

Section 2-418 of the Maryland General Corporation Law permits a Maryland corporation to indemnify a director or officer who is made a party to any proceeding by reason of service in that capacity against judgments, penalties, fines, settlements and reasonable expenses actually incurred unless it is proven that: (1) the act or omission of the director or officer was material to the matter giving rise to the proceeding and was committed in bad faith or with active and deliberate dishonesty; (2) the director or officer actually received an improper personal benefit; or (3) in the case of a criminal proceeding, the director or officer had reason to believe that his conduct was unlawful. The Maryland General Corporation Law provides that where a director or officer is a defendant in a proceeding by or in the right of the corporation, the director or officer may not be indemnified if he or she is found liable to the corporation. The Maryland General Corporation Law also provides that a director or officer may not be indemnified in respect of any proceeding alleging improper personal benefit in which he or she was found liable on the grounds that personal benefit was improperly received. A director or officer found liable in a proceeding by or in the right of the corporation or in a proceeding alleging improper personal benefit may petition a court to nevertheless order indemnification of expenses if the court determines that the director or officer is fairly and reasonably entitled to indemnification in view of all the relevant circumstances.

Section 2-418 of the Maryland General Corporation Law provides that unless limited by the charter of a Maryland corporation, a director or an officer who is successful on the merits or otherwise in defense of any proceeding must be indemnified against reasonable expenses. Section 2-418 also provides that a Maryland corporation may advance reasonable expenses to a director or an officer upon the corporation's receipt of (a) a written affirmation by the director or officer of his or her good faith belief that he or she has met the standard of conduct necessary for indemnification by the corporation and (b) a written undertaking by the director or officer or on his or her behalf to repay the amount paid or reimbursed by the corporation if it is ultimately determined that the standard of conduct was not met

The Company's charter provides for indemnification of directors and officers to the maximum extent permitted by the Maryland General Corporation Law.

Under a directors' and officers' liability insurance policy, directors and officers of the Company are insured against certain liabilities.

Item 7. Exemption from Registration Claimed.

Not Applicable.

Item 8. Exhibits.

See Exhibit Index.

Item 9. Undertakings.

(a) The undersigned registrant hereby undertakes:

(1) To file, during any period in which offers or sales are being made, a post-effective amendment to this registration statement:

(i) To include any prospectus required by section 10(a)(3) of the Securities Act of 1933;

(ii) To reflect in the prospectus any facts or events arising after the effective date of the registration statement (or the most recent post-effective amendment thereof) which, individually or in the aggregate, represent a fundamental change in the information set forth in the registration statement. Notwithstanding the foregoing, any increase or decrease in volume of securities offered (if the total dollar value of securities offered would not exceed that which was registered) and any deviation from the low or high end of the estimated maximum offering range may be reflected in the form of prospectus filed with the Commission pursuant to Rule 424(b) if, in the aggregate, the changes in volume and price represent no more than a 20% change in the maximum aggregate offering price

set forth in the "Calculation of Registration Fee" table in the effective registration statement; and

(iii) To include any material information with respect to the plan of distribution not previously disclosed in the registration statement or any material change to such information in the registration statement;

provided, however, that paragraphs (a)(1)(i) and (a)(1)(ii) do not apply if the information required to be included in a post-effective amendment by those paragraphs is contained in reports filed with or furnished to the Commission by the registrant pursuant to Section 13 or Section 15(d) of the Securities Exchange Act of 1934 that are incorporated by reference in the registration statement.

(2) That, for the purpose of determining any liability under the Securities Act of 1933, each such post-effective amendment shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

(3) To remove from registration by means of a post-effective amendment any of the securities being registered which remain unsold at the termination of the offering.

(b) The undersigned registrant hereby undertakes that, for purposes of determining any liability under the Securities Act of 1933, each filing of the registrant's annual report pursuant to Section 13(a) or Section 15(d) of the Securities Exchange Act of 1934 that is incorporated by reference in the registration statement shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

(c) Insofar as indemnification for liabilities arising under the Securities Act of 1933 may be permitted to directors, officers and controlling persons of the registrant pursuant to the foregoing provisions, or otherwise, the registrant has been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer or controlling person of the registrant of expenses incurred or paid by a director, officer or controlling person in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Act and will be governed by the final adjudication of such issue.

SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, the registrant certifies that it has reasonable grounds to believe that it meets all of the requirements for filing on Form S-8 and has duly caused this Registration Statement to be signed on its behalf by the undersigned, thereunto duly authorized in the City of Chula Vista, State of California, on the 2nd day of March, 2011.

FIRST PACTRUST BANCORP, INC.

By: /s/ Gregory A. Mitchell
Gregory A. Mitchell
President and Chief Executive Officer
(Duly Authorized Representative)

POWER OF ATTORNEY

We, the undersigned officers and directors of First PacTrust Bancorp, Inc., hereby severally and individually constitute and appoint Gregory A. Mitchell and Regan Lauer, and each of them, the true and lawful attorneys and agents of each of us to execute in the name, place and stead of each of us (individually and in any capacity stated below) any and all amendments (including post-effective amendments) to this registration statement and all instruments necessary or advisable in connection therewith and to file the same with the Securities and Exchange Commission, each of said attorneys and agents to have the power to act with or without the others and to have full power and authority to do and perform in the name and on behalf of each of the undersigned every act whatsoever necessary or advisable to be done in the premises as fully and to all intents and purposes as any of the undersigned might or could do in person, and we hereby ratify and confirm our signatures as they may be signed by our said attorneys and agents or each of them to any and all such amendments and instruments

Pursuant to the requirements of the Securities Act of 1933, this Registration Statement has been signed by the following persons in the capacities and on the dates indicated.

/s/ Gregory A. Mitchell
Gregory A. Mitchell
President and Chief Executive Officer and
Director
(Principal Executive Officer)

/s/ Regan J. Lauer
Regan J. Lauer
Senior Vice President and Controller

(Principal Financial and Accounting
Officer)

Date: March 2, 2011

Date: March 2, 2011

/s/ Francis P. Burke
Francis P. Burke
Director

/s/ Timothy R. Chrisman
Timothy R. Chrisman
Director

Date: March 2, 2011

Date: March 2, 2011

/s/ Hans R. Ganz
Hans R. Ganz

/s/ Alvin L. Majors
Alan L. Majors

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Director

Director

Date: March 2, 2011

Date: March 2, 2011

/s/ Kenneth W. Scholz
Kenneth W. Scholz
Director

/s/ Jeffrey T. Seabold
Jeffrey T. Seabold
Director

Date: March 2, 2011

Date: March 2, 2011

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/s/ Steven Sugarman
Steven Sugarman
Director

Date: March 2, 2011

/s/ Donald A. Whitacre
Donald A. Whitacre
Director

Date: March 2, 2011

INDEX TO EXHIBITS

Exhibit Number	Document
3.1	Charter of the Company (attached as an exhibit to the Company's Registration Statement on Form S-1 filed on March 28, 2002 and incorporated herein by reference).
3.2	Articles Supplementary to the Charter of the Company containing the terms of the Registrant's Class B Non-Voting Common Stock (attached as an exhibit to the Current Report on Form 8-K/A filed by the Company on November 16, 2010 and incorporated herein by reference)
3.3	Bylaws of the Company, as amended (attached as an exhibit to the Current Report on Form 8-K filed by the Company on February 28, 2011 and incorporated herein by reference).
5	Opinion of Silver, Freedman & Taff, L.L.P.
23.1	Consent of Silver, Freedman & Taff, L.L.P. (contained in Exhibit 5)
23.2	Consent of Crowe Horwath LLP
24	Power of Attorney (contained on signature page)