

SECURITIES & EXCHANGE COMMISSION EDGAR FILING

Enochian Biosciences Inc

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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, DC 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the
Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): **December 5, 2018**

ENOCHIAN BIOSCIENCES INC.

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction
of incorporation)

000-54478

(Commission File Number)

45-2559340

(I.R.S. Employer
Identification No.)

2080 Century City East

Suite 906

Los Angeles, CA 90067

(Address of principal executive offices)

+1(510) 203-4857

(Registrant's telephone number, including area code)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- ☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 8.01 Other Events.

On December 5, 2018, Enochian Biosciences, Inc. issued a press release announcing the approval of its application to list its common stock on the Nasdaq Capital Market. A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

Item 9.01 Financial Statements and Exhibits

(d) Exhibits:

EXHIBIT NO.	DESCRIPTION	LOCATION
99.1	Press Release	Furnished herewith

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.

ENOCHIAN BIOSCIENCES, INC.

By: /s/ Eric J. Leire
Name: Eric J. Leire
Title: Chief Executive Officer

Date: December 6, 2018

ENOCHIAN BIOSCIENCES ANNOUNCES UPLISTING TO NASDAQ UNDER SYMBOL “ENOB”

- Appoints former President of GSK Global Vaccine business, Luc Debruyne, to Board of Directors –
- Advances ENO-1001 for HIV by entering into research collaboration with Scripps Research –
- Enters into agreement with Hitachi Chemical Advanced Therapeutics Solutions to further CMC development for ENO-1001 –

LOS ANGELES, Calif. – December 5, 2018 –Enochian Biosciences, Inc. (“Enochian” or the “Company”) (OTCQB: ENOB), a biopharmaceutical company developing potentially curative and preventative gene-modified cell therapy platforms to transform the lives of persons living with HIV and cancer patients, today announced that the Company has received confirmation that its application to list the Company’s common stock on the NASDAQ Capital Market has been approved by the NASDAQ Stock Market.

Enochian’s common stock is expected to begin trading on the NASDAQ Capital Market on December 10, 2018 under the ticker symbol “ENOB.” The Company’s common stock will continue to trade on the Over-the-Counter Bulletin Board under the ticker symbol “ENOB” until market close on December 7, 2018.

“We believe that the uplisting to NASDAQ will help attract institutional investors, broaden our shareholder base and enhance trading liquidity. We are excited about this milestone and look forward to progressing our gene-modified cell therapy platform to treat infectious disease and cancer patients,” stated Eric Leire, MD, CEO.

Board of Directors Update

Luc Debruyne joined Enochian’s Board of Directors in November 2018. Mr. Debruyne held a series of senior management positions at GSK during his 27-year career. Most recently, he served as President of Global Vaccines, during which time the company became the number one vaccines company in the world in sales, achieving global vaccines sales of more than \$6bn in 2017. In this role for the past five years, he oversaw the successful integration of the Novartis vaccines business, including incorporating R&D portfolios and manufacturing networks, aligning resources to priority projects, preparing the Shingrix launch and building a stronger presence in the US. Mr. Debruyne will leave GSK at the end of 2018. Mr. Debruyne holds a Masters Degree in Physical Education from University of Leuven.

Mr. Debruyne stated, *"It is an exciting time to join the Enochian Biosciences' Board, and I am looking forward to making an active contribution to bring its innovative science to many patients."*

"We have made tremendous progress over the past year in advancing our mission to develop therapies designed to change the course of treatment for people living with HIV and for cancer patients. We are equally excited about all the world leading competences we have been able to get onboard based upon our promising science -the latest being Luc Debruyne's appointment to our board, as he brings close to three decades of pharmaceutical industry expertise to Enochian," stated Mr. Rene Sindlev, Chairman.

RESEARCH AND DEVELOPMENT UPDATE

Scripps Research

Enochian and Scripps Research, one of the most notable medical research institutions in the world, entered a fee-for-service agreement to conduct a series of syngeneic and humanized mice studies. The research is being conducted in the laboratory of Phillippe Gallay, PhD, Professor of Immunology in the Scripps Research Department of Immunology and Microbiology, to assess the efficacy of ENO-1001. The Company anticipates that this agreement will help advance the pre-clinical work necessary to obtain an Investigational New Drug application (IND) with the FDA and provide further valuable insights into the HIV program.

Hans Peter Kiem, Director of Stem Cell and Gene Therapy Program at Fred Hutch and Member of Enochian's Scientific Advisory Board, remarked, *"It is so important to find a cure for HIV, so many people are affected and would benefit. We need companies like Enochian Biosciences to pursue this very important goal."*

R&D Agreement with Dong Sung An, MD, PhD, Professor at UCLA

Enochian also entered into an R&D agreement with Dong Sung An, MD, PhD, professor at UCLA. The team focuses on employing genetic modification techniques to make the human population resistant to HIV. Professor An will support the Company's pre-clinical development program, including but not limited to viral vector design. UCLA is one of the leading academic centers in the field of HIV/AIDS research. Dr. An's prior work for vector designs for an efficient stem cell gene modification to develop anti-HIV will provide valuable insights to Enochian HIV program.

David Hardy, MD, Adjunct Professor of Medicine at John Hopkins University School of Medicine, former Chief Medical Officer of Calimmune and Member of Enochian Biosciences' Scientific Advisory Board, stated, *"Enochian's efforts to pursue a cure for HIV using a novel gene-modified stem cell delivery system builds upon and extends previous successful research in this therapeutic space. While cautiously optimistic, I am excited to support these efforts to take on this high priority therapeutic challenge."*

Hitachi Chemical Advanced Therapeutics Solutions (HCATS)

Enochian and HCATS (ex-PCT Cell Therapy Services), a US subsidiary of Hitachi Chemical Co, one of the world's largest cell therapy contract development and manufacturing organization (CDMO), signed an agreement to perform a manufacturing assessment of Enochian Biosciences' ENO-1001 in support of Enochian's efforts to develop the CMC section of ENO-1001. This agreement allows Enochian Biosciences to leverage HCATS' extensive experience in cell therapy development and manufacturing technology and wide-ranging manufacturing locations and we believe will allow us to provide clinical supply for our clinical trials in the future.

Intellectual Property Update

Enochian is pleased to announce the filing of a series of patent applications directed to ENO-1001, ENO-2001 (preventative HIV vaccine, and ENO-5001, the Company's off the shelf, genetically-modified allogeneic dendritic cell-based therapy that is under development as a therapeutic cancer vaccine. This genetically-modified allogeneic dendritic cell-based technology platform is for solid tumors (80% of the cancer market) what the Car-T Cell technology is for liquid tumors (20% of the cancer market) - and potentially more potent.

Mark Dybul, MD, former head of the US President's Emergency Plan for AIDS Relief (PEPFAR) and the Global Fund to Fight AIDS, Tuberculosis and Malaria, now Chairman of Enochian Biosciences' Scientific Advisory Board and a member the Board of Directors, remarked, *"Enochian has innovative solutions to ensure that gene-modified cells that cannot be infected by HIV can take over without wiping out the immune system. This approach could be used throughout the world and help end the HIV/AIDS epidemic. The Company also has novel approaches to achieve lifelong remission of major cancers. After a career dedicated to controlling and treating HIV and major cancers, nothing could be more exciting and fulfilling than being a part of Enochian."*

About Enochian

Enochian Biosciences is a biopharmaceutical company focused on the development and commercialization of novel gene-modified cell therapies aimed to change the course of treatment in HIV/AIDS and cancer. The Company utilizes its proprietary expertise in gene therapy, gene regulation and cell therapy to alter the course of multiple indications. The Company's lead candidate, ENO-1001 (pre-IND) is a potential cure for HIV/AIDS. ENO-2001 is an HIV vaccine in preclinical stage, and its additional compounds ENO-5001 (gene-modified allogeneic dendritic cell therapy for solid cancers) and ENO-4002 (for prevention of relapse in colon cancer patients) are in discovery stages.

Forward-Looking Statements

Statements in this press release that are not strictly historical in nature are forward-looking statements. These statements are only predictions based on current information and expectations and involve a number of risks and uncertainties. Forward-looking statements can be identified by the words “believe,” “anticipate,” “continue,” “estimate,” “project,” “expect,” “plan,” “potential,” “intend,” “will,” “would,” “could,” “should,” or the negative or plural of these words or other similar expressions that are predictions or indicate future events, trends or prospects. Forward-looking statements are subject to risks and uncertainties that could cause actual results to differ materially and reported results should not be considered as an indication of future performance. These risks and uncertainties include, but are not limited to: our ability to maintain a listing on the NASDAQ Capital Market, the safety, effectiveness and timing of related pre-clinical studies, clinical trials, manufacturing and CMC progress, or the success of our collaborations regarding our program candidates, including, without limitation, ENO-1001.

These statements are also subject to the risk that pre-clinical data are subject to differing interpretations, and regulatory agencies, medical and scientific experts and others may not share Enochian’s views of such study data. In addition, promising interim results or other preliminary analyses do not in any way ensure that later or final results will replicate those interim results. The product candidates discussed are investigational and not approved and there can be no assurance that Enochian’s programs, including ENO-1001, will be successful in demonstrating safety and/or efficacy, that Enochian will not encounter problems or delays in pre-clinical or clinical development, or that any of Enochian’s product candidates will ever receive regulatory approval or be successfully commercialized. These forward-looking statements are based on information available to Enochian as of the date of this press release and speak only as of the date of this press release. Enochian disclaims any obligation to update these forward-looking statements, except as may be required by law.

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