# UNITED STATES SECURITIES AND EXCHANGE COMMISSION Washington, D.C. 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) January 12, 2015

### STELLAR BIOTECHNOLOGIES, INC.

(Exact name of registrant as specified in its charter)

**British Columbia, Canada** (State or other jurisdiction of incorporation)

**000-54598** (Commission File Number)

N/A (I.R.S. Employer Identification No.)

332 E. Scott Street Port Hueneme, California 93041

(Address of principal executive offices) (Zip Code)

(805) 488-2800

(Registrant's telephone number, including area code)

### Not applicable.

(Former name or former address, if changed since last report)

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 (see General Instruction A.2. below):

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

### Item 7.01 Regulation FD Disclosure.

Representatives of Stellar Biotechnologies, Inc. (the "Company") will be conducting meetings with investors beginning January 12, 2015, and will also be presenting at the 7th Annual Biotech Showcase<sup>TM</sup> conference in San Francisco. A copy of the corporate presentation is attached hereto as Exhibit 99.1 and incorporated herein by reference.

The information in this Item 7.01 of this Current Report on Form 8-K, including Exhibit 99.1, is furnished pursuant to Item 7.01 and shall not be deemed to be "filed" for the purpose of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that section.

Item 9.01	Financial Statements and Exhibits.	
Exhibit No.	Description	
<u>99.1</u>	January 2015 Corporate Presentation.	

### **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.

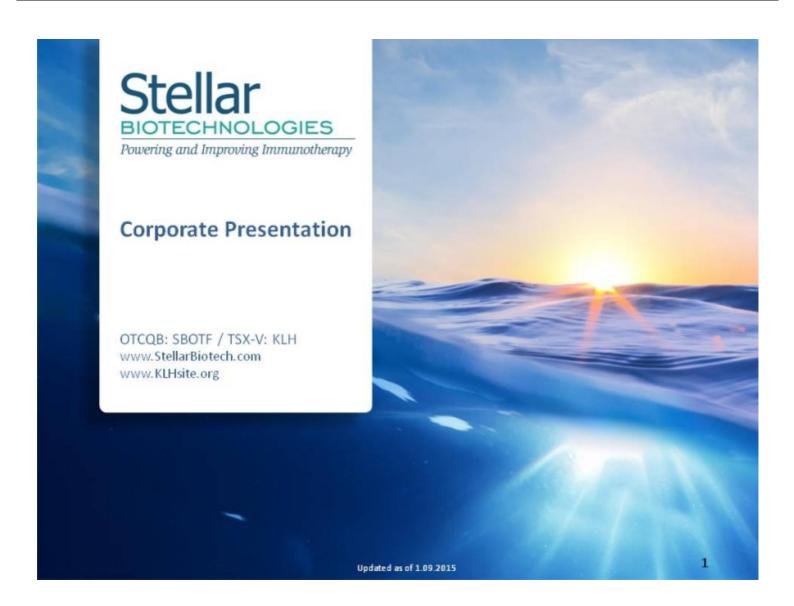
Stellar Biotechnologies, Inc.

Date: January 12, 2015 By: <u>/s/ Kathi Niffenegger</u>

Name: Kathi Niffenegger Title: Chief Financial Officer

### EXHIBIT INDEX

Description	
porate Presentation.	
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## Safe Harbor

This presentation may contain forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. Forward-looking statements may be identified by the use of words such as "anticipate," "believe," "plan," "estimate," "expect," "intend," "may," "will," "would," "could," "should," "might," "potential," or "continue" and variations or similar expressions. Readers should not unduly rely on these forward-looking statements, which are not a guarantee of future performance. There can be no assurance that forward-looking statements will prove to be accurate, as all such forward-looking statements involve known and unknown risks, uncertainties and other factors which may cause actual results or future events to differ materially from the forward-looking statements. Such risks include, but may not be limited to: general economic and business conditions; technology changes; competition; changes in strategy or development plans; governmental regulations and the ability or failure to comply with governmental regulations; the timing of anticipated results; and other factors referenced in Stellar's filings with securities regulators. For a discussion of further risks and uncertainties related to our business, please refer to our public company reports filed with the TSX Venture Exchange and the U.S. Securities and Exchange Commission. All forward-looking statements are made as of the date hereof and are subject to change. Except as required by law, we assume no obligation to update such statements. This presentation does not constitute an offer or solicitation of an offer for sale of any securities in any jurisdiction, including the United States. Neither the TSX Venture Exchange nor its Regulation Services Provider (as that term is defined in the policies of the TSX Venture Exchange) accepts responsibility for the adequacy or accuracy of the information contained in this presentation.

Note: All financial and stock price information is presented in U.S. dollars.



## Powering and Improving Immunotherapy™

## Unique, World-Leading Technology

 Specializing in sustainable/scalable and fully traceable supply of Keyhole Limpet Hemocyanin (KLH), the widely-used immunestimulating protein.

## Fastest-Growing Biopharma Sector

• Stellar KLH products & technology target immunotherapy and immunodiagnostics, biopharma's fastest-growing sectors.

## Strong Growth Roadmap

- Multiple commercial and clinical pathways.
- New expansion in core business of sustainable KLH manufacturing and supply.

## Environmental Advantage

- Our ground-breaking work revolutionized KLH manufacturing
- · Unprecedented standards, competitive edge.



## A History of Building Value

2004

•KLH supply

agreements for

cancervaccines

GMP-grade KLH

•\$3M NCI grant

funding for development of





### 2005-2009

- Patent for KLH protein extraction methods (U.S., Canada, Europe)
- •GMP KLH
- Vaccine & supply partnerships

### 2010-2011

- Stellar public on TSX Venture Exchange (TSX-V: KLH)
- •\$3.1M financing
- NSF Phase IIb grant funding
- Diagnostic codevelopment agreement

### 2012-2014

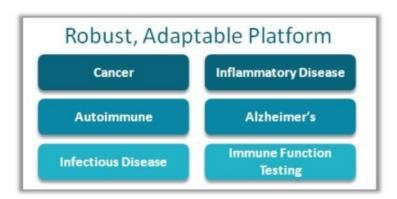
- Stellar on U.S. OTCQB Marketplace (OTCQB: SBOTF)
- Amaran Biotechnology collaboration (potential KLH carrier for OBI-822 in breast cancer)
- Araclon supply agreement (KLH for betaamyloid for Alzheimer's)
- •Biovest supply agreement (KLH for BiovaxID® in N-H Lymphoma)
- Exclusive WW C. diff license
- Multiple industry firsts in aquaculture science
- Expanded IP (mfg. & adjuvant technologies, immunotherapy)
- +KI H Site TH
- •Master File submission to U.S. FDA CBER
- •\$12M financing

- •Founding
- Private, U.S.-based company (Calif.)
- Aquaculture facility
- •\$1M NIH grant funding

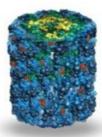


## What is Keyhole Limpet Hemocyanin (KLH)?

- Important immune-stimulating protein.
- Only source is scarce marine mollusk.
- 40+ years safe use in clinical immunology.
- · Vital in preclinical and clinical research.
- Rapid growth in immunotherapy = High demand.







KLH: A Complex Molecule A single KLH subunit can be an immunotherapy carrier

www.KLHsite.org



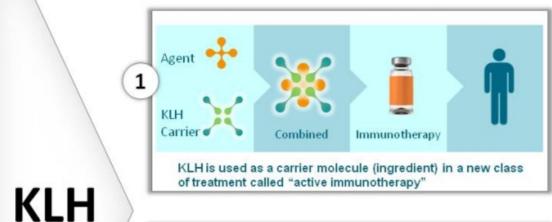
# Megathura Crenulata – Giant Keyhole Limpet







## The Power of KLH: Versatile, Safe, Widely Used



immune response to new drugs.

### KLH in Active **Immunotherapies**

Celldex, OBI Pharma, Neovacs, Araclon, Biovest, Affiris, Bayer, Axon, Scripps, NCI, NINDS, MabVax, Baylor, Abramson, Loyola, Rockefeller, MSKCC, Stanford



### KLH in TDAR Immunotoxicology

Amgen, Pfizer, Roche, Novartis, Biogen Idec, Bristol-Myers, J&J, NIAID, GSK, Novo Nordisk, Genentech

Uses described represent KLH in general; not limited to Stellar KLH™.

## **KLH Growing Demand & Market Potential**

## KLH-Based Active Immunotherapy Trials\*

Clinical Status	Indication	Company or Institute
EU MAA review	N-H Lymphoma	Biovest (BiovaxID®)
Phase III	Glioblastoma	Celldex (Rindopepimut)
	Breast Cancer	OBI Pharma (OBI-822)
Phase II	Crohn's Disease	Neovacs (TNF Kinoid)
	Lupus	Neovacs (IFNa Kinoid)
	Rheum atoid Arthritis	Neovacs (TNF Kinoid)
	Alzheimer's	Affiris/GSK (AD02)
	Multiple Myeloma	Abramson Center
	Melanoma	Baylor Research
	Lymphoma	Clinica Navarra
	Melanoma	Dermatologische Klinik
	Ovarian Cancer	Loyola University
	Sarcoma	MabVax
	Ovarian Cancer	MabVax / NCI
	Leukemia	NCI
Phase I	Alzheimer's	Araclon / Grifols
	Alzheimer's	Axon Neurosciences
	N-H Lymphoma	Bayer (Autologous)
	Brain Tumor	Rockefeller
	Glioblastoma	Roswell Park
	Lung Cancer	Sloan-Kettering
	Neuroblastoma	Sloan-Kettering
	Sarcoma, Neuroblast	NCI

- Not a comprehensive list. Not limited to Stellar KLH™. Does not include KLH in immunodiagnostics.
- Clinical trial costs are the responsibility of the sponsor company or institute.

### **Major Disease Categories**

Cancer Inflammatory Disease Alzheimer's Immune Disorders

KLH Market Potential \$10M to \$200M per Indication

### Major Biopharma Use

Celldex, Neovacs, Affiris, OBI, Bayer, Peptinov, Scripps, NCI, Genentech, MabVax, Chilka, Baylor, Biovest, Peptivir, Abramson, MSKCC, Stanford Pfizer, Sanofi, Merck, J&J

Sources: Clinicaltrials.gov, corporate news and websites, Decision Resources, Research & Markets, BCC Research, KLH Site.

# Stellar Biotech: A Leader in KLH Manufacturing







- Only producer WW of sustainable, scalable and fullytraceable GMP-grade KLH
- · Marine biotechnology pioneer with unique strengths:
  - Only-in-class aquaculture facility
  - Decades of experience across a range of disciplines
  - Industry firsts in aquaculture science
  - Advantageous location
- IP covering core KLH business + new R&D
- High barriers to entry
  - 5-10 years and \$20+ million investment ahead of any potential competitor
- Fiscal strength
  - Cash, cash equivalents and short-term investments of \$13.9 million (at Fiscal Year Ended 8/31/2014)



## Supply Dynamics Favor Stellar Biotech

- · KLH molecule is large and complex; has not been synthesized
- One marine source, one location
- Commercial scale constraints
  - Giant Keyhole Limpet requires 5 years until fully mature
  - Protein-rich hemocyanin can be extracted 3X/year
- 1 gram GMP KLH has commercial value ~ \$50,000
- Stellar's current production capacity is 1,000 gram GMP KLH scalable to 4,000 gram GMP KLH









## The Commercial Power of KLH

## Multiple High-Value Pathways

### Revenue & Alliances **Clinical Applications Partners & Markets** L-T Supply Agreements Major Biopharma Cancers Direct Sales Immunotherapy Immune Disorders Co-Development Alzheimer's Research Collaborations Inflammatory Disease Immunodiagnostics Immune Function Testing Joint Ventures Basic Research Stellar KLH™ Carriers, Adjuvants, and Finished Products

World-Leading Stellar KLH™ Platform



# Stellar KLH™ Products









- Vaccine Carriers
- Products for Immune Function Testing
- Custom Formulations



## **New Supply Agreements**



- Araclon Biotech SL (Spain) November 2014
  - Supply Stellar KLH™ for use in Araclon's beta amyloidtargeting immunotherapy against Alzheimer's disease

		Preclinical	Phase I/II	Phase II	Phase III
Beta amyloid	Alzheimer's				

Biovest, Inc. – October 2014



 Supply Stellar KLH™ for use in Biovest's BiovaxID® immunotherapy to treat non-Hodgkin's lymphoma





## **Key Strategic Corporate Partner**

- · Amaran Biotechnology (Taiwan)
  - Invested \$5 million in Stellar's 2013 financing
- Evaluate and develop Stellar KLH™ as a potential carrier molecule for OBI Pharma's OBI-822 immunotherapy
- OBI-822 Active Immunotherapy breast cancer
  - KLH is key ingredient



		Preclinical	Phase I/II	Phase II	Phase III
	Metastatic Breast Cancer (Taiwan)				
OBI-822	Metastatic Breast Cancer (U.S., So. Korea, India, Hong Kong)				
	Ovarian (Taiwan)				



## Long-Term Customer, Multiple Targets

- Neovacs S.A. (Alternext Paris: ALNEV)
- · Kinoid immunotherapy pipeline
- Stellar KLH™ used as carrier molecule
- 2 drugs in clinical development



		Preclinical	Phase I	Phase II	Phase III
TNF-Kinoid	Crohn's disease				
IFNa-Kinoid	Lupus				

Source: Neovacs<u>www.neovacs.fr</u>



## **Future Milestones & Catalysts**



- New collaborations and supply contracts with biopharma partners
- 2. R&D in KLH-based immunotherapy
- Aquaculture production capacity and expansion
- 4. Public company maturation
  - · Prepare for major U.S. exchange
  - Corporate governance & controls
- Regulatory advancements
  - · USP monograph
  - Investigational New Drug (IND) application



# Senior Executive Leadership

Frank Oakes President & CEO	<ul> <li>35 years experience; biotechnology and aquaculture. Aquaculture industry leader and KLH manufacturing expert. Formerly CEO of Abalone Farms, Inc.; leader through R&amp;D, capitalization and commercialization to become first profitable and largest abalone producer in U.S.</li> </ul>
Catherine Brisson, Ph.D. Chief Operating Officer	<ul> <li>20 years experience; biotech, pharma and medical device industries, including Sicor Pharmaceuticals (Teva Parenteral Products).</li> <li>Expertise in QA, QC, Regulatory and Manufacturing. Ph.D. Organic Chemistry.</li> </ul>
Kathi Niffenegger Chief Financial Officer	<ul> <li>30 years experience; accounting and finance, range of industries including pharma. Outside CPA to Stellar since Company founding. Previously partner at Glenn Burdette, CFO at Martin Aviation, Peat Marwick, Mitchell (KPMG LLP).</li> </ul>
Mark McPartland VP, Corporate Development & Communications	<ul> <li>16 years experience; business development, capital markets advisory, corporate communications. Previously Senior VP at MZ Group, VP and Partner at Alliance Advisors LLP, and Regional VP of Hayden Communications.</li> </ul>



# **Key Facts & Selected Financials**



Key Company Facts				
Trading Symbols:	OTCQB: SBOTF TSX-V: KLH			
Headquarters:	Port Hueneme, CA			
• Founded:	1999			
• Fiscal Year End:	August 31			
• Independent Auditor:	Moss Adams LLP Los Angeles, CA			
Outside Legal Counsel:	Greenberg Traurig, LLP			
	McMillan LLP			

Selected Financials (All \$ amounts in U.S.) Updated 1/09/2015	K)	
Stock Price OTCQB	\$1.13	
52 – Week Range	\$0.60-\$2.36	
Shares Outstanding	79.55M	
Average Trade Volume (90 day)	158,865	
Market Capitalization	\$89.9M	
Debt *	\$0	
Cash, Equivalents, Short Term Investments *	\$13.9M	
Shareholders Equity *	\$7.7M	
* As of Fiscal Year End 8/31/2014		

Stellar Financial Filings: http://ir.stellarbiotechnologies.com/all-sec-filings



## Stellar Biotechnologies Summary

- Industry-leading core competency in KLH
- Versatile technology platform and products
- KLH essential to immunotherapy, fastest-growing biopharma sector
- Multiple, high-value commercial pathways
- Progressive achievements and collaborations
- Environmental champion
- Fiscal strength = ability to execute

## Powering and Improving Immunotherapy™





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