
**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): October 22, 2018

**MABVAX THERAPEUTICS HOLDINGS, INC.
(Exact name of registrant as specified in its charter)**

**Delaware
(State or other jurisdiction
of incorporation)**

**001-37861
(Commission
File Number)**

**93-0987903
(IRS Employer
Identification No.)**

**11535 Sorrento Valley Rd., Suite 400
San Diego, CA 92121
(Address of principal executive offices and zip code)**

Registrant's telephone number, including area code: (858) 259-9405

**N/A
(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:

- 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))
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Indicate by check mark whether the registrant is an emerging growth company as defined in 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 7.01 REGULATION FD DISCLOSURE.

On October 22, 2018, MabVax Therapeutics Holdings, Inc. (the “Company”) updated and made available its corporate presentation. The presentation is attached hereto as Exhibit 99.1.

The information disclosed under this Item 7.01, including Exhibit 99.1 hereto, is being furnished and shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, nor shall it be incorporated by reference into any registration statement or other document pursuant to the Securities Act of 1933, as amended, except as expressly set forth in such filing.

ITEM 9.01 FINANCIAL STATEMENTS AND EXHIBITS

(d) Exhibits.

The exhibit listed in the following Exhibit Index is furnished with this Current Report on Form 8-K.

Exhibit No. Description

99.1 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.

MABVAX THERAPEUTICS HOLDINGS, INC.

Dated: October 22, 2018

/s/ J. David Hansen

J. David Hansen

President and Chief Executive Officer



Novel Therapeutic Antibody for the Prevention and Treatment of Pancreatitis

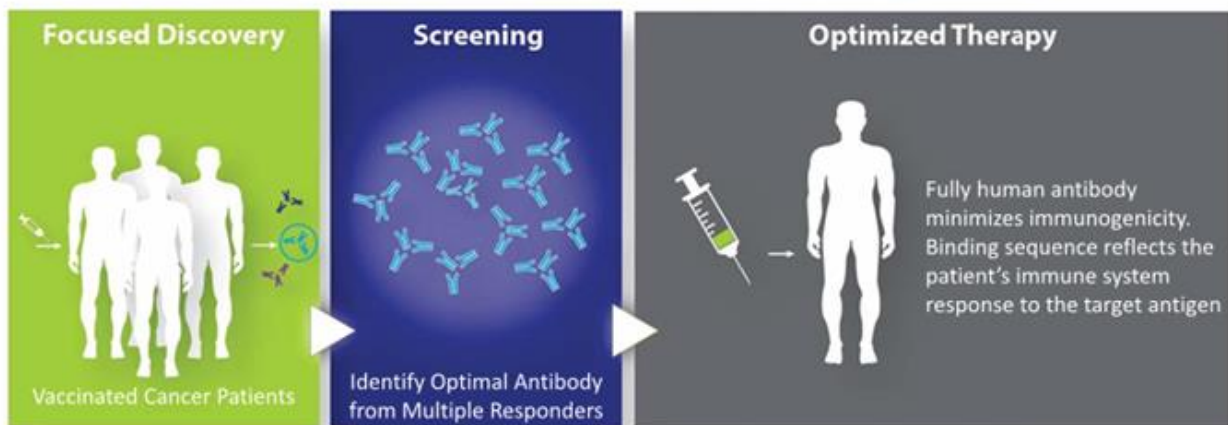
- Building upon a unique insight into the fundamental biology of pancreatitis
- Uniquely positioned to move into a phase 2 POC

Forward Looking Statements

- MabVax Therapeutics Holdings, Inc. (the "Company") files annual, quarterly and other reports with the Securities and Exchange Commission (the "SEC") including its Annual Report on Form 10-K for the year ended December 31, 2017 (the "Form 10-K") which was filed on April 2, 2018, and amended on Form 10-K/A as was filed on October 15, 2018. You may get these documents for free by visiting EDGAR on the SEC's website at www.sec.gov. For a more complete discussion of the risk factors affecting our business, please refer to the Form 10-K and Form 10-K/A. This presentation includes statements that are, or may be deemed, "forward-looking statements." In some cases, these forward-looking statements can be identified by the use of forward-looking terminology, including the terms "believes," "estimates," "anticipates," "targets," "expects," "plans," "projects," "intends," "predicts," "may," "could," "might," "will," "should," "approximately," "potential" or, in each case, their negative or other variations thereon or comparable terminology, although not all forward-looking statements contain these words. These statements appear in a number of places throughout this presentation and include statements regarding our intentions, beliefs, projections, outlook, analyses or current expectations concerning, among other things, clinical trials, corporate partnership opportunities and potential financing transactions. By their nature, forward-looking statements involve risks and uncertainties because they relate to events, competitive dynamics, and healthcare, regulatory and scientific developments and depend on the economic circumstances that may or may not occur in the future or may occur on longer or shorter timelines than anticipated or at all. Although we believe that we have a reasonable basis for each forward-looking statement contained in this presentation, we caution you that forward-looking statements are not guarantees of future performance and that our actual results of operations, financial condition and liquidity, and the development of the industry in which we operate may differ materially from the forward-looking statements contained in this presentation.

MabVax Company Background

Proprietary Approach to the Discovery and Development of Novel Fully Human Antibodies as Therapeutic and Diagnostic Agents



10/19/2018

Non-Confidential - MabVax Therapeutics Holdings, Inc.
Do Not Distribute Without Permission From Company

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Company Long Term Partnerships Result in Value Creation

Discovery & Development Platform

- Human antibody discovery platform has yielded multiple antibody development opportunities
- Highly specific antibodies rescued from the immune response of vaccinated patients
- Focus on abnormal carbohydrate antigens upregulated in multiple diseases
- Antibodies we develop are ideal targeting vehicles for antibody based therapeutics and diagnostics

Ongoing Partnerships With Premier Research Institutions

- Memorial Sloan Kettering Cancer Center (MSK) –
 - Multiple exclusive license agreements
 - Multiple basic research agreements, development collaborations, and clinical trial agreements
- Cold Spring Harbor Laboratories
 - Collaboration agreement
 - Exclusive license agreement
- National Cancer Institute
 - Clinical trial agreement

Recent Revenue Generating Corporate Transactions

- June 2018 - Neuroblastoma vaccine licensed to Y-mAbs for \$1.3M plus share of pediatric disease voucher
- July 2018 - Early stage antibody divested to Boehringer Ingelheim for total of \$11M.
 - \$4M initial payment
 - \$7M in milestones to Phase 1

Overcoming Corporate Challenges for a Successful 2018

Challenges Faced in 2018

Investor misconduct led to our delisting and caused us not to be current in SEC reporting

- January 2018 became aware of SEC investigation focused on prior investor group
- Preferred shares converted to common possibly invalid due to investor group actions
- July 2018 company ceased SEC reporting and delisted from Nasdaq
- September 2018 SEC filed complaint against investor group

Actions Taken With Positive Outcomes

Our corrective actions have remedied uncertainty about our capitalization and brought us current in SEC reporting

- September 20, 2018 successfully petitioned the Delaware Chancery Court to validate common shares and prior stockholder votes
- Eliminated uncertainty about our capitalization
- October 15, 2018 reinstated audited financials for 2016 and 2017 and filed 1st and 2nd quarter 10-Qs
- Now current with SEC reporting requirements
- Have applied for listing on OTCQB Marketplace with target of November 1st for listing

R&D Progress Continues Despite Challenging 2018

Ongoing Research Institution Collaborations Achieved Significant Progress

Memorial Sloan Kettering Cancer Center

- R01 (NIH) funds 5B1 immunoPET Phase 1b (MVT-2163)
- U01 (NIH) funds pre-targeting use 5B1 antibody in Phase 1 trial
- CAR-T program for 5B1 and GD2 binding domains

NIH / NCI (National Cancer Institute)

- Phase 1b study to assess 5B1 (MVT-5873) clinical MOA

Cold Spring Harbor Collaboration - Pancreatitis

- Novel scientific insights indicating rapid path to POC in pancreatitis with 5B1 (MVT-5873)

Technology Validation and Continued Value Creation for Investors

BI (Boehringer Ingelheim)

- Divestiture of HuMab-Tn asset nets \$4MM in 2018 with potential for \$3MM in 2019

Y-mAb

- Sale of neuroblastoma vaccine nets \$1.3 MM and share of pediatric voucher

Pancreatitis Market Opportunity: Critical Unmet Medical Need

- Acute and Chronic pancreatitis drives 361,000^{1,2} hospitalizations annually in the US
 - 275,000¹ for acute and 86,000³ for chronic disease
 - Direct medical costs exceed \$3.1B^{1,2} annually
 - Approximately 20% of acute pancreatitis classified as severe. Mortality from severe acute pancreatitis is 15% - 30%⁴
- 500,000 ERCP procedures annually with acute pancreatitis as AE in 3% to 15% of patients³
- Recurrent attacks can lead to permanent loss of structure and function of the pancreas
- There are limited therapeutic interventions available today to treat the underlying pathophysiology of pancreatitis
- Primary treatment includes palliative care, pain management, fluid resuscitation, NSAIDs, antibiotics and imaging. Surgery is option for biliary pancreatitis.

1. Forsmark et al, NEJM 375;20
2. Yadav et al, Pancreapedia, July 28, 2016
3. Huffman et al, Medscape Nov 30 2017
4. Baron et al, BMJ Open 2013:e002689
5. Carroll et al, Am Family Phys 775, No10, May15, 2007

Attractive Commercial Opportunity to Treat Pancreatitis

Significant Costs for Treatment

Acute Pancreatitis

- Hospitalization LOS = Ave. 7 days
- Cost \$9,000 to \$18,000 per patient or Ave. \$1690/day

Severe/Moderate Acute Pancreatitis

- Hospitalization LOS = Ave. 28 days
- Cost \$83,000 to \$132,000 per patient
- 12% of admissions and 49% of all costs

Chronic Pancreatitis

- Average hospital cost = \$9700
- Patients present frequently
- Experience significant pain
- Enzyme replacement therapy
- Diabetes management
- Significant outpatient costs and QOL impacts

Opportunities for cost savings

- Reduction in mortality
- Reduction in hospital LOS or in ICU days
- Reduction in frequency of attacks
- Reduction in testing and supportive care
- Reduction in opiate administration
- Reduce or prevent organ failure
- Reduction on outpatient costs
- Reduce or delay progression to more severe disease

Significant Annual Treatment Population

Pancreatic Severity/Origin	Acute Mild	Moderate or Severe	Chronic	ERCP Induced
Hospitalized/Treated Annually	220,000	55,000	86,000	400,000
Estimated % of Patients Treated	8%	50%	40%	3%
Number of Patient Treated with MVT-5873	17,600	27,500	34,400	10,000
Total Patients Treated Annually				89,500

Discovery In Dr. David Tuveson's Lab at Cold Spring Harbor Laboratory

- Introduction through Vice Chair of Radiology at MSKCC Dr. Jason Lewis
- Dr. Tuveson serves as Director of the Cold Spring Harbor Laboratory Cancer Center and the Chief Scientist for the Lustgarten Foundation
- The Tuveson lab investigates the fundamental biology of pancreatic cancer using murine and human models to replicate the disease in humans
- MabVax provided an anti-CA19-9 antibody, HuMab-5B1, to support development of novel genetically engineered PDAC mouse models to study pancreatic cancer
- Dr. Dannie Engle discovered that CA19-9 induced mice developed pancreatitis and demonstrated potential utility of anti-CA19-9 antibody as a target for the treatment and prevention of acute and chronic pancreatitis
- Further clinical development in pancreatitis is warranted

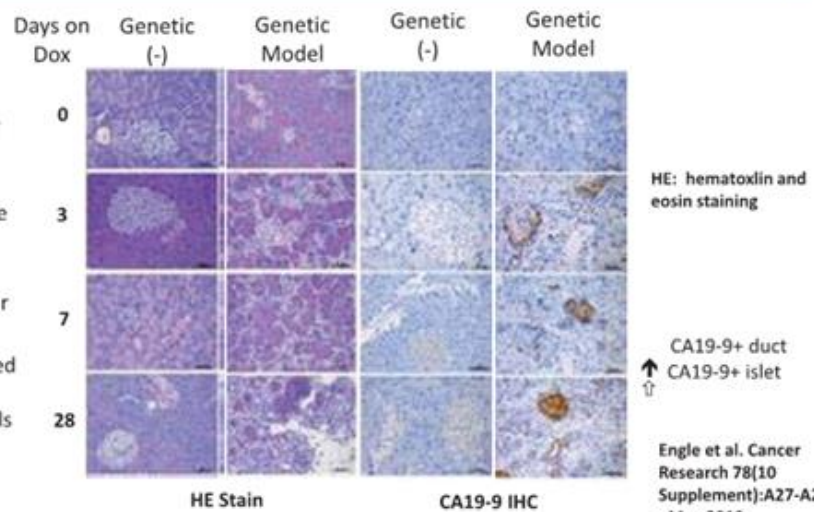
Clinical Implications of Inducible Expression of CA19-9 in Mice as a Tool to Study Pancreatitis

CA19-9 is a promising new target for the treatment of pancreatitis

- CA19-9 is an established serological clinical biomarker routinely used as a prognostic indicator of PDAC disease progression; CA19-9 is frequently elevated in pancreatitis
- Our collaborator Dr. David Tuveson (CSHL) established a genetically engineered humanized mouse model with inducible production of CA19-9
- Mice that now express CA19-9 develop acute and chronic pancreatitis
- Elevation of CA19-9 resulted in rapid elevation of pancreatic enzymes, pancreatic infiltration of immune cells, acinar-to-ductal metaplasia and atrophy
- Turning off CA19-9 expression results in the normalization of pancreatic enzyme levels
- We hypothesize that blocking CA19-9 expression with anti-CA19-9 antibodies has potential therapeutic utility in treating pancreatitis

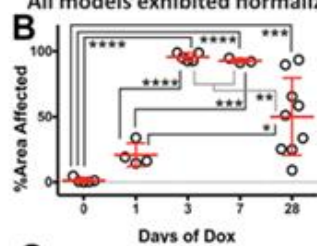
CA19-9 Expression Induces Histologic Signs of Pancreatitis in Genetically Engineered Mouse Models

- Non-pancreatic tissues exhibited normal histology relative to genetically negative littermate controls following Dox time-course
- All models demonstrated acinar atrophy, immune cell invasion, collagen deposition, elevated lipase and amylase
- No pancreatitis observed in Dox treated genetic negative controls or untreated mice
- CA19-9 was predominantly detected in intralobular and intercalated pancreatic ductal cells and islet cells – with rare positive acinar cells

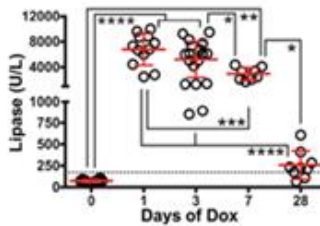
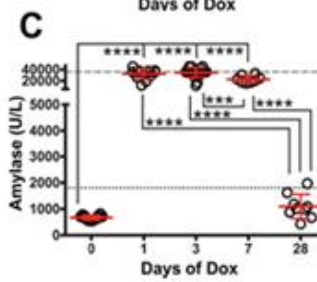


CA19-9 Expression in Mice Promotes Pancreatic Enzyme Elevation in Plasma

All models exhibited normalization of amylase and lipase after 4-weeks but exhibited histological signs of chronic pancreatitis



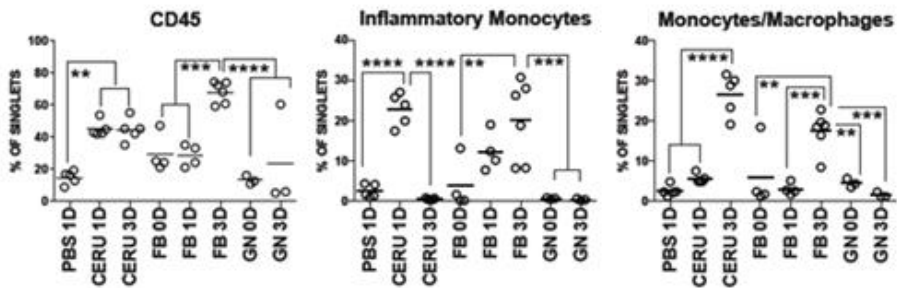
- Time dependent progression of disease state by continued dox induction
- Elevated amylase, lipase and CA19-9 levels aligned with histopathology
- Day 28 showed significant signs of collagen infiltration no weight loss



Engle et al. Cancer Research 78(10 Supplement):A27-A27 · May 2018

CA19-9 Expression Induces Recruitment of Inflammatory Monocytes

The percentage of immune cell types present in the pancreas quantified by flow cytometry (FB;LSL;PDX)



Engle et al. Cancer Research 78(10 Supplement):A27-A27 · May 2018

MVT-5873 Is Currently Active In Three Clinical Trials

MVT-5873 Prior Human Experience in Pancreatic Cancer and CA19-9 Positive Cancers

- Safety established in over 50 subjects in 3 Phase 1 investigations
 - ✓ NCT02672917 (MVT5873), NCT02687230 (MVT-2163), NCT03118349 (MVT-1075)
- Monotherapy in late stage PDAC patients with 5 of 32 patients on therapy for ≥ 6 months and one subject for 22 months

Move Quickly to IND and Clinic

- Prior successful INDs provide major components to support new IND for Pancreatitis
- Clinical supplies inventory sufficient for clinical proof of concept Phase 2 trial
- Experienced team of CMC, Toxicology, Pharmacology and Clinical consults to support the program

Clinical Plan: Severe Acute Pancreatitis

Intent to treat population: Moderate to Severe Acute Pancreatitis (SAP)

- Utilizes well established patient assessment to identify candidate patients
- Typically within 24 hours of admission for pancreatitis
- Treatment initiated as soon as SAP diagnosis is confirmed
- MVT-5873 treatment every two weeks (Q2W) until patient recovers and leaves hospital

Clinically Utilized Patient Assessment and Diagnosis Criteria

- Abdominal pain
- Lipase/amylase > 3x normal
- BUN > 20 mg/dL or rising in 24 hrs
- C-reactive protein > 150 mg/L
- Serum creatinine > 1.8 mg/dL
- SIRS – 2 or more criteria
- APACHE II score > 8
- Organ system failure
- CT scan for necrosis

Therapeutic Benefit

- Reduction in mortality
- Reduction in hospital days
- Reduced pain and opiate use
- Reduction in organ dysfunction
- Suppression of systemic inflammatory response
- Block progression to chronic pancreatitis
- Resulting in reduced medical costs

Development Plan to End of Phase 2

4Q 2018	1Q 2019	2Q 2019	3Q 2019	4Q 2019
<ul style="list-style-type: none"> Working to establish KOL network Finalize clinical protocol Schedule Pre-IND meeting with FDA Select Clinical sites 	<ul style="list-style-type: none"> File IND with FDA IRB Submission and Review Complete CTA Process Initiate first clinical sites 	<ul style="list-style-type: none"> First patients enrolled Expand enrollment to additional sites Complete IRB and CTA process at all additional sites 	<ul style="list-style-type: none"> Early assessment of first subjects Enrollment for full Phase II target 	<ul style="list-style-type: none"> Complete Phase II
1Q 2020	2Q 2020	3Q 2020	4Q 2020	
<ul style="list-style-type: none"> Complete Phase II study Decision to license product or initiate Phase III 	<ul style="list-style-type: none"> Complete Phase II analysis for efficacy and safety Decision to apply for Phase III 	<ul style="list-style-type: none"> Initiate Phase II meeting with FDA Reconcile FDA advice and Phase III initiate 	<ul style="list-style-type: none"> Expand clinical sites for Phase III Complete IRB and CTA process Initiate Phase III enrollment 	

Two-Year Expense Plan To Reach End of Phase 2

Top Line Summary of Expense Forecast

	Year - 2019 Forecast					Year - 2020 Forecast					End of Phase 2 2-Year Total
	Q1	Q2	Q3	Q4	Total 2019	Q1	Q2	Q3	Q4	Total 2020	
GENERAL & ADMINISTRATIVE	\$ 1,168,000	\$ 1,131,000	\$ 1,223,000	\$ 987,000	\$ 4,507,000	\$ 1,361,000	\$ 1,488,550	\$ 1,053,550	\$ 1,130,550	\$ 5,033,650	\$ 9,540,650
RESEARCH & DEVELOPMENT	\$ 436,255	\$ 1,476,000	\$ 1,718,000	\$ 1,486,000	\$ 5,116,255	\$ 1,268,000	\$ 770,000	\$ 581,000	\$ 617,000	\$ 3,236,000	\$ 8,352,255
DEBT & OTHER CASH EXPENDITURES	\$ 724,261	\$ 681,200	\$ 611,015	\$ 592,086	\$ 2,608,561	\$ 489,990	\$ 172,114	\$ 102,283	\$ 83,953	\$ 848,340	\$ 3,456,901
TOTAL EXPENSES	\$ 2,328,516	\$ 3,288,200	\$ 3,552,015	\$ 3,065,086	\$ 12,231,816	\$ 3,118,990	\$ 2,430,664	\$ 1,736,833	\$ 1,831,503	\$ 9,296,437	\$ 21,528,253

Unique Opportunity To Capitalize On Fundamental Discoveries Addressing Pancreatitis

MVT-5873 a Potential Pharmacological Agent to Improve Patient Care and Reduce Medical Costs

- Significant unmet medical need with few if any therapeutic options
- Groundbreaking work at CSHL reveals for first time key biological pathways of pancreatitis
- Convincing proof of concept that MabVax antibody can have a profoundly positive effect on course of disease
- Antibody is fully human antibody already in the clinic with sufficient human experience to justify initiation of mid-stage clinical trial
- Adequate clinical supplies available to complete mid-stage trial
- POC phase 2 study would be relatively quick to enroll with rapid readouts
- 24 month timeline to end of phase 2 with \$21M budget



For Further Information Please Contact

MabVax Therapeutics Holdings, Inc.
11535 Sorrento Valley Road, Suite 400
San Diego, CA 92121
David Hansen, CEO 858-500-8455
Greg Hanson, CFO 858-500-8457
Paul Maffuid, Exec. VP 858-500-8459