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): September 4, 2019

HALOZYME THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Commission File Number 001-32335

Delaware	**88-0488686**
(State or other jurisdiction of incorporation or organization)	*(I.R.S. Employer Identification No.)*
11388 Sorrento Valley Road **San Diego** **California** *(Address of principal executive offices)*	**92121** *(Zip Code)*

(858) 794-8889
(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:

☐ 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))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, $0.001 par value	HALO	The Nasdaq Stock Market LLC

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 7.01 Regulation FD Disclosure.

On September 4, 2019, Halozyme Therapeutics, Inc., a Delaware corporation ("Halozyme"), presented at the 2019 Wells Fargo Healthcare Conference to provide a corporate update on certain strategic programs. Attached hereto as Exhibit 99.1, and incorporated herein by reference, is a copy of the slides used by Halozyme in making the presentation that are expected to be used in subsequent presentations to interested parties, including analysts and stockholders.

This information is being furnished pursuant to Item 7.01 of this Report and shall not be deemed to be "filed" for the purposes of Section 18 of the Securities and Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that section and will not be incorporated by reference into any registration statement filed by Halozyme, under the Securities Act of 1933, as amended, unless specifically identified as being incorporated therein by reference. This Report will not be deemed an admission as to the materiality of any information in this Report that is being disclosed pursuant to Regulation FD.

Please refer to the slide deck attached as Exhibit 99.1 for a discussion of certain forward-looking statements included therein and the risks and uncertainties related thereto.

Item 9.01. Financial Statements and Exhibits.

Exhibit No.	Description
99.1	Halozyme Therapeutics, Inc. corporate update presentation dated September 4, 2019

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.

HALOZYME THERAPEUTICS, INC.

September 4, 2019

By: */s/ Harry J. Leonhardt, Esq.*

Name: Harry J. Leonhardt, Esq.
Title: Senior Vice President, General Counsel and Corporate Secretary

Halozyme

2019 Wells Fargo Healthcare Conference

Building a Premier Oncology Biotech

Dr. Helen Torley, President and CEO

September 4, 2019

Forward-Looking Statements

All of the statements in this presentation that are not statements of historical facts constitute forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Examples of such statements include possible activity, benefits and attributes of PEGPH20, future product development and regulatory events and goals, anticipated clinical trial results and strategies, product collaborations, our business intentions and financial estimates and results, including projected revenue amounts. These statements are based upon management's current plans and expectations and are subject to a number of risks and uncertainties which could cause actual results to differ materially from such statements. A discussion of the risks and uncertainties that can affect these statements is set forth in the Company's annual and quarterly reports filed from time to time with the Securities and Exchange Commission under the heading "Risk Factors." The Company disclaims any intention or obligation to revise or update any forward-looking statements, whether as a result of new information, future events, or otherwise.

Two Engines for Growth

ENHANZE®

- Proven 'IV to Sub Q' Partnering Platform
- Accelerating Partner Investment for Approvals
- High Potential:
  ~$1B Annual Royalty Revenue Projection in 2027
  ~$1B in Lifetime Milestones

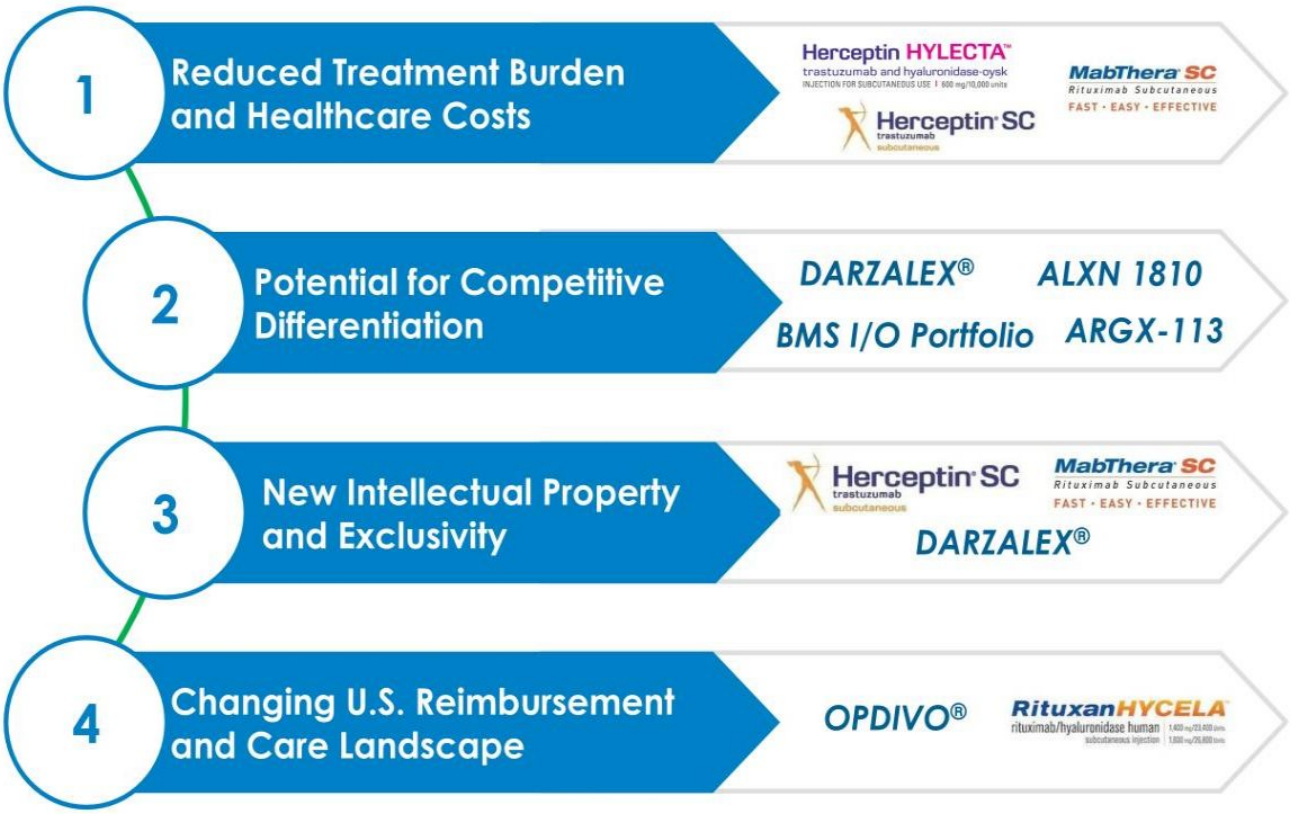
PEGPH20

- Late Stage Targeted Oncology Asset
- Phase 3 Data Readout Currently Projected in Q4 2019
- Potential ~$1B Global Pancreas Indication with Additional Pan-tumor Potential

Halozyme

ENHANZE®

ENHANZE® Offers Four Potential Paths for Differentiation and Value Creation for Partners



ENHANZE® High-Growth Business

9 Agreements signed to date:
Roche (Genentech), Baxalta, Pfizer, Janssen, Eli Lilly, Abbvie BMS, Alexion, and argenx

3 Approved Products

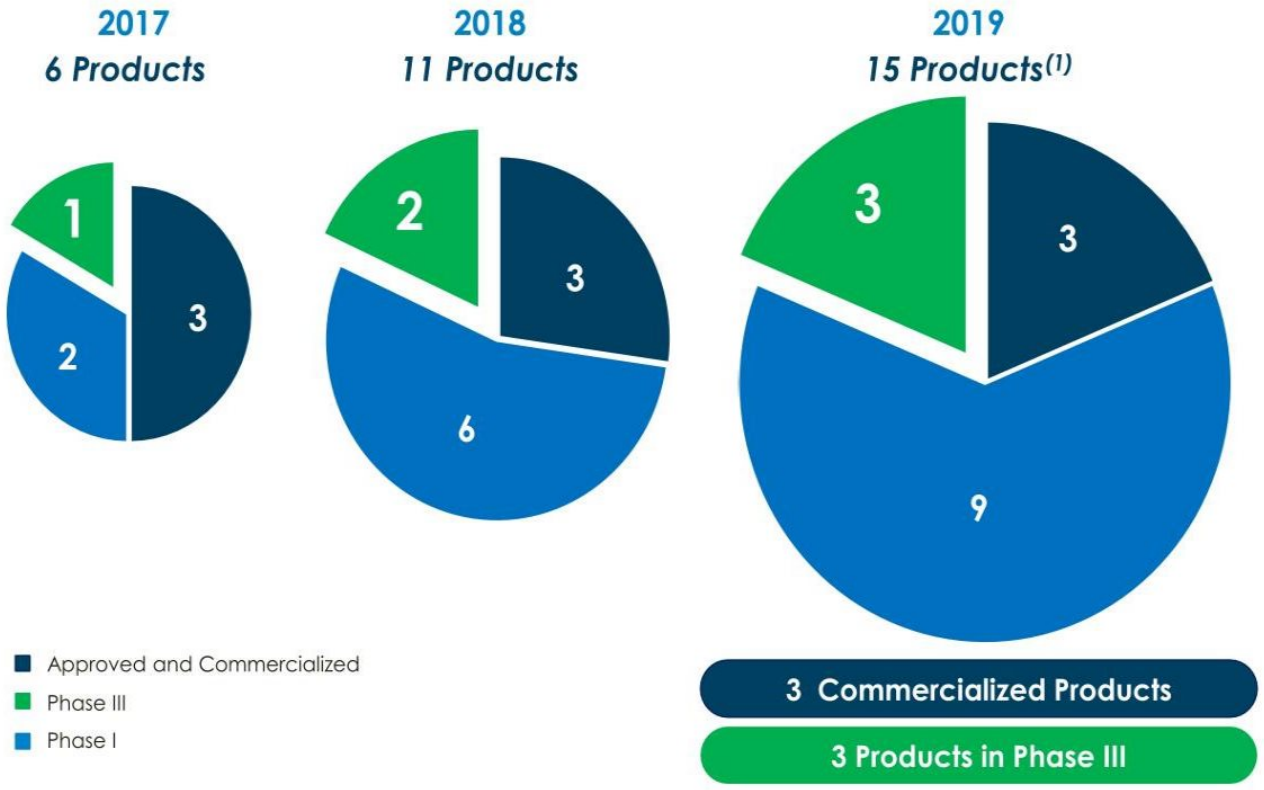
8 Targets in development today

>20 Target slots available to current partners

Bristol-Myers Squibb Agreement Terms

Number of Targets	11
Upfront	$105M
Milestones/ Target	$160M
Royalties	Mid-single digit average across all agreements

Near Term Catalysts:
Project 3 Potential Blockbuster Programs in Phase III in 2019



[1] Projected by year-end as of January 9, 2019

Three Products Successfully Commercialized in Global Markets

US	ROW
HyQvia [Immune Globulin Infusion 10% (Human) with Recombinant Human Hyaluronidase]	HyQvia [Immune Globulin Infusion 10% (Human) with Recombinant Human Hyaluronidase]
RituxanHYCELA rituximab/hyaluronidase human subcutaneous injection 1,400 mg/23,400 Units 1,600 mg/26,800 Units	MabThera SC Rituximab Subcutaneous FAST · EASY · EFFECTIVE
Herceptin HYLECTA™ trastuzumab and hyaluronidase-oysk INJECTION FOR SUBCUTANEOUS USE | 600 mg/10,000 units	Herceptin SC trastuzumab subcutaneous

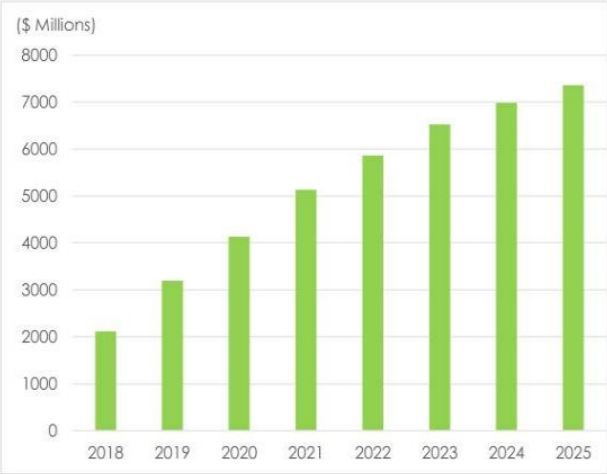
ENHANZE® Development Pipeline

	Partner	Product/Target		
Phase III in 2019	Janssen	DARZALEX®	PERJETA® pertuzumab / Herceptin® trastuzumab	Undisclosed
	Undisclosed	*Regulatory Applications Submitted*	*Ongoing*	*Initiating*
	Roche			
Phase I in 2019	BMS, ALEXION	Anti-CD73	OPDIVO®	ALXN1810
	argenx	TECENTRIQ® atezolizumab	ARGX-113	Undisclosed
	Lilly, Roche			

PLUS 3 Potential New Phase I Starts in 2019

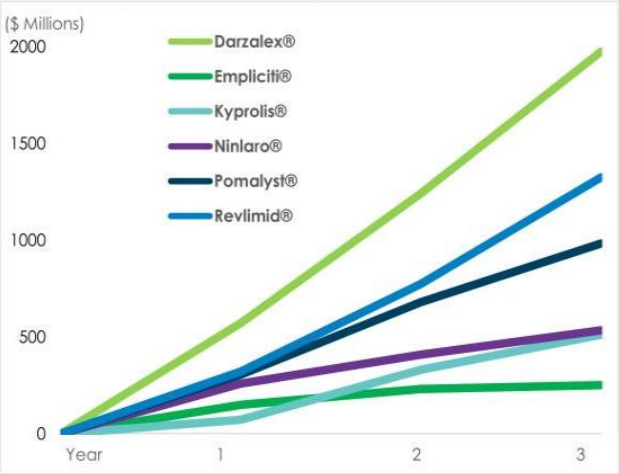
Daratumumab IV:
Blockbuster Multiple Myeloma Treatment

Analyst Estimates for DARZALEX®



Source: Analyst estimates via Nasdaq IR Insight

Early Launch Data Compares Favorably with Other Multiple Myeloma Drug Launches



Source: Bloomberg, company press releases

Sell-side analysts estimate >$7 billion in sales by 2025

Daratumumab SC Regulatory Path

Potential Benefits of Subcutaneous Formulation[1]

- **Faster infusion time being tested (3-5 minutes)[2] compared with 4-6 hour IV infusion, initially weekly**
- **Well tolerated with fewer infusion related reactions (IRRs) than with IV[3]**

BLA/MAA Submissions Made in July 2019 Based on:

- **COLUMBA study in Relapsed and Refractory Multiple Myeloma**
  - **Achieved 2 primary endpoints: non-inferiority in Response Rate and C trough**
- **Phase 2 PLEIADES Study[4]**

Multiple Ongoing Phase 3 Trials[1] with ENHANZE®

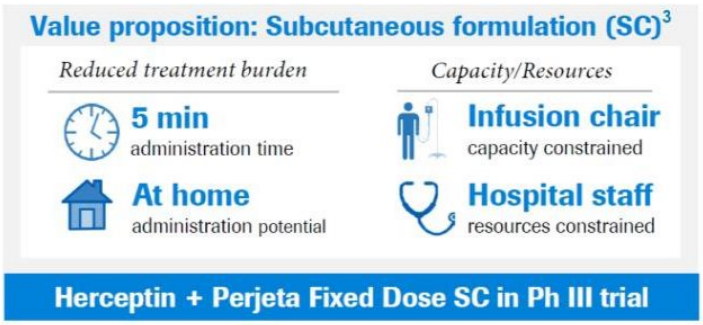
[1] Genmab corporate presentations (Jeffries November 2018, R&D Update and 2018 ASH Data Review December 2018)
[2] Subcutaneous Delivery of Daratumumab in Patients with Relapsed or Refractory Multiple Myeloma Pavo, an Open-Label, Multicenter, Dose Escalation Phase 1b Study (*Blood* 2017)
[3] Subcutaneous Daratumumab in Patients With Relapsed or Refractory Multiple Myeloma: Part 2 Safety and Efficacy Update of the Open-label, Multicenter, Phase 1b Study (PAVO) Ajai Chari et al (ASH December 2018)
[4] Janssen Pharmaceutical Companies' press release dated July 12, 2019

Perjeta®/Herceptin® Fixed Dose Combination with ENHANZE®: Potential Regulatory Submissions First Half 2020

Potential Opportunity

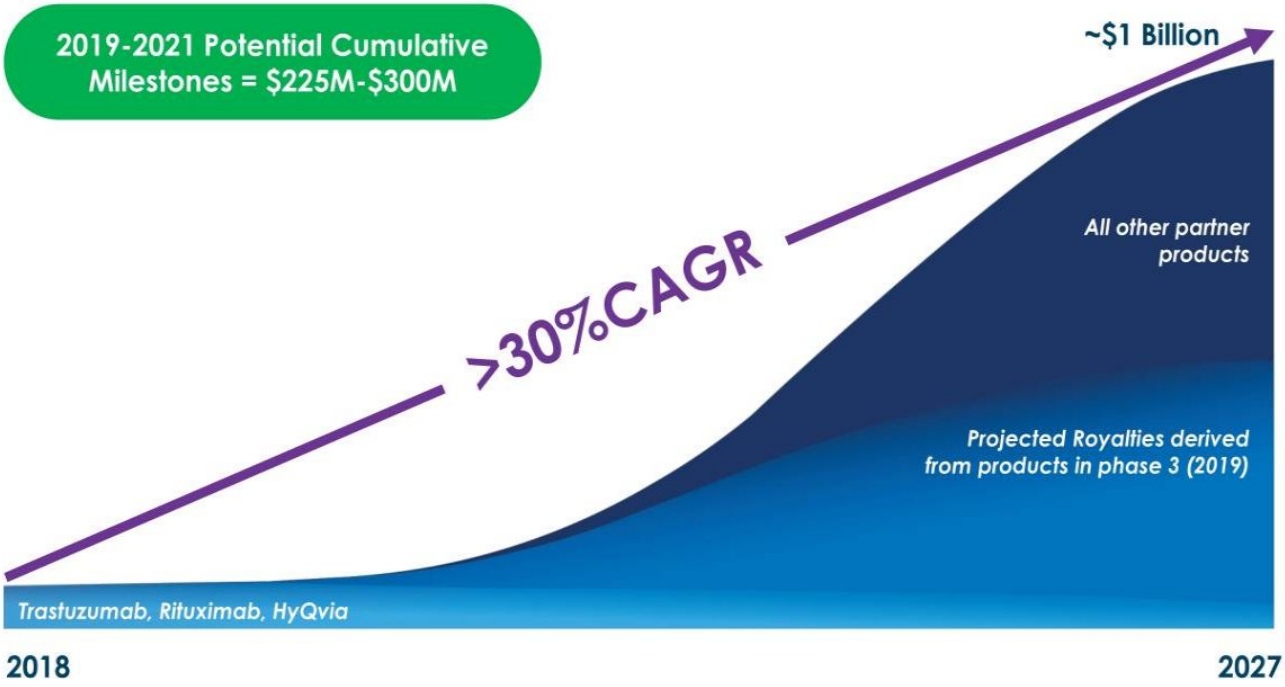
- PERJETA® indicated for use with Herceptin® and chemotherapy for adjuvant treatment of patients with HER2+ early-stage breast cancer (EBC) at high risk of recurrence
- Target population size[2]: ~75,000 in US and EU 5
- Strong IV adoption since launch: ~46% share in high risk early breast cancer in U.S.[1]

Value proposition of Perjeta®/Herceptin® Fixed Dose SC with ENHANZE [3]



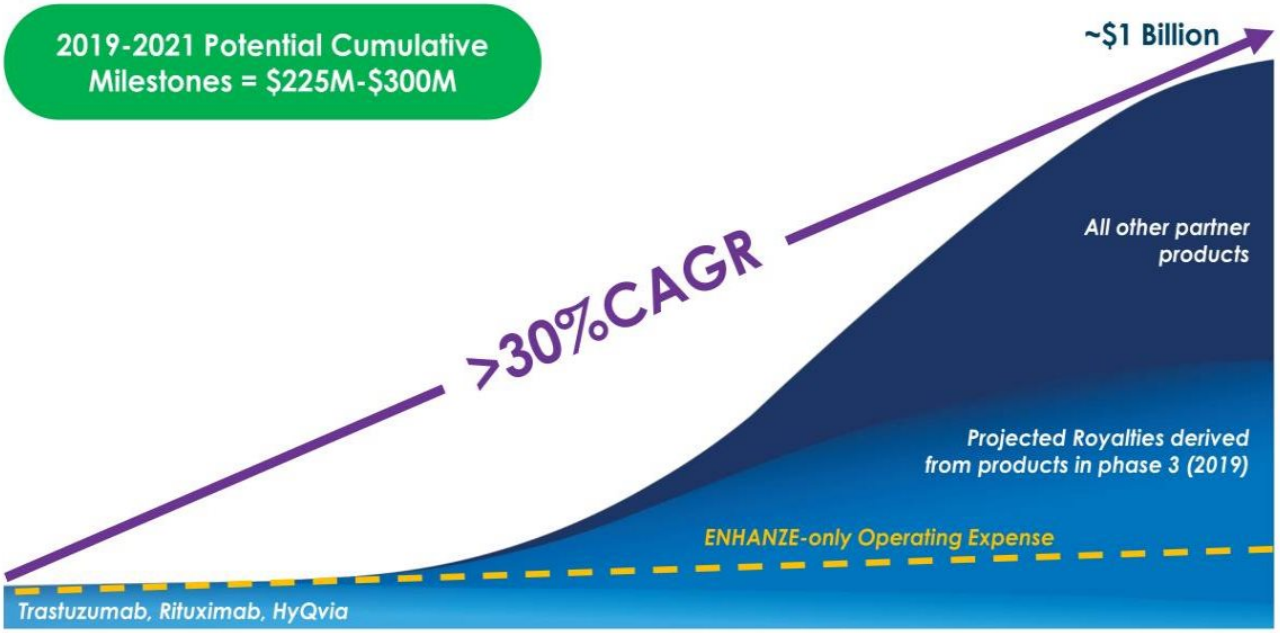
[1] Roche twelve-month 2018 results
[2] Roche HY 2019 Update Presentation
[3] Roche Virtual Late Stage Pipeline Event 2018 presentation (September 13, 2019)

ENHANZE®:
~$1B Royalty Revenue Potential in 2027



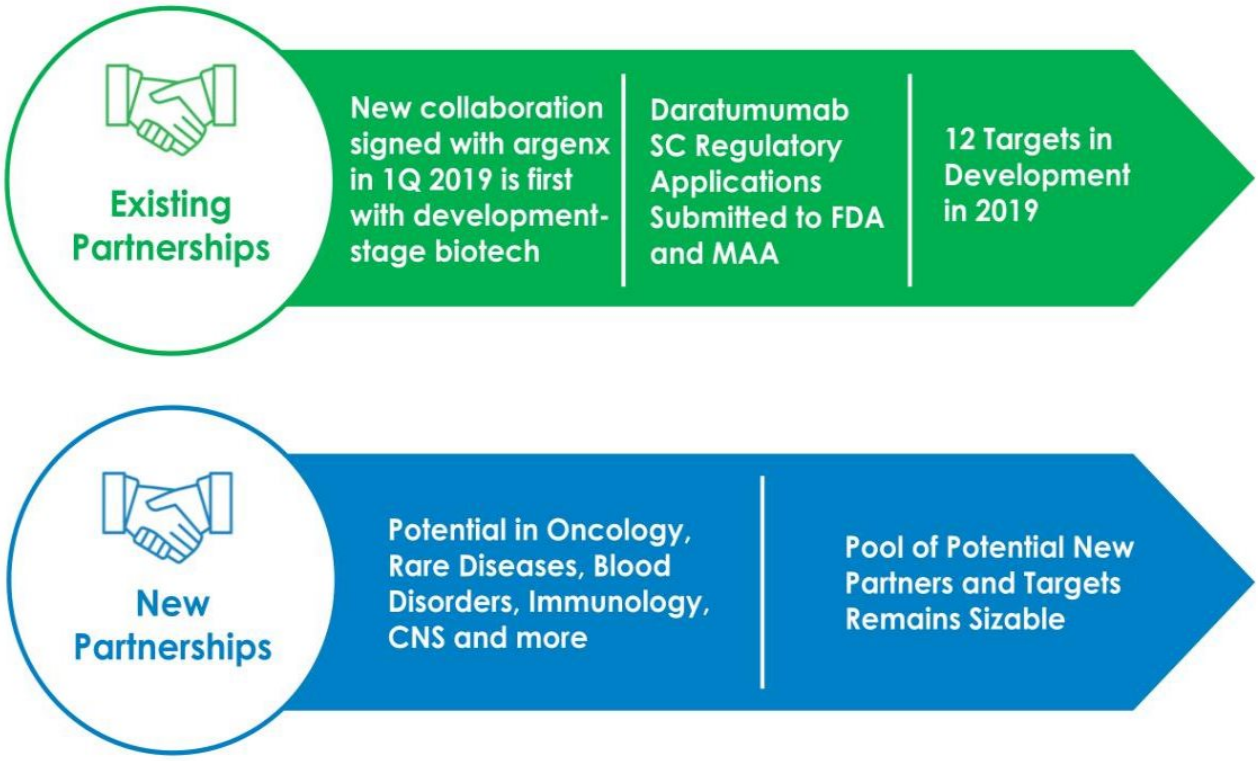
Projection based on approved products and assumes global approval and launches for 12 additional products in multiple indications. Includes projections for subcutaneous versions of targets not currently approved or commercially available. Innovator revenues based on Bloomberg analyst projections, when available. Conversion rates based on Halozyme internal projections. Royalty revenue projection includes targets selected but not yet disclosed. Projected royalty revenue is not risk–adjusted.

ENHANZE®:
Royalties Exceed Pro Forma ENHANZE-only Operating Expenses



Projection based on approved products and assumes global approval and launches for 12 additional products in multiple indications. Includes projections for subcutaneous versions of targets not currently approved or commercially available. Innovator revenues based on Bloomberg analyst projections, when available. Conversion rates based on Halozyme internal projections. Royalty revenue projection includes targets selected but not yet disclosed. Projected royalty revenue is not risk–adjusted. Operating expense represents pro-forma expenses that exclude COGS, and all costs related to Hylenex and PEGPH20.

Accelerating ENHANZE® Growth

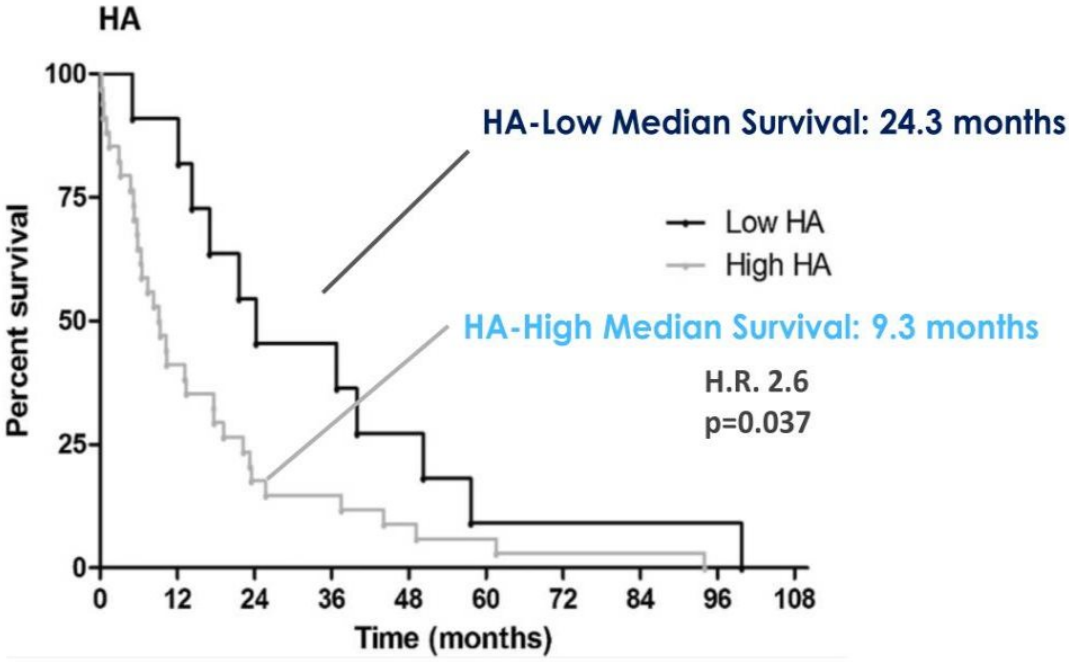


Halozyme

PEGPH20

Tumor HA Overexpression Associated with Shorter Survival in Pancreas Cancer

Retrospective Evaluation of Pancreatic Cancer Survival in ~50 Patients[1]

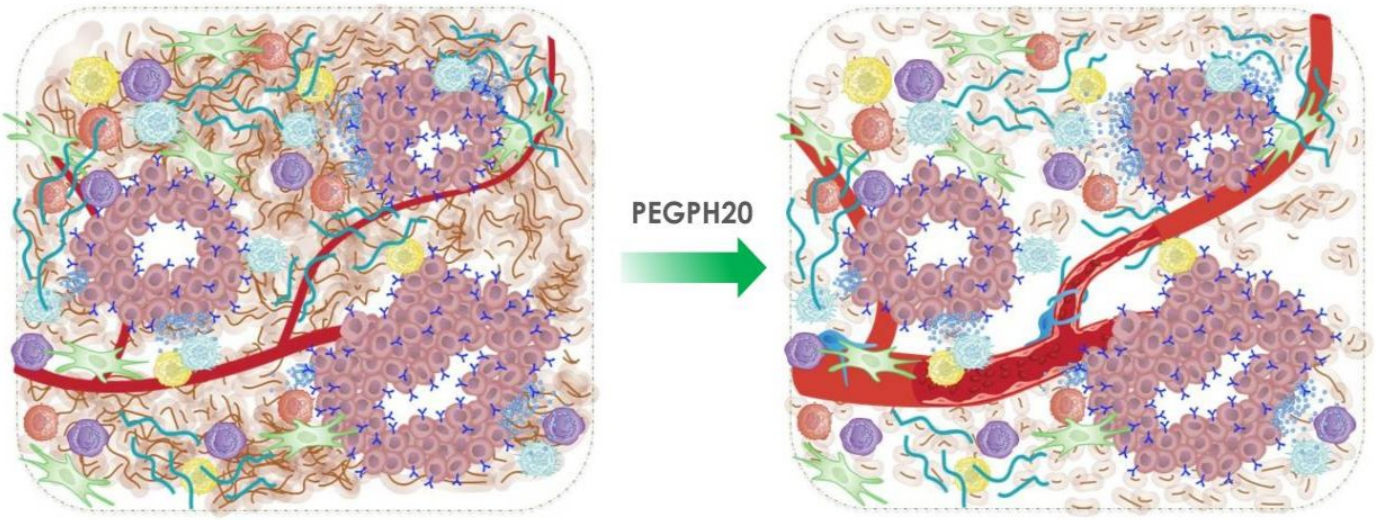


[1] Whatcott et al: Clin Cancer Res 2015, 21:3561-3568. HA staining by HABP. Scoring algorithm assessed percent staining and intensity.

PEGPH20 Targets Hyaluronan (HA) in the Tumor Microenvironment

In HA-High Tumor Animal Models, Removal of HA by PEGPH20 Demonstrated to:

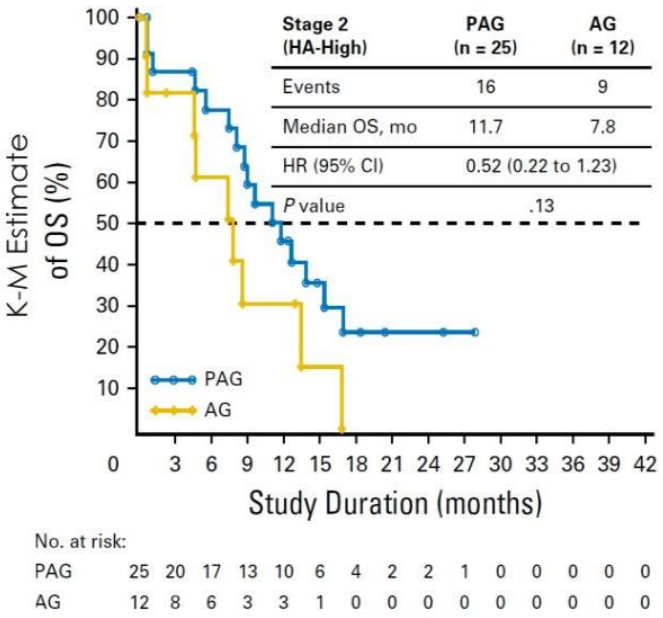
Decrease intratumoral pressure	Decompress vasculature	Increase perfusion	Increase access for therapeutics	Increase access for immune cells



Proprietary Test Developed in Phase II to Identify HA-High Patients for Phase III

- Partnered with Roche Tissue Diagnostics (formerly Ventana) for Companion Diagnostic
- Phase II Study HALO 202 key to develop Companion Diagnostic
  - 279 1L metastatic PDA
  - PEGPH20 plus Abraxane® and Gemcitabine versus Abraxane® and Gemcitabine alone
  - HA all-comers population
- Stage 1: identification of HA algorithm/cut point
  - >50% score =HA-high
- Stage II: validation of cut-point/ algorithm for Phase III
  - 37 of 133 patients HA-high

Analysis of OS in HA-High, Stage II HALO 202[1]



Stage 2 (HA-High)	PAG (n = 25)	AG (n = 12)
Events	16	9
Median OS, mo	11.7	7.8
HR (95% CI)	0.52 (0.22 to 1.23)	
P value	.13	

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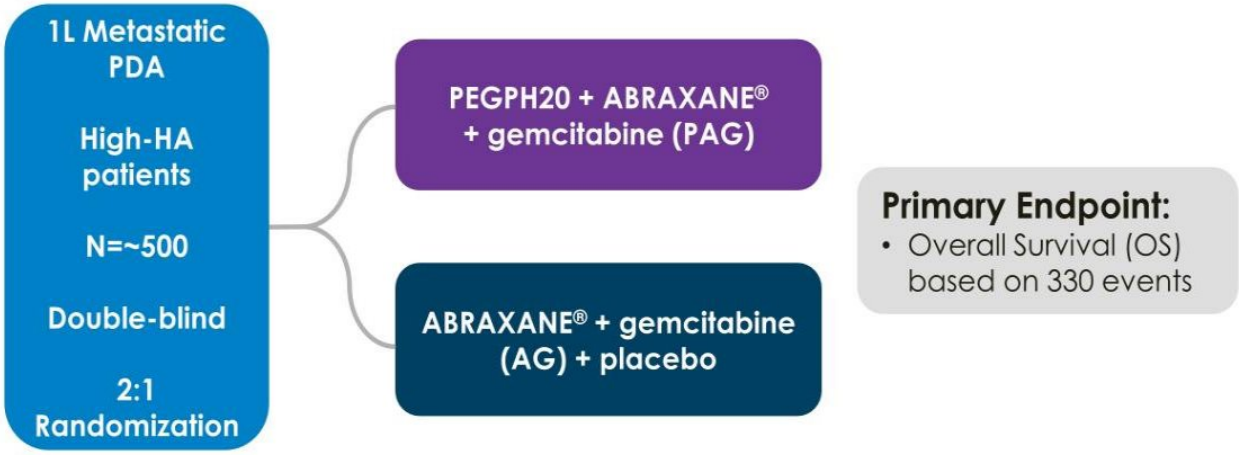
[1] HALO 202: Randomized Phase II Study of PEGPH20 Plus Nab-Paclitaxel/Gemcitabine Versus Nab-Paclitaxel/ Gemcitabine in Patients With Untreated, Metastatic Pancreatic Ductal Adenocarcinoma *Journal of Clinical Oncology*, Hingorani et al (December 2017)

HALO-301 Study in Metastatic Pancreas Cancer



Expect topline data announcement by December 2019

~$1B Potential Opportunity in Pancreas Cancer

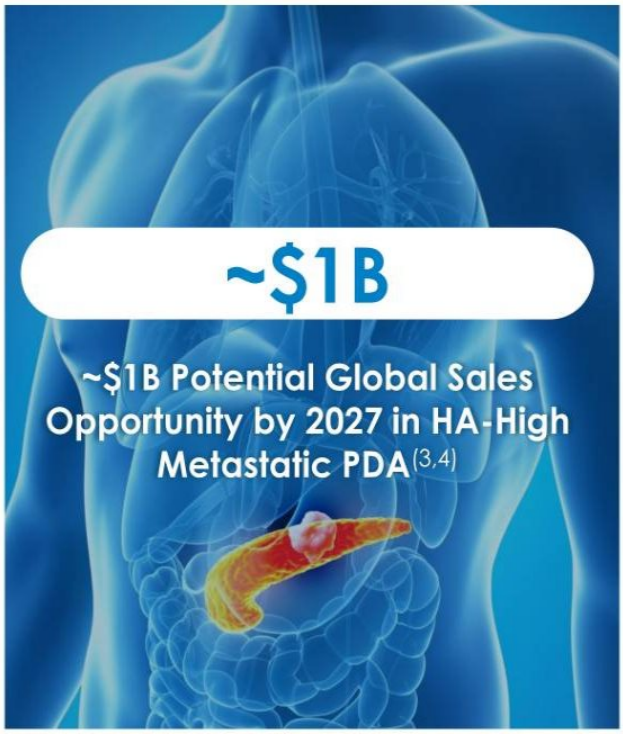
65,000

Annual Diagnosed Metastatic Pancreatic Ductal Adenocarcinoma (PDA) U.S. and EU 5[1]

25,000

Estimated Number of HA-High Patients

35–40% of Population[2]



Halozyme

[1] SEER 18 2006-2012, Globocan 2012, DRG Epidemiology data.
[2] Halozyme estimates for HA-High %.
[3] DRG Epidemiology data, Halozyme internal estimates.
[4] Final revenue potential dependent on risk-benefit profile.

Ongoing Studies Evaluating Pan-tumor Potential of PEGPH20

Combination	Tumor	Stage	Status
Checkpoint Inhibitors			
Atezolizumab (Tecentriq®) *Roche*	Pancreas Cancer (second-line)	Phase 1b Dose Finding Started 2H 2017	Enrollment completed
Atezolizumab (Tecentriq®)	Gall Bladder Cancer, Cholangiocarcinoma	Phase 1b Dose Expansion Initiated Q3 2018	Enrolling additional 15 patients

2019 Financial Guidance

	May 2019	August 2019
Net Revenue	$205M to $215M -Royalties of $72-74M	No Change
Operating Expenses	$265 to $275M	$255 to $265M
Operating Expenses (excl. COGS)	$225 to $235M	$215 to 225M
Operating Cash Burn	($45M) to ($55M)	($40M) to ($50M)
Debt Repayment	~$90M	No Change
Year-end Cash	$210M to $220M	$220M to $230M

Outlook

- **Growing ENHANZE momentum**
  - ~$1 billion in annual royalty revenue potential by 2027
  - Multiple near-term catalysts in a high margin business
- Each pillar offers **strong potential upside**
  - ENHANZE: New deals *plus* up to $1 billion in lifetime milestones
  - PEGPH20: ~$1 billion global sales opportunity in pancreas cancer
- Each pillar has been incrementally **de-risked:**
  - ENHANZE: 3 approved products, DARZALEX® SC regulatory applications submitted in July 2019
  - PEGPH20: HALO-301 fully enrolled
- Expect to end 2019 in **strong financial position**
  - Projected post-301 cash balance provides operational flexibility