

**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): January 15, 2025

OPKO Health, Inc.

(Exact Name of Registrant as Specified in its Charter)

Delaware

(State or Other Jurisdiction
of Incorporation)

001-33528

(Commission
File Number)

75-2402409

(IRS Employer
Identification No.)

4400 Biscayne Blvd.

Miami,

Florida

33137

(Address of Principal Executive Offices)

(Zip Code)

Registrant's telephone number, including area code: (305) 575-4100

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, par value \$0.01 per share	OPK	NASDAQ Global Select Market

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 January 15, 2025, members of management for OPKO Health, Inc. (the “Company”) attended and will participate in meetings with investors at the 43rd Annual J.P. Morgan Healthcare Conference. A copy of the Company’s presentation materials is furnished as Exhibit 99.1 to this Current Report on Form 8-K and incorporated herein by reference. The presentation materials are also available on the Company’s website at www.opko.com under Investor Relations. The information contained on the Company’s website shall not be deemed part of this report.

The information contained in Item 7.01 to this Current Report on Form 8-K and Exhibit 99.1 attached hereto shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934 as amended (“Exchange Act”), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing by the Company under the Securities Act of 1933 as amended (“Securities Act”) or the Exchange Act, except as expressly set forth by specific reference in such a filing.

ITEM 9.01. Financial Statements and Exhibits.

(d) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
99.1 104	OPKO Health, Inc. Presentation Materials Cover Page Interactive Data File (embedded within the Inline XBRL document)

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.

OPKO Health, Inc.

Date: January 15, 2025

By: /s/ Steven D. Rubin
Name: Steven D. Rubin
Title: Executive Vice President - Administration

OPKO

J.P. Morgan Healthcare Conference

January 15, 2025
NASDAQ: OPK

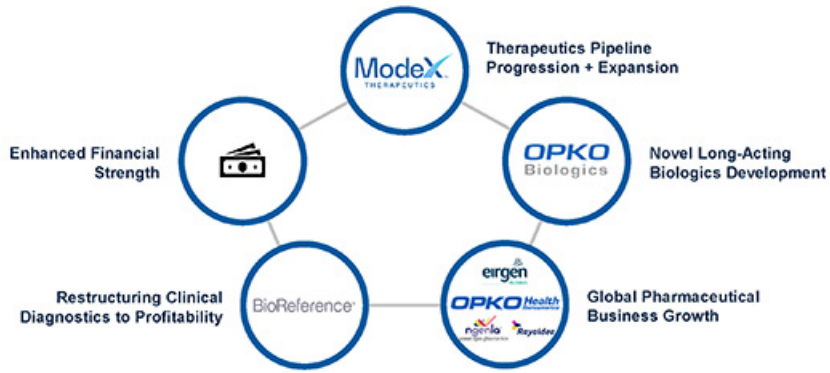


Forward-Looking Statements

This presentation contains "forward-looking statements," as that term is defined under the Private Securities Litigation Reform Act of 1995 (PSLRA), which statements may be identified by words such as "expects," "plans," "projects," "will," "may," "anticipates," "believes," "should," "intends," "estimates," and other words of similar meaning, including statements regarding financial strength and anticipated financial performance, and expectations regarding the market for and sales of our products, whether our product development efforts will be successful and whether the expected benefits of our products will be realized, including whether the data for products in trial will be positive and whether efforts to develop a daily oral dual-agonist GLP-1/gucagon peptide will be successful and we can successfully progress the development of oxyntomodulin in both subcutaneous and oral formulations, whether we will continue to repurchase shares under a buyback program and whether we will continue to purchase convertible notes, whether NGENLA profits will be sufficient to provide long term upside after satisfying our obligations under the note purchase agreement, whether the relationships with our commercial and strategic partners will be successful, our ability to market and sell any of our products in development, whether we will continue to successfully advance products in our pipeline and whether they can be commercialized, whether BioReference will be able to streamline its laboratory services business and better position the division for sustained growth and profitability, whether BioReference's attempts at returning its core business to profitability will be successful, whether our strategic efforts to grow the Company will ultimately be successful and create shareholder value, as well as other non-historical statements about our expectations, beliefs or intentions regarding our business, technologies and products, financial condition, strategies or prospects. Many factors could cause our actual activities or results to differ materially from the activities and results anticipated in forward-looking statements. These factors include those described in our Annual Reports on Form 10-K filed and to be filed with the Securities and Exchange Commission and under the heading "Risk Factors" in our other filings with the Securities and Exchange Commission, as well as the continuation and success of our relationship with our commercial partners, liquidity issues and the risks inherent in funding, developing and obtaining regulatory approvals of new, commercially-viable and competitive products and treatments. In addition, forward-looking statements may also be adversely affected by general market factors, competitive product development, product availability, federal and state regulations and legislation, the regulatory process for new products and indications, manufacturing issues that may arise, patent positions and litigation, among other factors. The forward-looking statements contained in this press release speak only as of the date the statements were made, and we do not undertake any obligation to update forward-looking statements. We intend that all forward-looking statements be subject to the safe-harbor provisions of the PSLRA.

2024 In Review: A Transformative Year

OPKO is well-positioned for growth and value across its businesses



ModeX Proprietary Technologies

Since OPKO's acquisition in May 2022, ModeX has further validated its core technologies and advanced 3 pipeline assets to clinical stages

MULTISPECIFIC ANTIBODIES



- Designed to bind to 2 T cell antigens and 2 tumor antigens
- Offers greater specificity than existing I/O treatments
- Broad potential applications across I/O, immunology and viral diseases

MULTIVALENT NANOPARTICLE VACCINES



- Nanoparticle vaccine technology targeting 4+ viral proteins
- Next-generation vaccines for cancer prevention

IMMUNO-ONCOLOGY

IMMUNOLOGY

VIRAL DISEASES

ModeX Development Pipeline

ModeX has promising portfolio assets with 3 in clinical stage and 2 pre-IND assets to enter clinic in 2025

	PRODUCT	INDICATION	EARLY STAGE	PRE-IND	PHASE 1	PHASE 2	PARTNER
Immunology-Oncology	CD3/CD28/ICMET/Trop2 Tetraspecific T Cell Engager	Treatment of Solid Tumors	MOX201				
	CD3/CD28/CD19/CD20 Tetraspecific T Cell Engager	Treatment of Leukemia/Lymphoma	MOX203				
	Multispecific Immune Modulator	Solid Tumors, Infectious Disease, Autoimmune	MOX204				
	Antibody-radiionuclide Conjugate	Solid Tumors, Diagnostics	Lead Generation				
Antiviral	HIV Trispecific COOV Antibody	Treatment and Prevention of HIV	SAR441226 - Phase 1 Complete				NIH
	EBV Nanoparticle Vaccine	Prevention of EBV-related Diseases	MOX201				MERCK
	COVID Multispecific Antibodies	Prevention of COVID-19	MOX201, MOX202				NIH
	HIV Multispecific Antibody	Treatment and Prevention of HIV	Lead Generation				NIH
	Influenza Multispecific Antibody and Gene Delivery	Prevention of Influenza	Lead Generation				NIH

OPKO

Antiviral

Immunology-Oncology

ModeX Partnerships and Business Development

OPKO has formed productive partnerships to share development costs and leverage commercial capabilities



EBV NANOPARTICLE
VACCINE

PH1 TRIAL

COMMENCED DEC 2024

ELIGIBLE FOR UP TO

\$872.5M

IN TOTAL MILESTONE PAYMENTS AND
ROYALTIES ON GLOBAL SALES

\$87.5M

PAYMENTS RECEIVED TO DATE¹



COVID-19 / FLU
MULTISPECIFICS

\$51M

ADDITIONAL FUNDING AWARDED IN Q4 2024

NOW ELIGIBLE FOR UP TO

\$205M

IN TOTAL FUNDING
FOR VIRAL PROGRAMS

\$110M

COMMITTED TO DATE²



ADDITIONAL
PARTNERSHIPS

- Active business development discussions around several programs
- Non-dilutive collaborations support and accelerate development of assets while retaining value creation

1) Through 12/31/24. Includes milestone payments of \$62.5M and expense reimbursements of ~\$25M

2) As of 12/31/24

Advancement in Long-Acting Biologics

OPKO Biologics has developed a robust technology and portfolio of long-acting therapeutic proteins and peptide drug candidates which have the potential to address large, high-need markets

- ✓ Created NGENLA™ (somatrogen), once-weekly injectable **hGH molecule** now marketed by Pfizer in over 40 countries
- ✓ Utilize novel technologies to develop **next-generation, bio-better, long-acting biologics**
- ✓ In-house expertise and **state-of-the-art facilities in Israel** support mission of developing new and better drugs

In Development: Oxyntomodulin Analog

Oral

Collaborating on development of oral GLP2 and dual-agonist GLP-1/GCGR



Injectable

Targeting treatment of diabetes, obesity and MASH



Growth of Pharmaceutical Product Sales

Business lines across the globe generate durable, growing revenues

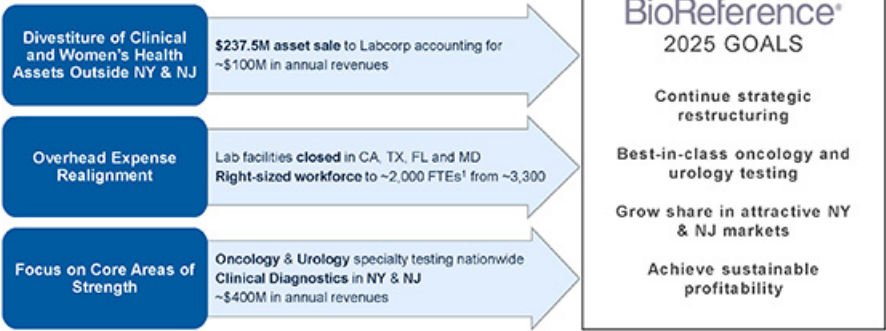
OPKO

 Global Health Sales 5% local currency sales growth ¹ 19% EBITDA margin ¹ Organic and inorganic growth opportunities	 hGH Franchise Growth Expansion of indications to adult and other pediatric populations \$19M YTD profit share payments earned ²	 Sustained Sales of CKD Therapy Commercial launch in Greater China by partner Nicoya in 2025 Recent scientific publications expected to increase physician awareness	 Production Capabilities Utilize manufacturing expertise for OPKO and others 57% Eirgen sales growth ³
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1) For 9 months ended 09/30/24, local currency growth compared to the same period in 2023
2) Profit share payments paid by Pfizer for 9 months from 01/01/24 to 09/30/24
3) Eirgen generics revenue for 9 months ended 09/30/24 compared to 9 months ended 09/30/23 in local currency

Clinical Diagnostics Reset: A Streamlined BioReference

A re-calibration of the organization and improved cost structure position BioReference for profitability in 2025



1) Full-time employees as of 01/06/25

Realignment of Capital Structure in 2024

A series of transactions in 2024 to recapitalize the balance sheet provide flexibility to execute long-term plans

OPKO

Balance Sheet Reset	\$300M	convertible note conversion from 2025 to 2029 maturity
	\$250M	NGENLA royalty monetization with retention of upside and milestone rights of \$100M
	\$238M	sale of clinical diagnostics and women's health assets outside NY & NJ to Labcorp

Shareholder Value	\$189M	proceeds from selling partial stake in GeneDx (NASDAQ:VIGS) ¹
	\$90M	to repurchase and retire 81M shares (avg. of \$1.11 per share) ²

Strongly Positioned for 2025+

-  Enhanced Financial Position
-  R&D Investment
-  Return Capital to Shareholders

1) Gross proceeds on the sale of ~3.19 million GeneDx shares between 07/01/24 to 01/10/25, 370,841 GeneDx shares held in remaining stake as of 01/10/25
 2) Shares of common stock repurchased and retired between 01/01/2024 to 01/09/25, 671,500,270 shares of common stock outstanding as of 12/31/24
 3) Amount spent to repurchase 3.75% Convertible Senior Notes due 2029 between 05/01/24 to 01/09/25, ~\$20.5 in principal

2025 Priorities to Generate Long-Term Value

Focused on execution of strategic priorities to produce clinical and financial success

ModeX Pipeline Progression	<ul style="list-style-type: none"> ✓ Produce safety and early efficacy data for Ph1 assets ✓ Prepare 2 additional assets to enter clinical development ✓ Extend growth in non-dilutive partnerships
Biologics Development	<ul style="list-style-type: none"> ✓ Advance 2 molecules to IND stages ✓ Explore potential partnerships
Global Pharmaceutical Business	<ul style="list-style-type: none"> ✓ Maintain and accelerate revenue growth ✓ Improve profitability
BioReference	<ul style="list-style-type: none"> ✓ Continued strategic restructuring ✓ Grow share in NY & NJ market ✓ Achieve profitability
Enhanced Financial Strength	<ul style="list-style-type: none"> ✓ Recapitalized financials achieved in 2024 ensures sustained funding for R&D and commercial operations



OPKO