Market Scope®
Ophthalmic Market Perspectives

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June 22, 2023

Q1-2023 VOLUMES

Refractive: ↓ 10.9%

Glaucoma: ↑ 11.5%

IOL: ↑ 5.2%

Retina: ↑ 0.2%

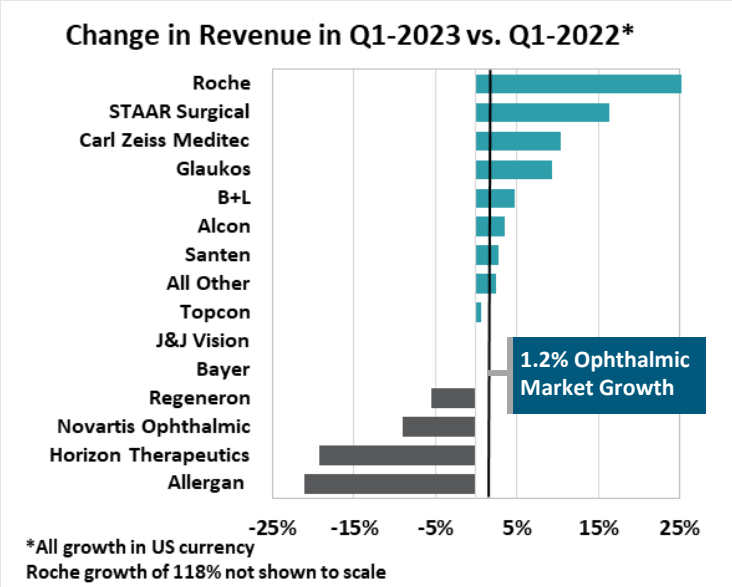
Ophthalmologists Report 1.7 Percent Increase in Q1-2023 Procedure Volume

By Chelsea Jones

US ophthalmologists reported that ophthalmic procedures grew 1.7 percent in Q1-2023 compared with the same quarter in 2022, according to Market Scope's latest survey. Year-over-year performance varied across

(continued on page 11)

Q1-2023 COMPANY REVENUE



Ophthalmic Company Revenue Increases 1.2 Percent in First Quarter of 2023

By Chelsea Jones

Ophthalmic manufacturer revenue in Q1-2023 totaled $11.1 billion. Most public companies reported above-average revenue in Q1-2023 compared with the past three years, while two public companies had below-average quarters.

(continued on page 6)

Octane Dives into Tough Debates, Remains Optimistic for Ophthalmic Market's Future

By William Freeman and Kristen Harmon Ingenito

Octane's 2023 Ophthalmology Tech Forum tackled some of the industry's biggest concerns: office-based surgery, market regulations, digital reimbursement, top fears, and surgery waste.

The accelerator held its annual meeting June 8-9 at the Balboa Bay Resort in

(continued on page 24)

Balboa Bay Resort

Ultrasonic Phaco Continues to Thrive after Half a Billion Procedures and a Rocky Start

By William Freeman

Ultrasonic phacoemulsification—invented by Charles D. Kelman in 1969—has significantly improved cataract patients' quality of life while becoming the most frequently performed procedure in ophthalmology. By our estimate, surgeons have performed half a billion ultrasonic phaco (USP) procedures globally since USP's launch 54 years ago.

(continued on page 20)

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IN THIS ISSUE

Refractive Surgery Has Grown into One of China's Biggest Ophthalmic Markets

By Peter Downs

Investor-owned eye hospital chains in China have seen revenue from refractive surgery soar since the advent of COVID-19, boosting the refractive segment into a tie for third among China's ophthalmic markets. Thirty-seven percent of revenue at the top four investor-owned

(continued on page 22)

OPHTHALMIC NEWS

Novaliq Gains US Approval of Vevye for the Signs and Symptoms of Dry Eye

By Joan McKenna

Novaliq, of Heidelberg, Germany, reported June 8 that the US FDA had approved Vevye (cyclosporine ophthalmic solution) 0.1% for the treatment of the signs and symptoms of dry eye disease. June 8 was the target action date.

Vevye, formerly called CyclASol, is a topical anti-inflammatory and immunomodulating solution in Novaliq's water-free, preservative-free EyeSol delivery vehicle.

Novaliq has said drops formulated with EyeSol do not induce blinking or tearing, so the drug stays on the eye longer.

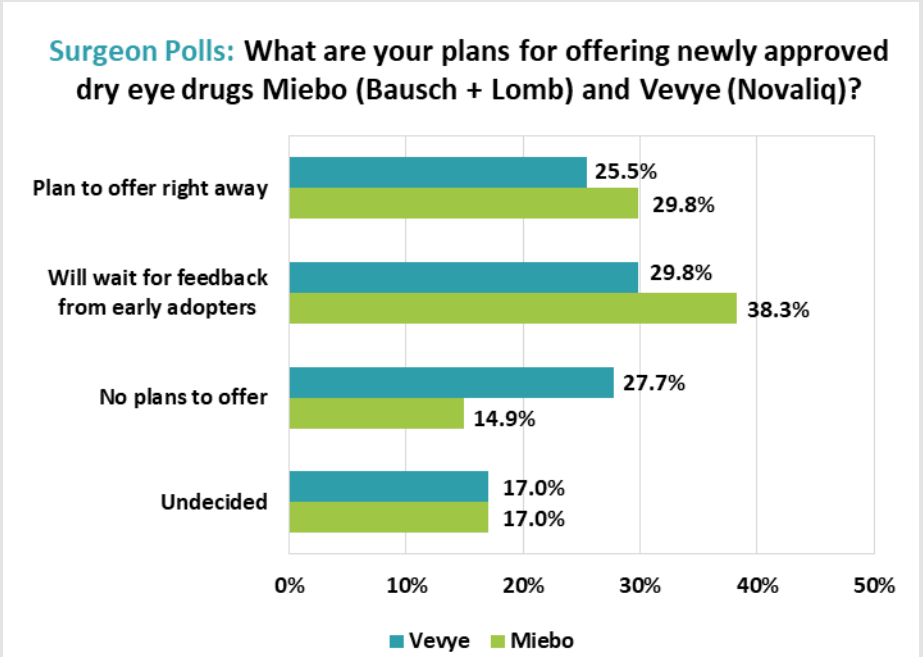
The approval is a second milestone win for Novaliq in three weeks, following FDA approval on May 18 of Bausch + Lomb's Miebo (perfluorohexyloctane ophthalmic solution), formerly NOV03, for the signs and symptoms of dry eye. Bausch + Lomb licensed Miebo from Novaliq in 2019 for the US and Canada.

On June 12, Senju Pharmaceuticals announced it had licensed Miebo for development in Japan.

Miebo also is a water-free, preservative-free drop based on the EyeSol technology.

Novaliq calls the two products complementary, describing Miebo as a tear film stabilizer to prevent excessive tear evaporation and restore tear balance in evaporative dry eye, while Vevye is a powerful and comfortable drug with rapid onset, designed to address inflammatory dry eye.

Vevye also is intended to address corneal surface damage resulting from the chronic inflammatory nature of dry eye.



Market Scope's Weekly Surgeon Polls, May 29-June 4, 2023, and June 12-16, 2023; N=47 for each.

Novaliq has said drops formulated with EyeSol do not induce blinking or tearing, so the drug stays on the eye longer.

Novaliq's Vevye gained US approval a month after Bausch + Lomb's Miebo.

John D. Sheppard, MD, an investigator in the development program, said in Novaliq's announcement that Vevye's clinical trials consistently showed significant improvement in ocular surface damage and associated symptoms.

Novaliq has said it intends to seek approval for Vevye in other geographies, including the European Union.

In China, the candidate was exclusively licensed to Hengrui in November 2019, and a Phase III study began in March 2021.

A third dry eye drop using the EyeSol technology, NovaTears, is marketed by Ursapharm as EvoTears in Europe and by AFT Pharmaceuticals as NovaTears in Australia and New Zealand.

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Market Scope

Our proprietary disease models offer extensive country-level prevalence data for various ophthalmic diseases and conditions by age group.

All countries with a population over a million are modeled for your own analyses.

Disease Models

Our proprietary global disease models take into consideration the latest clinical research and demographic projections on a global scale and can be customized by geography and disease category to meet clients' diverse needs. Disease models can be used to evaluate target markets for clinical-stage and commercial-stage products and gain insights into the volume and demographics of diseased populations.

Current offerings include country-level analysis and projections for:

- **Retinal Conditions:** RVO, AMD, DME, and others
- **Refractive Error Distribution:** myopia, hyperopia, and presbyopia
- **Dry Eye:** patients with signs and symptoms
- **Glaucoma:** OHT, OAG, ACG, secondary glaucoma
- **Cornea:** ectasias, keratitis, dystrophies, congenital, trauma

Acelyrin Leads Latest Ophthalmic Fundraising with $621 Million IPO

By Jennie Crabbe

Los Angeles-based Acelyrin led recent fundraising efforts by ophthalmic companies with a $621 million upsized initial public offering. Funding announced in the past four weeks totaled $1.1 billion.

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Recent Ophthalmic Fundraising			
Date	**Company**	**Amount**	**About**
June 14	Invirsa	$7.7 million in Series B funding	The Columbus, Ohio, company said the funds will support a series of Phase II studies of INV-102 in acute infectious keratoconjunctivitis, dry eye, and Fuchs corneal dystrophy.
June 12	Beacon Therapeutics	$120 million investment	The newly launched, UK-based company is developing gene therapies for blinding retinal diseases. Beacon's lead clinical asset is AGTC-501, a gene therapy program in Phase II for the treatment of XLRP. Syncona, the lead investor in Beacon, acquired AGTC in November 2022. Preclinical candidates target dry AMD and cone-rod dystrophy. The company is led by David Fellows, former CEO of Nightstar.
June 6	Cellusion	$21 million in Series C funding	The Japanese company is advancing CLS001, a system for producing mass cultures of corneal endothelial cells from induced pluripotent stem cells, reducing the need for cornea transplants in bullous keratopathy patients. Funding will go in part toward advancing CLS001 and subsequent pipelines.
June 6	CoFi	$3.5 million in seed funding	The Boston-based company provides a multi-party payment platform for practices offering elective ophthalmic procedures, allowing patients to pay multiple providers involved in their surgery at once.
June 6	AAVantgarde Bio	$65.2 million in Series A funding	The Milan, Italy, company has two lead gene therapy candidates: one in RP associated with Usher type 1B, and one in Stargardt. The company said it also intends to pursue programs beyond ophthalmology.
June 5	Alkeus Pharmaceuticals	$150 million in Series B funding	The Cambridge, Massachusetts, company said it would use the proceeds to advance gildeuretinol (ALK-001) in Stargardt. Alkeus says gildeuretinol substantially reduces vitamin A dimerization, or clumping, in the eye, without any impact on normal vision.
Early June	VivaVision	$14.1 million in Series D2 funding	The Chinese company, founded in 2016, said it would use the proceeds in part to advance multiple ophthalmic drugs and to continue preclinical research and development. VivaVision is a portfolio company of Viva BioInnovator.
May 31	Oculis	$42 million public offering	The Swiss company said it would use the proceeds in part to advance its pipeline. Oculis is developing a high-concentration dexamethasone eye drop for DME and postsurgical pain and inflammation; a topical biologic for dry eye; and a neuroprotective agent for optic neuritis and glaucoma.
May 30	Belite Bio	$30 million public offering of American Depositary Shares	The San Diego company said it would use the net proceeds for further development of tinlarebant; for research and development of other pipeline products; and for working capital and other general corporate purposes. Tinlarebant (LBS-008) is an oral Stargardt candidate targeting toxic vitamin A byproducts in the retina.
May 24	Ocugen	$16.5 million public offering	The Malvern, Pennsylvania, company said it would use the proceeds for general corporate purposes. Ocugen is developing gene therapy candidates for DME, dry AMD, and inherited retinal diseases such as Stargardt, RP, and LCA.
May 23	Abionyx Pharma	$12.9 million equity-linked financing	The French company said the funding would allow it to launch production of new batches of CER-001, a bio-HDL mimetic treatment candidate for LCAT deficiency; and to finance other expenses. CER-001 has orphan drug status in the US and EU.
May 9	Acelyrin	$621 million upsized initial public offering	The Los Angeles company started trading May 5 on the Nasdaq under the symbol SLRN. The company is developing izokibep (anti-IL-17A) for uveitis and other indications; and lonigutamab (anti-IGF-1R) for thyroid eye disease.

Select US FDA Approvals and Clearances in May 2023

By Kristen Harmon Ingenito

The US FDA granted three clearances through the ophthalmic device division using the 510(k) pathway in May 2023, according to the agency's database. Two of those clearances were for New World Medical's submissions to update the material used in its Ahmed Glaucoma Valves to a slightly firmer grade of silicone.

C. Light Technologies gained clearance for its device, the Retitrack, billed as an eye movement monitor that uses SLO technology and integrated software to record, view, measure, and analyze eye movement. C. Light is an AI-driven health tech company that has previously described its tracking devices as aimed at detecting multiple sclerosis and other central nervous system conditions (more coverage on Page 34).

The FDA approved six ophthalmic premarket approval (PMA) applications in May, most relating to small changes in process regarding manufacturing, sterilization, quality testing, packaging, labeling, or suppliers. However, J&J Vision Surgical gained approval for a design modification to its Tecnis Synergy PC-IOL.

There were no *de novo* classifications announced in May.

Market Scope will continue to update this table with important FDA filings from the previous month.

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Select Ophthalmic Devices Gaining FDA Approval or Clearance in May 2023

Decision Date	Applicant	Device	Pathway	Description
May 23	J&J Vision Surgical	Tecnis Synergy IOL	PMA Supplement	Change in design
May 12	New World Medical	Ahmed Glaucoma Valve Models Fp7 and Fp8	510(k)	Update to silicone material used
May 9	C. Light Technologies	Retitrack	510(k)	Eye movement monitor

HanAll's Dry Eye Candidate Tanfanercept Misses Primary Endpoints in Phase III Trial

By Jennie Crabbe

South Korea-based HanAll Biopharma reported May 19 that its topical anti-inflammatory dry eye candidate tanfanercept missed its primary endpoints in the Phase III VELOS-3 trial.

Tanfanercept did not demonstrate statistical significance in either of the primary outcome measures of improvement in central corneal staining score or improvement in Eye Dryness Score (EDS) at week 8 vs. vehicle.

The candidate did, however, demonstrate a highly statistically significant improvement on a secondary outcome measure, Schirmer score of tear volume. Fifteen percent of treated subjects achieved a 10 mm or greater improvement in Schirmer score at week 8, vs. 4 percent on vehicle.

The company noted that the US FDA, in draft guidance on dry eye drug development in 2020, listed 10 mm improvement or more in Schirmer score as an acceptable primary efficacy endpoint.

Tanfanercept targets tumor necrosis factor alpha (TNF-α) and was co-developed with Daewoong Pharmaceutical.

The companies hold global rights for tanfanercept except in Greater China, where Harbour BioMed owns the rights.

Sean Jeong, MD, MBA, co-CEO of HanAll, said the company would continue to analyze clinical data for tanfanercept and evaluate its potential at higher concentrations or in additional indications.

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REGULATORY UPDATE

CorNeat Vision Gains US Clearance for EverPatch Ophthalmic Graft Material

By Joan McKenna

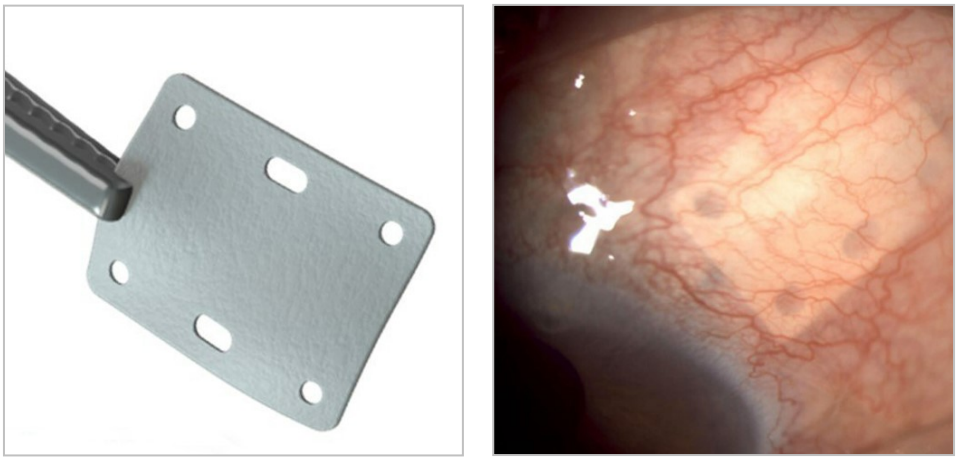
Israel-based CorNeat Vision reported June 8 that the US FDA had cleared its EverPatch scleral reinforcement patch.

The graft is the first synthetic, nondegradable tissue-integrating matrix for use in ophthalmic surgeries, CorNeat said.

It is composed of a non-woven, polymer matrix that integrates with surrounding tissue and is intended to reinforce the sclera and aid the physical reconstruction of the ocular surface.

The company said the patch will be launched initially at leading US ophthalmic centers in Q3-2023, with the rollout expanding nationwide later in the year.

Dr. Gilad Litvin, CorNeat Vision's chief medical officer and co-founder, said the graft was designed to meet the goals of being long-lasting, sterile, immunologically inactive, cosmetically acceptable, and readily available.



The CorNeat EverPatch is shown before implantation (left) and under the conjunctiva at nine months post-implantation.

He noted that CorNeat had received extremely positive feedback from surgeons.

Litvin said the EverPatch is "significantly thinner than processed patch tissue, provides better handling as it does not 'cheesewire' when sutured, and has holes that allow for accurate positioning and anchoring. These holes also facilitate direct conjunctival adhesion to the sclera, thus supporting its bio-integration."

The company's portfolio also includes the CorNeat KPro synthetic cornea; the CorNeat eShunt glaucoma device; and the CorNeat gPatch periodontal regeneration membrane.

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Q1-2023 Revenue

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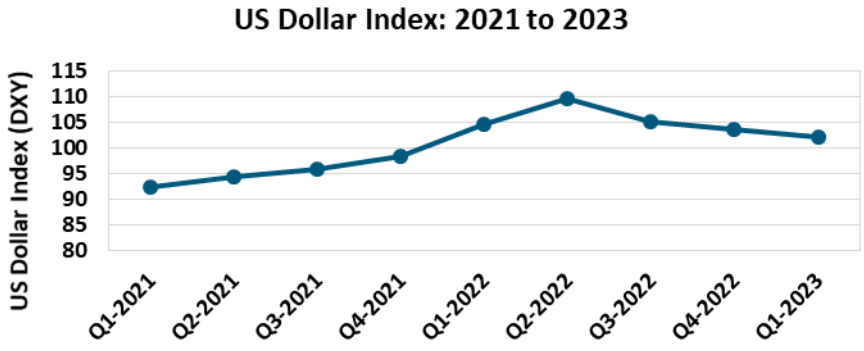
Revenue increased 1.2 percent from the same quarter in 2022 and decreased 0.6 percent from Q4-2022.

The total includes Market Scope estimates for private companies and excludes contact lenses and contact lens care products.

Eight of the 14 publicly held companies tracked for this report saw growth in Q1-2023 compared with Q1-2022, and five companies reported declines.

Among those with growth, Roche saw an increase of 118.2 percent.



Source: ICE Futures US

STAAR Surgical reported growth of 16.3 percent. Carl Zeiss Meditec saw a rise in revenue of 10.5 percent (12.7 percent in home currency).

Note that the US dollar has increased steeply since Q1-2021.

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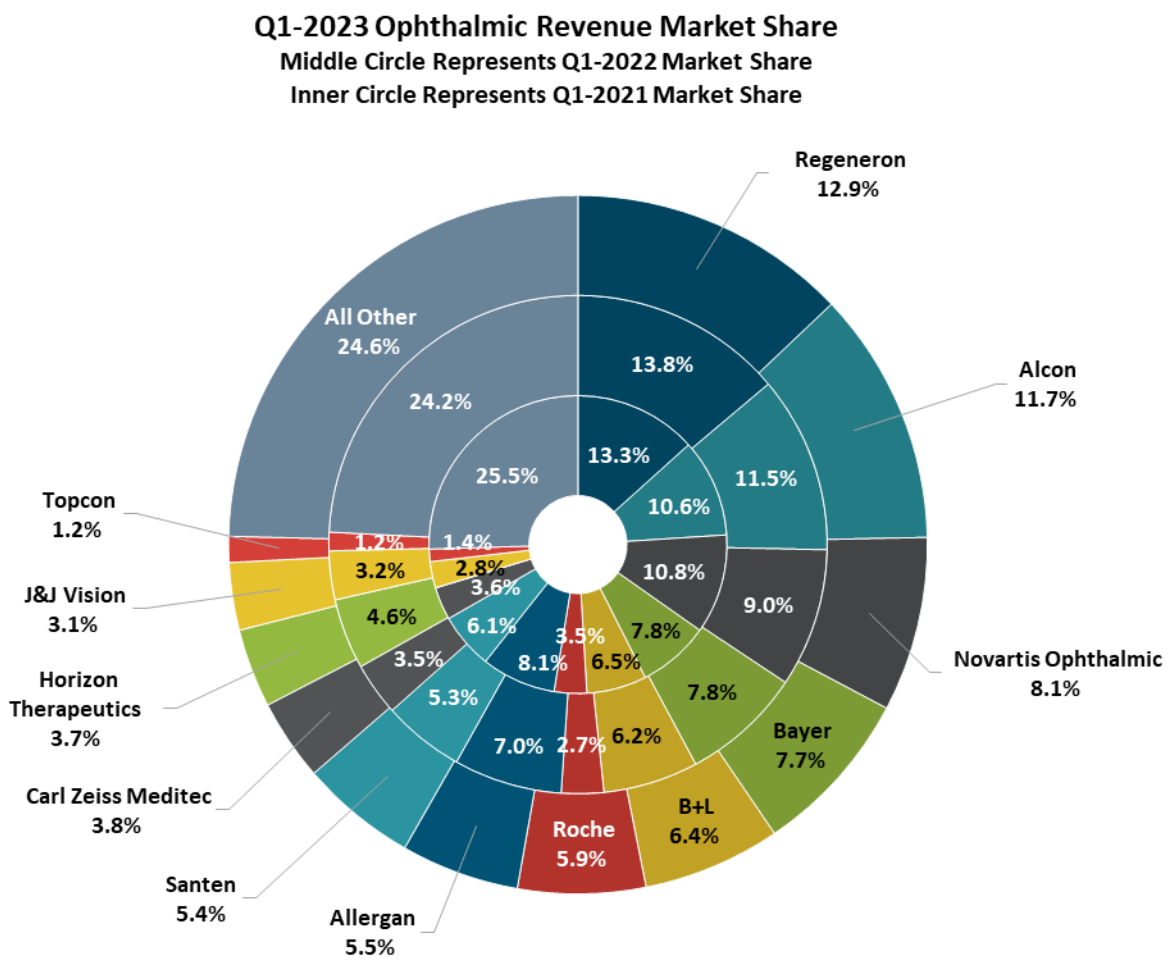

Source: Market Scope

Q1-2023 Revenue

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Other currencies have declined against the dollar. In this analysis, all currencies are converted to USD for comparison; by comparing against periods where the US dollar is well above the average, companies reporting revenue in other currencies may appear to have had more depressed growth—even though growth in home currencies was strong (or less depressed).

Company Ophthalmic Market Share

The 14 publicly held companies accounted for 76.7 percent of total revenue during the quarter, and Market Scope estimates that other ophthalmic firms represented 23.3 percent, or $2.6 billion in revenue.

Ten companies were responsible for 71.1 percent of total Q1-2023 revenue.

Regeneron had an ophthalmic market revenue share of 12.9 percent, based on $1.4 billion in revenue from the US Eylea franchise.

Alcon followed with $1.3 billion, for 11.7 percent of all ophthalmic revenue, up from 11.5 percent in Q1-2022. Other leading companies included Novartis Ophthalmic at $898.0 million, or 8.1 percent; Bayer at $857.8 million, or 7.7 percent; Bausch + Lomb at $708 million, or 6.4 percent; Roche at $656 million, or 5.9 percent; Allergan at $608.0 million, or 5.5 percent; Santen at $596.8 million, or 5.4 percent; Carl Zeiss Meditec at $417.9 million, or 3.8 percent; Horizon at $405.3 million, or 3.7 percent; and Johnson & Johnson Vision Surgical at $347.0 million, or 3.1 percent.

Roche gained 3.2 percent in market share, and Allergan lost 1.6 percent in share year over year.

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Q1-2023 Revenue

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Selected Product Revenue

STAAR Surgical reported a revenue increase of 20.3 percent for its phakic IOLs compared with Q1-2022.

Retinal pharmaceutical revenue increased by 5.2 percent when compared with Q1-2022. Eylea generated decreased revenue of 5.5 percent for Regeneron (US market). Eylea sales for Bayer outside the US (OUS) were down 0.1 percent. Lucentis' revenue decreased in the US market (Roche) by 34.2 percent and decreased in OUS regions (Novartis) by 20.0 percent when compared with Q1-2022. Beovu (Novartis) revenue increased 6.3 percent and Vabysmo (Roche) increased nearly 2 thousand percent (from a small base).

Ophthalmic Pharmaceutical and Device Revenue

Revenue for ophthalmic pharmaceuticals totaled $7.5 billion in Q1-2023, on par with $7.5 billion in Q1-2022. Device and equipment revenue totaled $3.6 billion in Q1-2023, up from $3.5 billion in Q1-2022.

Regeneron accounted for 19.1 percent of ophthalmic pharmaceuticals revenue, followed by Novartis Ophthalmic with 11.9 percent. Alcon accounted for 36.4 percent of ophthalmic device and equipment revenue, followed by Carl Zeiss Meditec, with 11.7 percent of revenue categorized as device and equipment.

Bausch + Lomb reported a realignment in segment structure that resulted in a change in the former reporting units, which are now divided into Vision Care, Ophthalmic Pharmaceuticals, and

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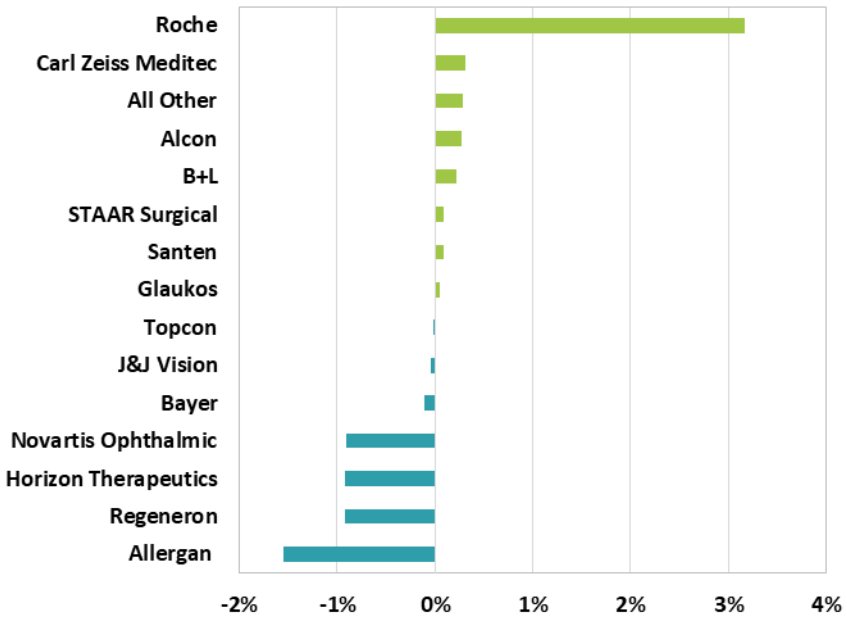
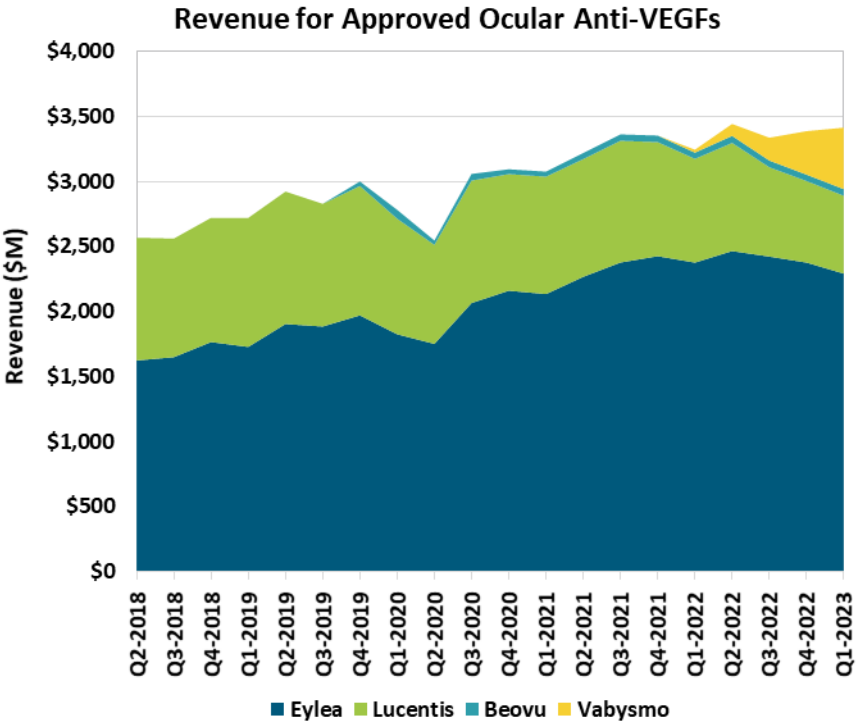
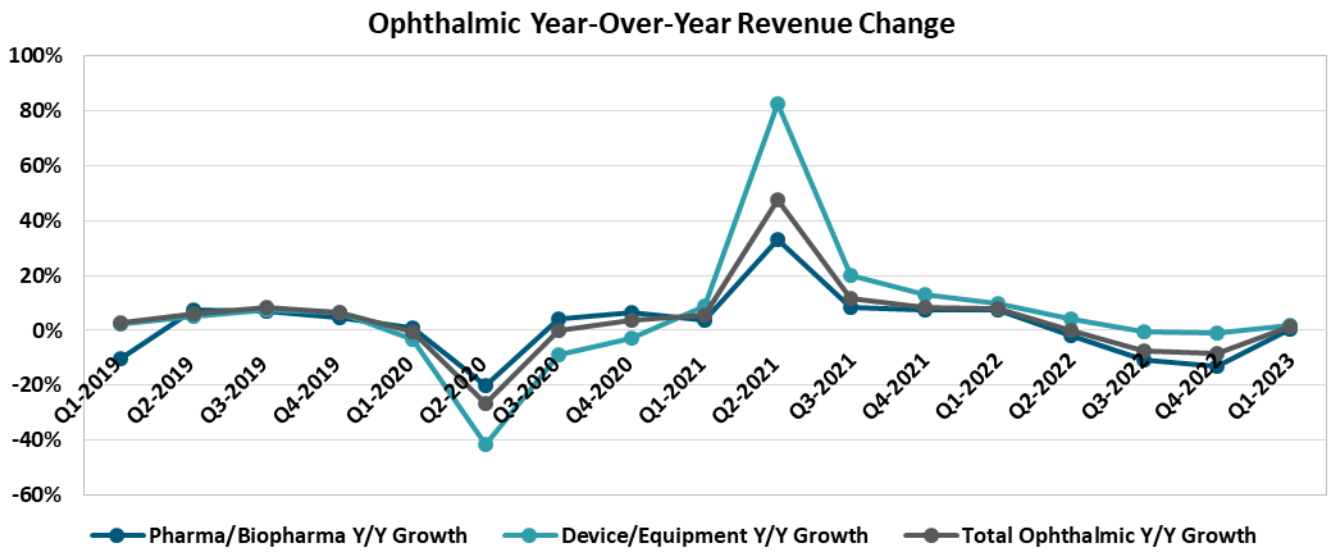


Source: Market Scope



Note: Eylea includes revenue from Regeneron and Bayer; Lucentis includes revenue from Genentech/Roche and Novartis.

Source: Market Scope



Source: Market Scope

Q1-2023 Revenue

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Surgical reporting units. As a result of this realignment, the revenue attributed to consumer health products previously tracked in this analysis is not available. To ensure that products previously reported in the "Consumer Health Care" segment (drops for eye allergies, conjunctivitis, and dry eye) are included and products previously

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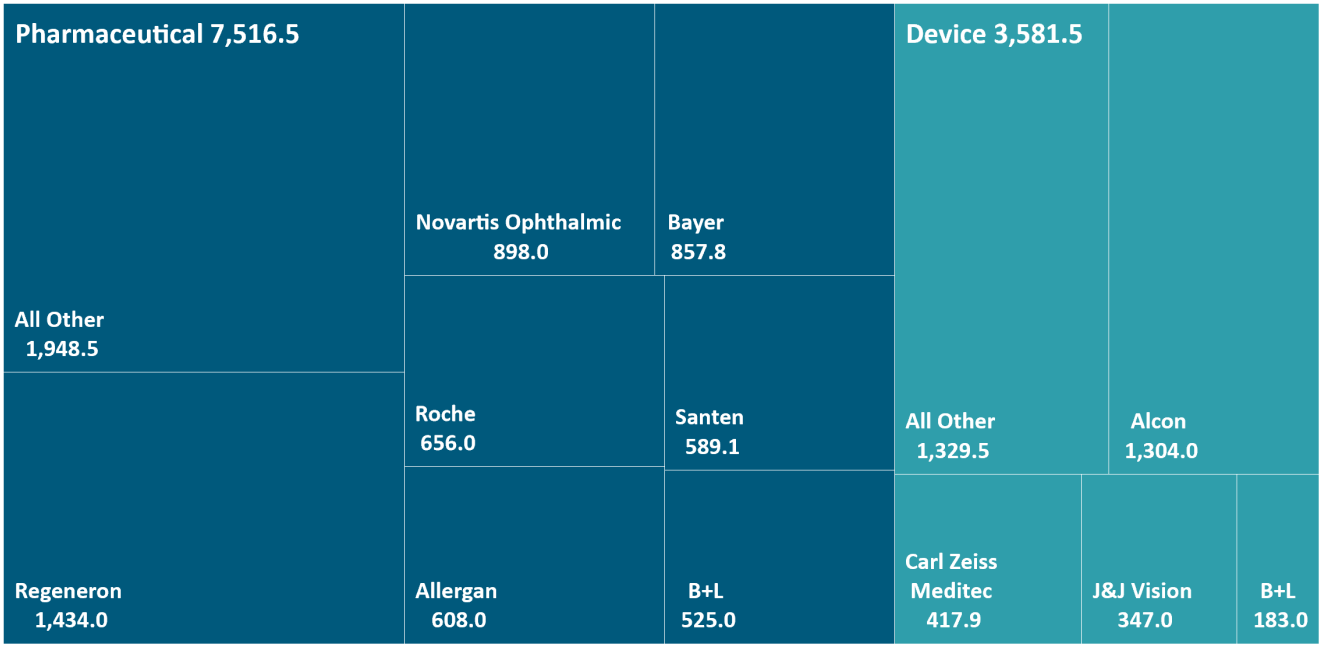

Source: Market Scope

Q1-2023 Revenue

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included in the "Vision Care" segment (contact lenses and lens care) are omitted, we have estimated the previously reported "Consumer Health Care" segment. This estimate is based on the 2021 allocation of revenue between the now-combined reporting segments.

Compared with Q1-2022, pharmaceutical revenue increased 0.7 percent, while device and equipment revenue increased 1.6 percent.

Outlook

While COVID-19 had a significant impact on the ophthalmic market in 2020, most companies covered here experienced a healthy rebound in 2021 and were back on track in 2022.

The deviation between device and pharmaceutical growth in 2022 was relatively stable, although device revenue growth outpaced pharmaceuticals during the past 12 quarters.

Enduring market instabilities, such as inflation, supply chain disruptions, and the Russia/ Ukraine conflict are still creating challenges for the ophthalmic market.

However, the market continues to recovery quickly from crisis, as demonstrated by the sharp rebound following COVID-19.

Investments and innovation continue to drive new product development, as demonstrated by venture capital investment and the rate of new market entrants outpacing most markets.

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Amgen Pledges not to Bundle Horizon Products in Response to FTC Anti-trust Suit

By Joan McKenna

Amgen said it intends to work with the court on a schedule that would allow the acquisition to close by mid-December.

Amgen, of Thousand Oaks, California, responded publicly May 16 to a lawsuit filed by the Federal Trade Commission seeking to block Amgen from acquiring Horizon Therapeutics.

Amgen had announced in December 2022 that it would buy Horizon for $27.8 billion, with the deal originally expected to close in the first half of 2023.

The FTC claimed in its suit that the acquisition would allow Amgen to use rebates on its existing blockbuster drugs to pressure insurance companies and pharmacy benefit managers (PBMs) into favoring Horizon's two monopoly products, Tepezza for thyroid eye disease and Krystexxa for gout.

The FTC noted that Horizon charges about $350 thousand for a six-month course of Tepezza and $650 thousand for an annual supply of Krystexxa.

The agency said Amgen had a history of cross-market bundling—conditioning rebates on products such as Enbrel in exchange for giving Amgen drugs preferred placement on the insurers' and PBMs' lists of covered medications.

FTC Bureau of Competition Director Holly Vedova said, "Today's action—the FTC's first challenge to a pharmaceutical merger in recent memory—sends a clear signal to the market: The FTC won't hesitate to challenge mergers that enable pharmaceutical conglomerates to entrench their monopolies at the expense of consumers and fair competition."

Amgen said it had been working to address the FTC's questions, especially the bundling concern, and was disappointed with the FTC's decision to sue: "The FTC's claim that Amgen might 'bundle' these medicines (offer a multi-product discount) at some point in the future is entirely speculative and does not reflect the real world competitive dynamics behind providing rare-disease medicines to patients. And we committed that we would not bundle the Horizon products raised as issues; however, the commission still decided to pursue this path. Furthermore, we are unaware of any prior acquisition that has been blocked under a bundling theory."

Amgen added: "We firmly believe in the benefits of this acquisition and intend to work with the court on a schedule that would allow the transaction to close by mid-December."

Amgen is one of the world's largest biopharmaceutical companies, with 2022 global sales of $26.3 billion. Its portfolio includes blockbuster drugs Enbrel (rheumatoid arthritis), Otezla (psoriasis), and Prolia (osteoporosis).

Horizon, based in Dublin, Ireland, and Deerfield, Illinois, had 2022 sales of about $3.6 billion, with Tepezza accounting for $2 billion.

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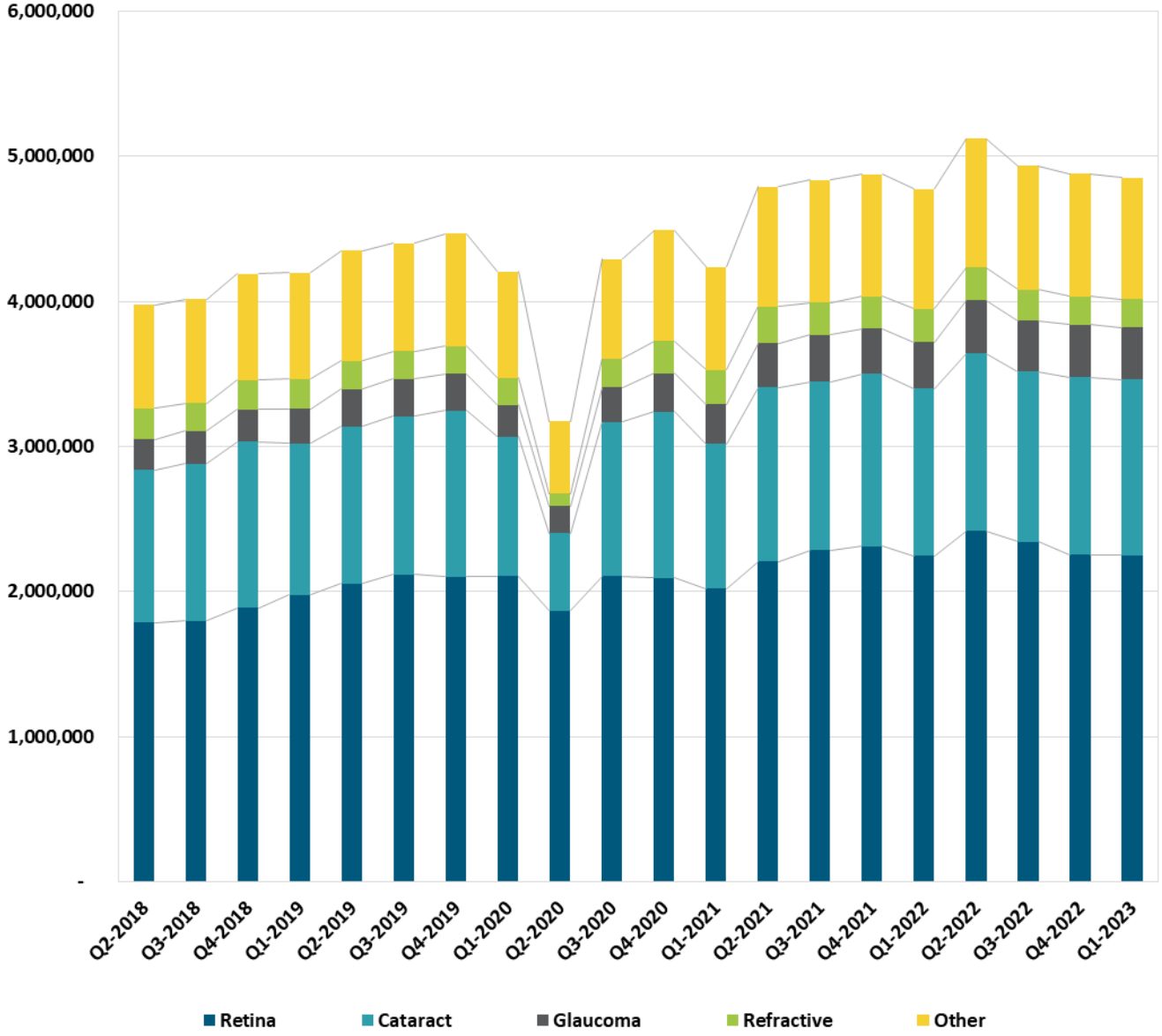

Note: Refractive lens exchange (RLE) procedures are included in cataract procedure count. "Other" includes Market Scope estimates for ophthalmic surgeries in areas for which Market Scope does not conduct quarterly surveys; these procedures include oculoplasty, cornea transplants, foreign body removal, lacrimal surgery, pterygium surgery, trauma surgery, and tumor removal.

Source: Market Scope

Q1-2023 Volumes

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subspecialties, ranging from 11.5 percent growth for glaucoma surgery to a 10.9 percent decrease for refractive procedures. Glaucoma procedure volume has seen higher growth each quarter than the other segments since Q3-2021.

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Refractive Surgical Procedures Decrease 10.9 Percent in Q1-2023

Phakic IOL procedures accounted for 5 percent of refractive procedures during the quarter.

US refractive surgical procedures in Q1-2023 decreased 10.9 percent compared with Q1-2022. Procedures were up 10 percent from Q4-2022. A 14.1 percent decline in laser-based refractive procedures was offset by growth in phakic IOLs, though that growth was from a small base.

Refractive surgery has been on a bit of a pandemic-related roller coaster. Quarterly volumes in 2021 exceeded Market Scope's pre-pandemic forecasts, but the end of 2021 saw a slight decline in refractive procedures when compared with late 2020 and early 2021. Q2-2021 refractive procedure volumes reached the highest quarterly volume in over six years, and Q3-2021 procedures were above average; procedures began to normalize in Q4-2021.

Use of femtosecond lasers has been the most common method to make flaps associated with LASIK since 2014. Responding surgeons said the devices were used in 93.6 percent of all LASIK procedures in Q1-2023 and 74.1 percent of all laser refractive procedures (including surface ablation and SMILE). Most high- and mid-volume surgery centers offer femtosecond flaps.

Surface ablation techniques were used in 13.2 percent of laser refractive procedures, according to survey respondents. Surface ablation's share of quarterly laser refractive procedures has fluctuated between 11.2 and 13.8 percent during the past three years. Lenticule extraction procedures accounted for 7.6 percent of laser refractive procedures.

Phakic IOL growth offset the decline in LVC procedures. Phakic IOLs grew 79.7 percent over Q1-2022. STAAR gained US approval for the EVO and EVO+ phakic IOLs in late March 2022, and the company has been ramping up commercialization and physician training.

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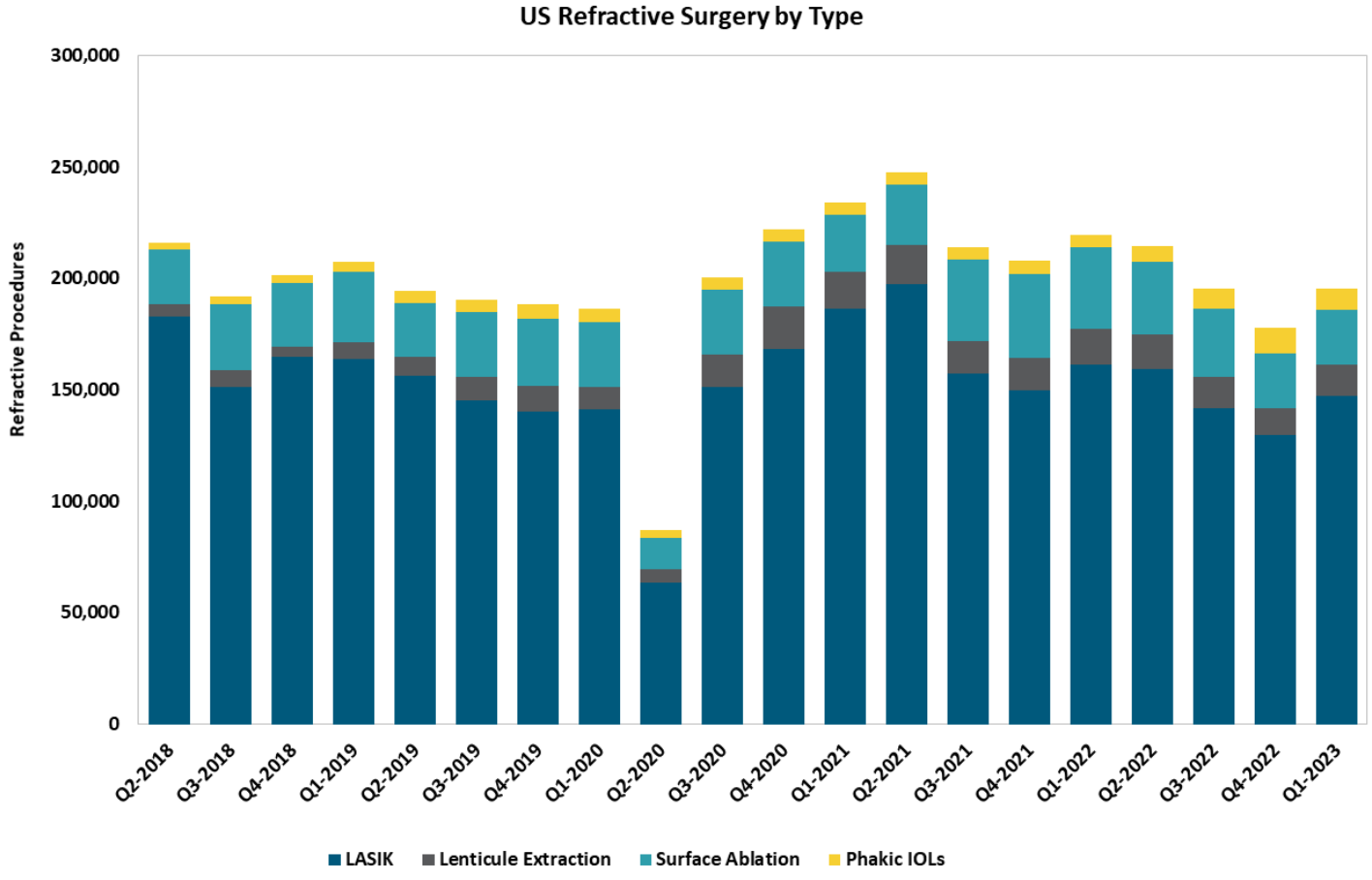


Source: Market Scope

US IOL Procedures Increase 5.2 Percent in First Quarter of 2023

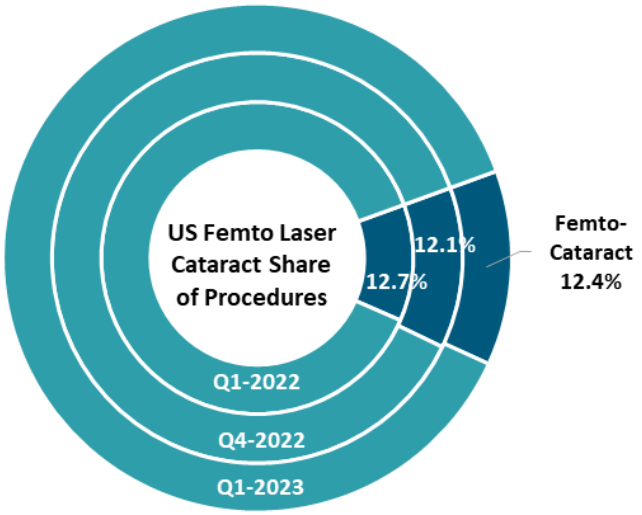
Survey respondents said they used premium IOLs in 18.4 percent of their cataract procedures.

US IOL surgery volume increased 5.2 percent in Q1-2023 compared with Q1-2022 while decreasing 0.8 percent vs. Q4-2022.

Ophthalmologists performed over 1.2 million IOL surgeries in Q1-2023, and cataract procedures accounted for 95.9 percent of the volume. The balance was made up of refractive lens exchange procedures and IOL exchanges/add-ons.

Many cataract surgeons and manufacturers are focused on growth in the premium IOL segment of the cataract market. Survey respondents said 18.4 percent of Q1-2023 cataract procedures were premium IOL procedures, down from 19.4 percent in Q1-2022 and down from 18.9 percent in Q4-2022. Premium IOLs' market share in the US has declined slightly after rising to 20.2 percent in Q4-2021. That growth was due to new developments in EDOF, PC-toric, and trifocal IOL designs, but PC-IOL procedures are now declining. Going forward, increasing adoption of post-op adjustable IOL lenses is expected to increase premium IOLs' US share once again.

Although opinions vary broadly on the clinical benefits of femtosecond cataract procedures, patients generally are interested in high-tech procedures, and many cataract surgeons are proponents of the technique. During Q1-2023, survey respondents said they used the technology in 12.4 percent of their cataract procedures, on average.



Source: Market Scope

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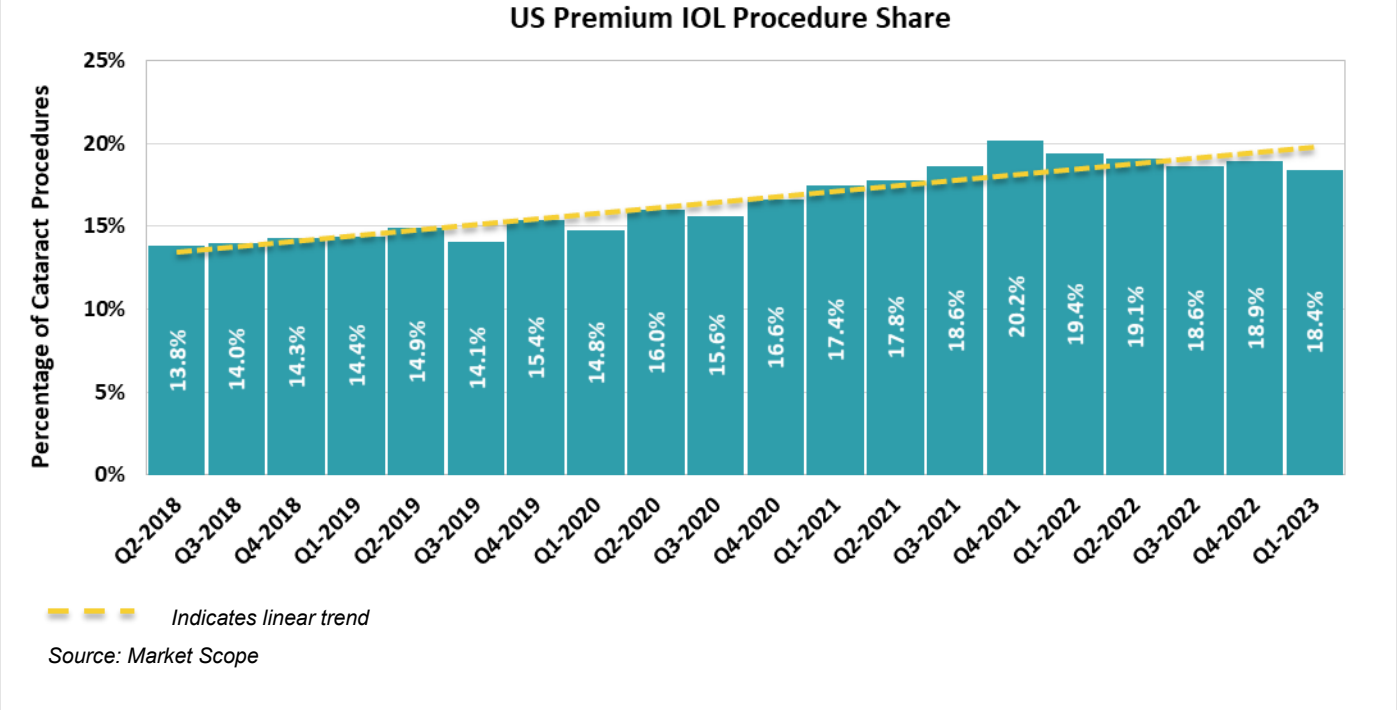

Source: Market Scope

Glaucoma Procedures Increase 11.5 Percent in Q1-2023

Survey respondents reported that 4.7 percent of their OAG patients were not taking any medications.

US laser and surgical glaucoma procedures increased 11.5 percent in Q1-2023 compared with Q1-2022. Nearly 356 thousand laser and surgical glaucoma procedures were performed in Q1-2023, up from over 319 thousand in Q1-2022 and down from more than 361 thousand in Q4-2022.

Non-laser glaucoma surgical procedures increased 2.8 percent over Q1-2022 and 8.8 percent over Q4-2022.

Recent approvals of canal-based procedures (Glaukos iPrime, New World Medical Streamline, Sight Sciences SION) may have an impact on procedure share, and we will be closely monitoring surgeon adoption and use in our quarterly US surgeon surveys.

Medications remain the primary method of glaucoma treatment, and many patients are prescribed multiple medications. Survey respondents reported an average of 1.3 medications per patient during Q1-2023. One medication was the most common recommendation, accounting for 51.3 percent of ocular hypertension (OHT) patients and 50.4 percent of open-angle glaucoma (OAG) patients; however, 4.1 percent of OHT patients were using three or more medications, as were 19.5 percent of OAG patients.

Glaucoma surgeons reported that 4.7 percent of their OAG patients were not taking any medications.

These shares were in line with previous quarters.

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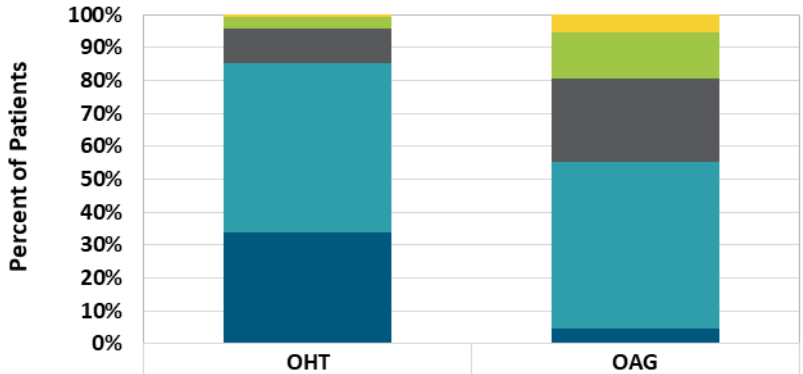
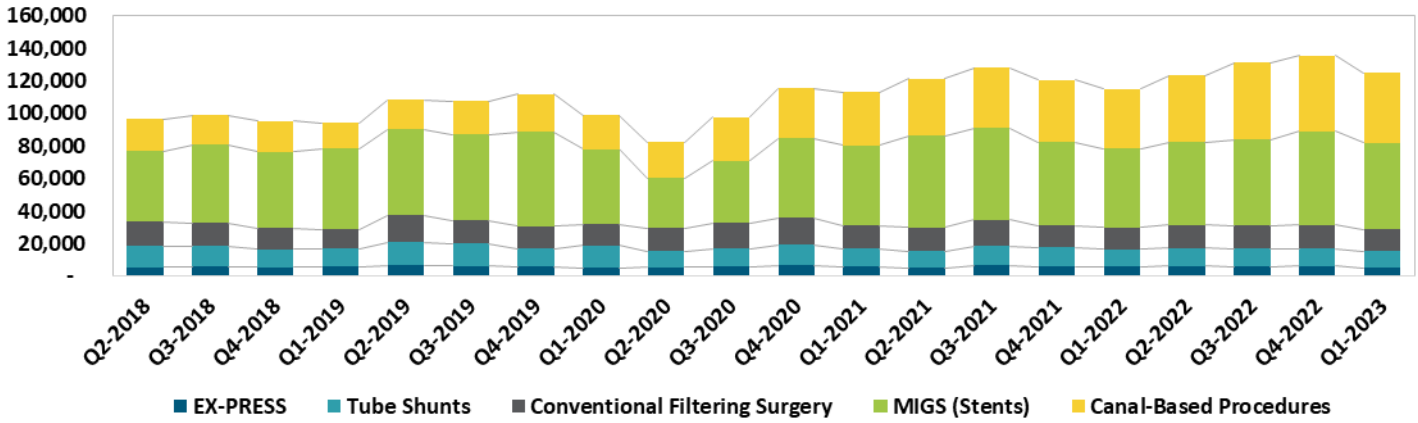
Glaucoma Medications in US



	OHT	OAG
More Than 3 Medications	0.9%	5.3%
3 Medications	3.2%	14.2%
2 Medications	10.8%	25.3%
1 Medication	51.3%	50.4%
No Medication	33.8%	4.7%

Source: Market Scope

US Glaucoma Procedures



Note: Canal-based procedures include the following: ECP, Kahook Dual Blade (New World Medical), canaloplasty/iTrack (Nova Eye), OMNI and SION (Sight Sciences), Trabectome (NeoMedix/MST), and Goniotome (NeoMedix/MST). MIGS (stents) include the following: iStent Inject (Glaukos), iStent (Glaukos), XEN Gel (Allergan), and Hydrus (Ivantis).

Source: Market Scope

Retinal Procedures Increase 0.2 Percent in First Quarter of 2023

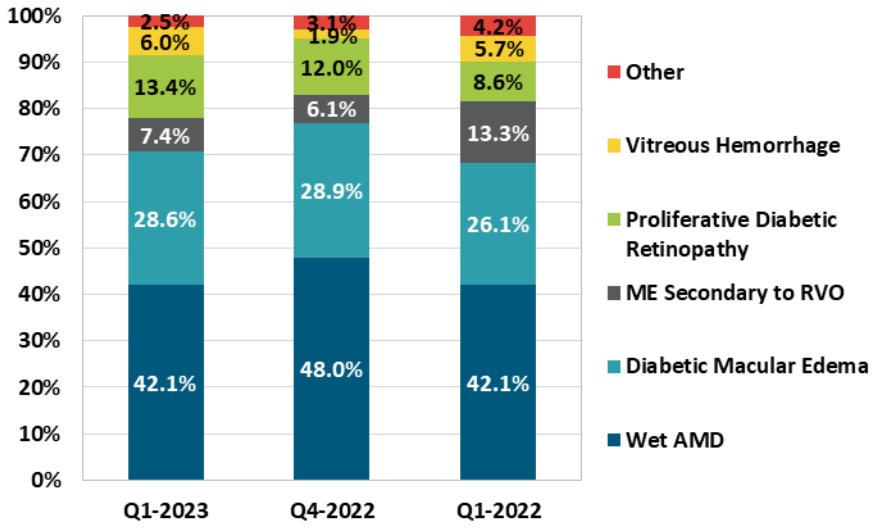
Nearly 91 thousand vitrectomies were performed in the quarter, an increase of 7.6 percent from Q1-2022.

US retina specialists performed nearly 2.3 million retinal procedures in Q1-2023, an increase of 0.2 percent from Q1-2022. Volume decreased 0.2 percent from Q4-2022.

IVT injections accounted for 86 percent of Q1-2023 retinal procedures and decreased 0.8 percent compared with Q1-2022.

Note that recent years have seen injections increase steadily due to added indications—including expanded labeling for diabetic retinopathy and diabetic macular edema (DME)—that have brought more patients into the treatment pool.

Wet age-related macular degeneration remained the most common reason for IVT injections, according to survey responses, accounting for 42.1 percent of injections in Q1-2023. DME was also a frequent reason and was reported as the primary diagnosis in 28.6 percent of cases. Respondents reported that macular edema secondary to retinal vein occlusion accounted for an additional 7.4 percent. These three reasons combined accounted for 78.1 percent of reported reasons for IVT injections.



Source: Market Scope

We estimate nearly 91 thousand vitrectomies were performed in Q1-2023, up 7.6 percent from Q1-2022.

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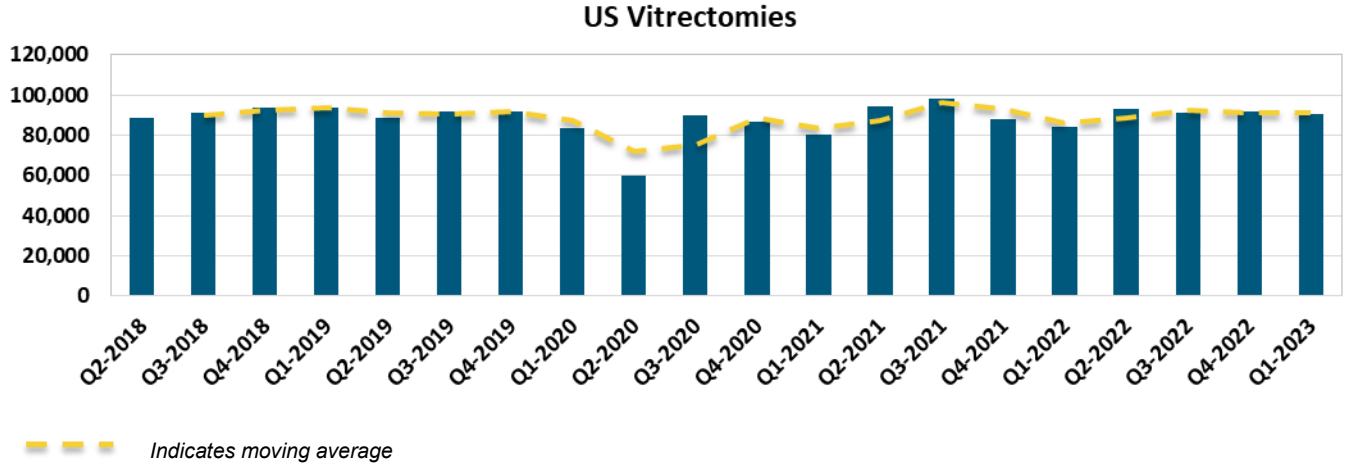


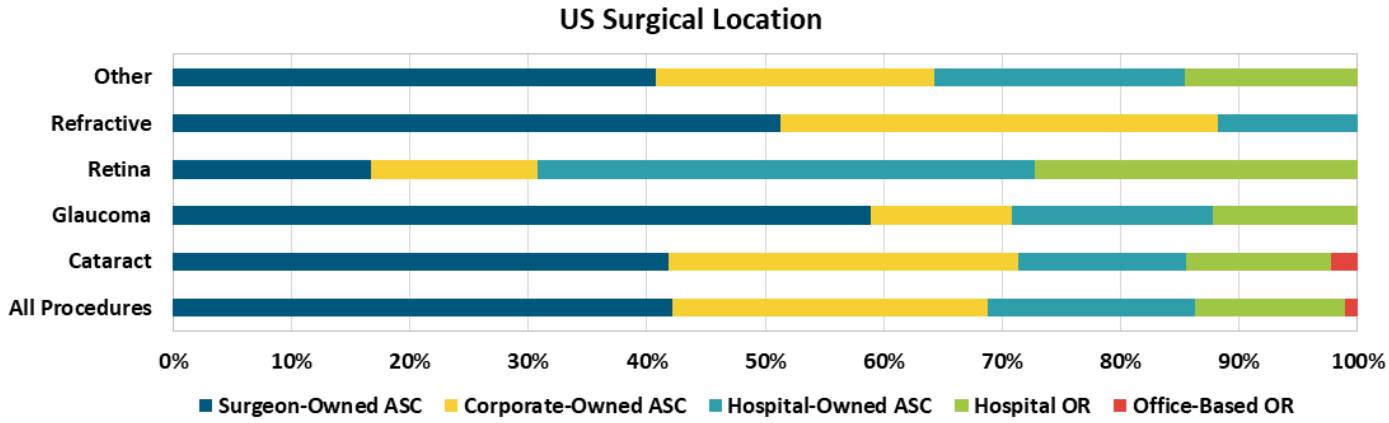
Source: Market Scope

ASCs Account for 86.3 Percent of Ophthalmic Procedures in Q1-2023

Surgical location continued to follow trends and varied widely by type of ophthalmic surgery, according to survey respondents. In Q1-2023, 86.3 percent of all ophthalmic procedures were performed in ambulatory surgery centers or free-standing laser refractive centers, while 12.7 percent were performed in hospital operating rooms; the remaining 1.1 percent were performed in office-based operating rooms. Refractive procedures more often occurred in outpatient centers than cataract or retinal surgical procedures.

Surgeon- and corporate-owned facilities garnered 71.3 percent of all cataract procedures, while 26.5 percent of cataract procedures were performed in hospital-owned ASCs or hospital operating rooms; the remaining 2.2 percent of cataract procedures were performed in office-based surgical suites. Retinal surgeons were more likely to use hospital-owned surgery centers or hospital operating rooms for their surgical procedures.

Market Scope is actively tracking office-based cataract procedures. As noted, office-based cataract surgeries accounted for 2.2 percent of Q1-2023 cataract procedures. This share has slowly increased over the past few quarters. Major obstacles for in-office procedures include lack of Medicare reimbursement and facility requirements for a surgery suite, but there are dedicated companies, such as iOR Partners, that assist surgeons in implementing a turnkey in-office setup.



Source: Market Scope

Hoya Recalls Vivinex iSert Toric IOLs

By Joan McKenna

Hoya Surgical Optics has issued a recall in India and Australia of eight models of its Vivinex iSert Toric IOL manufactured from June 2022 to January 2023.

India's Central Drugs Standard Control Organization posted information on the recall May 8 and said the recall affected 3,823 IOLs in India.

Australia's Therapeutic Goods Administration published recall information April 12 but did not provide a total of affected units in the country.

The eight aspheric hydrophobic acrylic recalled models are the XY1AT2, XY1AT3, XY1AT4, XY1AT5, XY1AT6, XY1AT7, XY1AT8, and XY1AT9.

The recall notifications said Hoya received reports of customer complaints in Australia and Japan of damage, such as scratches on the IOL optic surface and polypropylene (PP) resin fragments from inside the injector tip adhering to the IOL surface (PP adhesion).

The notifications say Hoya's investigation of returned samples found damage had occurred to the nozzle tip of the iSert injector during toric IOL implantation.

The Australian recall notice said Hoya was asking customers to quarantine impacted IOLs for collection. The company was not recommending IOL explantation; instead, it was recommending that doctors monitor patients for the need for any future medical treatment in cases where lenses had experienced PP adhesion.

Emerging Companies Pursuing Ophthalmic Indications

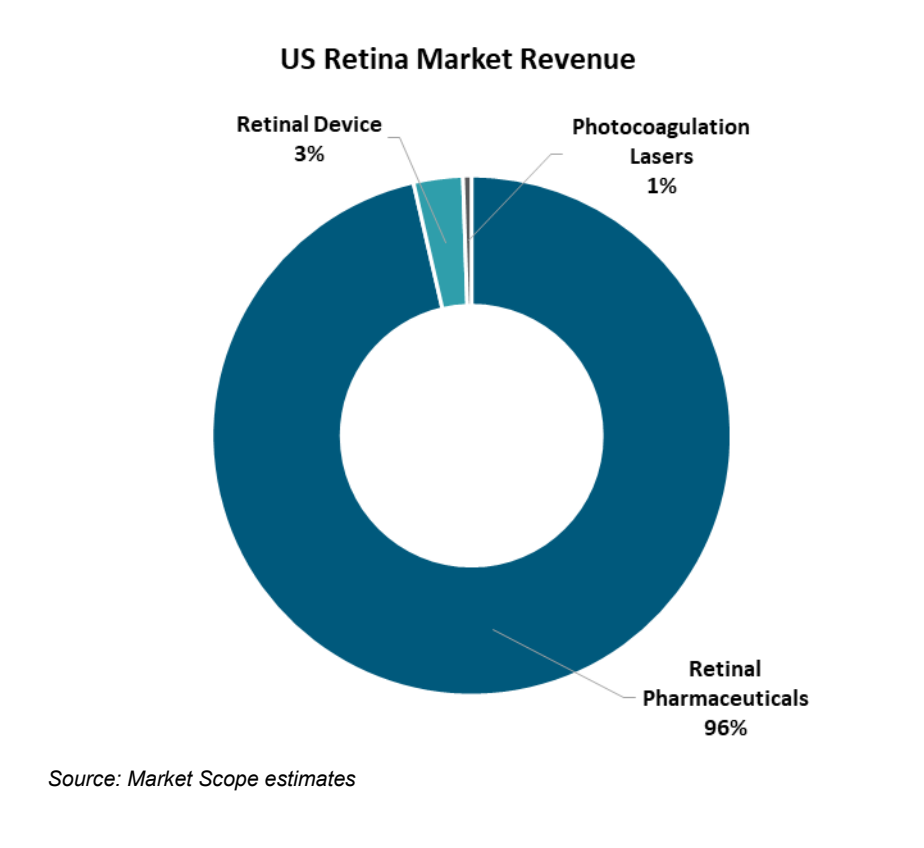
Market Scope is tracking companies that have announced new candidates to diagnose and treat eye disease.

By Jennie Crabbe

Emerging Companies in the Ophthalmic Industry		
Company	**Location**	**About**
Beacon Therapeutics	London, United Kingdom	The ophthalmic gene therapy company is developing lead clinical asset AGTC-501, in Phase II trials, for the treatment of XLRP. The candidate was acquired as part of Syncona's acquisition of AGTC in November 2022; Syncona is the main investor in Beacon. David Fellows, former CEO of Nightstar, will lead Beacon, joined by Nadia Waheed, MD, formerly of Gyroscope, as chief medical officer.
Ikarovec	Norwich, United Kingdom	The company was spun out of Quethera, which was acquired by Astellas Pharmaceuticals in 2018. Ikarovec's lead program, a gene therapy candidate for GA, is in preclinical studies. Other programs target wet AMD, DME, and glaucoma.
OnPoint Vision	Aliso Viejo, California	The company is developing an intraocular magnifier for secondary implantation in the capsular bag with a pre-existing IOL. The device is a neutral optic with a +10.0 diopter 1.8 mm zone designed to magnify near images in patients with low vision from AMD. OnPoint has filed an IDE application to begin a pivotal trial in the US.
Allgenesis Biotherapeutics	Taipei, Taiwan	The company is developing AG-73305, a humanized, bi-specific Fc-fusion protein designed to simultaneously block VEGFs and integrins in DME, wet AMD, and RVO; and AG-80308, a topical candidate targeting formyl peptide receptor 2 in dry eye.
AiViva Biopharma	Costa Mesa, California	The company is developing AIV007, a broad-spectrum tyrosine kinase inhibitor, for wet AMD and DME. Its proprietary JEL formulation is designed to be dosed periocularly once or twice a year.
Invirsa	Columbus, Ohio	The company is developing dry eye drop candidate INV-102, which activates two major pathways: the protein p53, known as "the guardian of the genome"; and Pax6, which is critical for cellular stability.
Visgenx	San Diego, California	The company is developing a gene therapy candidate, VGX-0111, for dry AMD. Visgenx' approach is based on the ELOVL2 gene and its role in the biosynthesis of lipids necessary for retinal cell function. Studies in aged mice show that a single subretinal administration of VGX-0111 enhances photoreceptor and Müller cell function and protects from aging-induced photoreceptor loss.
Avixgen	Seoul, South Korea	The company is developing dry eye candidate AVI-4015, a DDR1 receptor inhibitor that targets immune cells to treat corneal inflammation; and AVI-3207, an inhibitor of VEGFR-2, which the company says addresses exudative retinal disease with fewer side effects and could potentially be dosed as eye drops.
BNS Ophthalmics	Athens, Greece	Greece's Rafarm and Israel's BioNanoSim have created the company to develop BNSO-1, a topical ocular emulsion of tacrolimus. Tacrolimus in its oral form is a powerful immunosuppressant, but it is unstable, insoluble in water, and can't penetrate the cornea. BNS says its nanoparticle platform will allow it to use tacrolimus to topically treat chronic anterior uveitis. A Phase I/IIa trial is planned for this year. Additional preclinical candidates target DME, wet AMD, and dry eye.

US Garners Half of Global Retinal Treatment Revenue; Atlas Pinpoints Top Metro Areas

By Chelsea Jones



Source: Market Scope estimates

The US is the largest retinal treatment market, accounting for 51.5 percent of global manufacturer revenue in 2023. US ophthalmologists are expected to perform nearly 7.4 million intravitreal (IVT) injections in 2023 and 360 thousand vitrectomy procedures.

In 2023, the country is expected to generate $8.7 billion from retinal pharmaceuticals, $277 million from retinal surgical devices, and an additional $48 million from ophthalmic lasers used in retinal treatments; it is the world's highest revenue-producing country, and Market Scope estimates over $9.3 billion in manufacturer revenue in the US retina sector in 2023.

On a per capita share basis, most of the metro areas in the Southeast stand out for their potential pool of patients, driven largely by the region's older population and diabetes rates much higher than other US regions. While California has the most high-volume IVT providers (more than 1 thousand procedures annually), Florida has the most high-volume vitrectomy surgeons.

These insights and more can be found in Market Scope's "2023 United States Retina Atlas," which provides an objective, data-driven tool to compare the retinal treatment opportunity across US geographies. The 2023 edition includes a count by metro area of ASCs offering retinal surgery, and high-volume providers (in addition to total provider counts by geography).

To understand the potential for treatment more completely, we analyzed historical reimbursement records; population by age; health status and diabetes rates; prevalence of retinal diseases; retinal surgery trends; and aggregate facilities and providers by geographic area. Combining these data created a picture of the overall US market opportunity by detailed geography.

Market Scope has developed the *MedOp Index™ Analysis* to estimate the opportunities for all retinal treatments in each geography. This proprietary methodology identifies the treatment potential based on the key demographics of the population; volume and concentration of retina surgeons; surgical volumes; and ASC locations and volumes.

Miami and Philadelphia have notable concentrations of high-volume IVT providers. Phoenix has the highest concentration of high-volume vitrectomy providers in the country; metros such as Dallas and Atlanta have among the highest prolific diabetic retinopathy concentrations in the US—with over 40 thousand affected patients in each metro. Houston and Miami have wet age-related macular degeneration populations exceeding 30 thousand.

Market Scope's "2023 United States Retina Atlas" was published in June. Visit www.market-scope.com or call 314-835-0600 for details.

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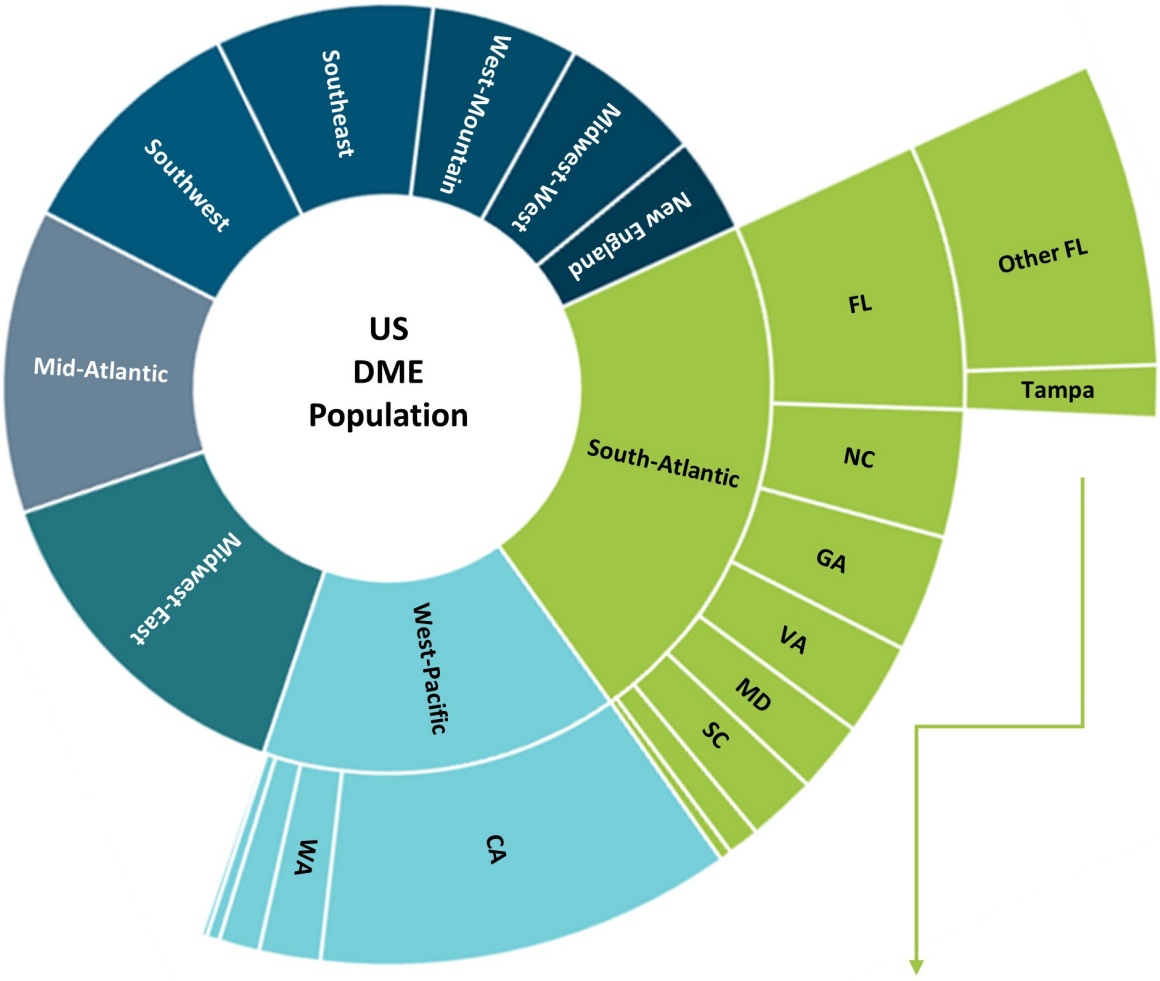
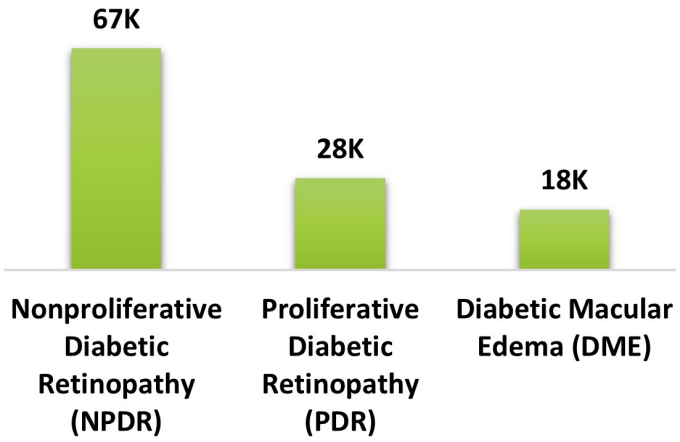
Analysis of Tampa Market for Retinal Treatment



Tampa Diseased Populations



Tampa, FL

Average annual vitrectomies per surgeon:
187

Average annual IVTs per provider:
1,987

High-volume IVT providers:
13

Rank among all US metros:
13

Source: Market Scope's 2023 United States Retina Atlas

Cataract Equipment Market

(continued from page 1)

It's important to remember what pre-USP cataract surgery was like to fully appreciate what a difference USP has made: Surgeons most frequently used a technique employing a cryosurgery instrument to remove the cataract-clouded lens through a gaping incision of 180 degrees. The cryoprobe's tip froze the crystalline lens and pulled it intact from the eye, but the procedure also removed the surrounding capsule.

Complications were frequent, including loss of sight.

Recuperation from cryosurgery required cataract patients to lie in the hospital for days with sandbags against their head to stabilize and promote healing of the eye.

Since intraocular lenses were in the early stages of commercialization after being invented in 1949, patients often had to wear glasses with "Coke bottle" lenses that made it difficult to see and grossly magnified their eyes.

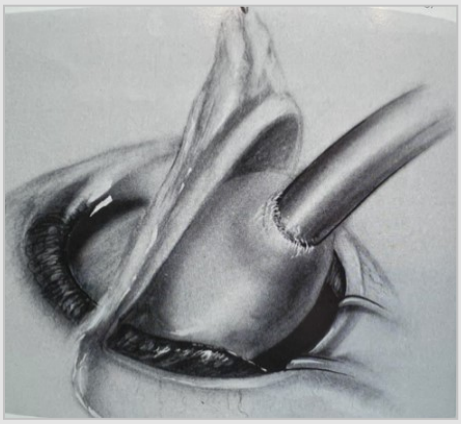
By comparison, USP could be performed through a 2 mm incision with very little disruption to the eye's internal structures, greatly reducing complications.

Today, USP has one of the highest surgery success rates of any ophthalmic procedure. About 98 percent of procedures are completely successful.

Complications are rare, and most can be resolved, so it's exceedingly rare for cataract patients today to lose their sight.

Hostile Reaction

One would think that such a significant invention, potentially benefiting millions of cataract patients, would have been adopted quickly, but the opposite was true. Ophthalmologists' early resistance was formidable, with many opinion leaders condemning the new technology as dangerous and demanding that it be banned.

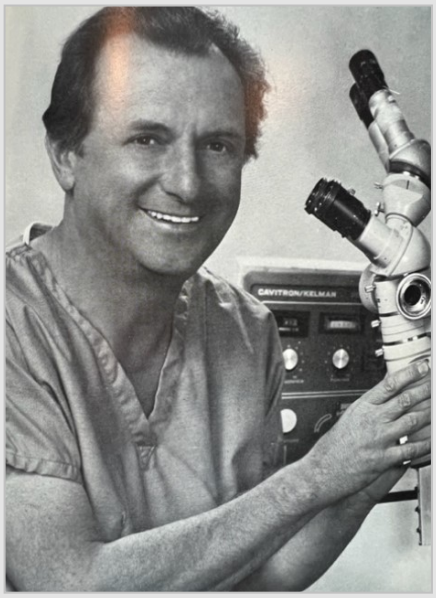


An illustration shows the cryosurgery method used to remove cataracts prior to the adoption of ultrasonic phaco.

Coke bottle aphakic glasses provided vision to cataract patients post-surgery prior to the invention of USP and IOLs.

For example, at the 1972 Welsh Congress, a forum on the dangers of USP included cataract surgeons being urged to talk about the complications they had witnessed in USP patients. One by one, surgeons took a microphone and described these complications, with many surgeons calling for an immediate ban on USP.

Fortunately, at one point during this session, a single surgeon issued a plea that disrupted the bandwagon to ban USP. Richard Kratz, MD, a well-known cataract surgeon, asked to speak with his colleagues.



Charles Kelman, MD, prepares to use the Cavitron USP machine in 1970.

He began by admitting USP technology was not yet where it needed to be, but he encouraged his colleagues to wait before writing it off. "If this technology is unsafe and doesn't benefit the patient, it will fail," he said. "However, if the technology can be improved and proven to benefit the patient, why would we want to stand in the way? The technology should rise or fall based on its own merits."

Many surgeons heeded his wise advice and continued to work with industry to refine USP.

By 1975, USP was fast becoming the gold standard for cataract removal in the US and other wealthy nations.

There have been various challenges to the dominance of USP over the years, but the procedure is still considered the gold standard worldwide a half-century later, with more than 70 percent of global cataract surgery patients benefiting from USP technology in 2023.

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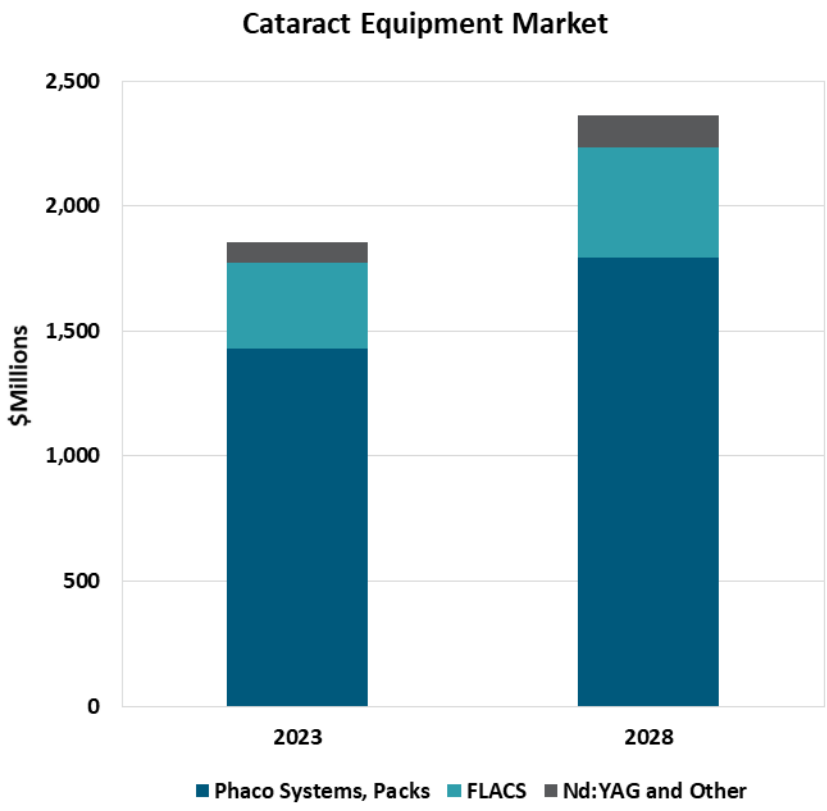

Source: Market Scope's 2023 Cataract Surgical Equipment Market Report

Cataract Equipment Market

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During that same half century, USP's safety and effectiveness have improved, and innovations continue today.

Market Scope's "2023 Cataract Surgical Equipment Market Report" projects that global cataract equipment revenue will total nearly $1.9 billion in 2023, growing to nearly $2.4 billion by 2028.

Many of the world's top ophthalmology companies participate in the market, manufacturing phaco machines and/or femtosecond lasers, surgical packs, and accessories. The leading companies are Alcon, Bausch + Lomb, BVI, Carl Zeiss Meditec, Dutch Ophthalmic Research Center (DORC), Hoya, Johnson & Johnson Vision, LENSAR, Nidek, Oertli, and Ziemer.

Each of these companies has launched new USP machines or significant platform upgrades or is planning to do so within the next year. The report focuses on these new machines and their effect on the market over the next five years.

Market Scope's "2023 Cataract Surgical Equipment Market Report" will be published in July. For more information, visit market-scope.com or contact Matthew Douty at matthew@market-scope.com.

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Envision Healthcare, Amsurg to Split After Bankruptcy Filing

By Joan McKenna

KKR-backed Envision Healthcare reported May 15 that it had filed for Chapter 11 bankruptcy protection. The Nashville, Tennessee, company said it had entered into a restructuring support agreement with key stakeholders for the company's $7.7 billion in debt.

Under the agreement, the company's Amsurg ambulatory surgery center (ASC) business and Envision Physician Services business will be owned separately by certain lenders. In addition, Amsurg will purchase the surgery centers held by Envision for $300 million, plus a waiver of intercompany loans held by Amsurg LLC.

Amsurg operates more than 250 ASCs in the US specializing in ophthalmology, gastroenterology, and orthopedic care. Envision provides medical services to health care facilities in 45 states and the District of Columbia.

Amsurg merged with Envision in 2016 in an all-stock transaction. KKR acquired the merged entity in 2018 for about $9.9 billion.

Envision attributed its recent financial troubles to:

—Patient volumes sharply declining at the outset of the pandemic.

—Health insurers excluding Envision clinicians from their networks and not providing appropriate reimbursement for care provided.

—Health insurer activism and the flawed implementation of the No Surprises Act (NSA).

—A national clinician shortage and rising inflation.

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China Market

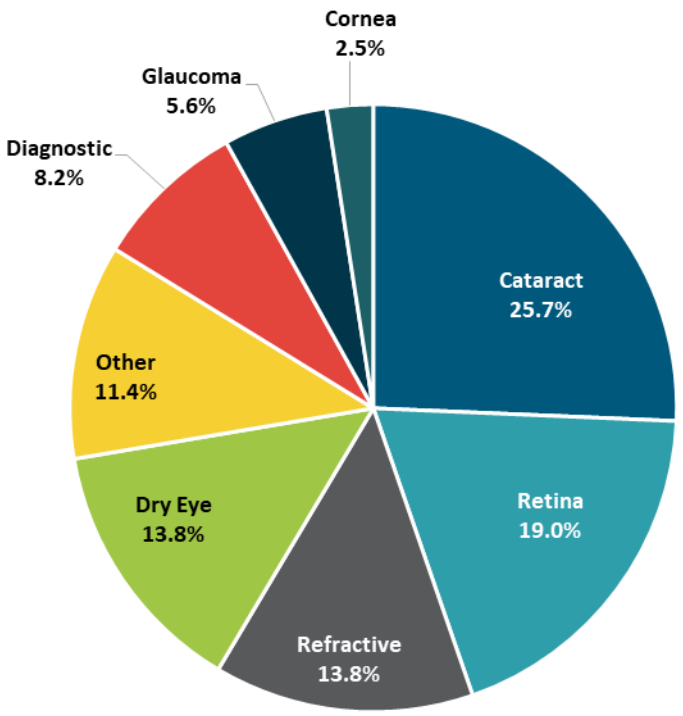
(continued from page 1)

eye hospital chains now comes from refractive surgery, more than twice as much as they earn from cataract surgery.

China is the largest refractive surgery market in the world and the largest market for various subtypes of refractive surgery, including lenticular extraction procedures, such as SMILE, and phakic intraocular lenses (phakic IOLs).

COVID-19 continues to be epidemic in China in 2023. Market Scope expects real and perceived difficulty with simultaneously wearing spectacles and masks to continue to boost adoption of refractive surgery in the short term. Ongoing public awareness campaigns that promote interventions to address myopia likely will have a spillover effect of boosting refractive surgery in the long term.

Market Scope forecasts a 6.9 percent average annual growth rate in refractive procedures in China, with lenticular extraction surgery extending its lead over LASIK as the No. 1 choice of refractive surgery in the country.



Source: Market Scope's 2023 China Ophthalmic Market Report

Cataract Surgery

The main providers of cataract surgery are public or government-owned hospitals. The population age 60 and over is growing at a robust 4.3 percent a year, even though the total population has started to decline. Plus, there is a large backlog of untreated cataracts.

Cataract surgery is the largest category in the ophthalmic market in China. Market Scope expects continued rapid growth in cataract surgery revenue, due in part to the growing population of aged people, but also due to the growing popularity of higher-priced enhanced and premium IOLs and the continued shift away from manual surgery to phacoemulsification and femtosecond laser-assisted cataract surgery. That shift requires spending to acquire semi-automated surgical systems.

Retinal Care

The growth of the older population in both absolute numbers and as a percentage of the population is putting pressure on the government to include treatments for retinal disease in medical insurance plan coverage. Retinal care is already the second largest market in ophthalmology in China.

Pharmaceutical manufacturers reap about three-quarters of retinal revenue in China, and surgical equipment manufacturers take the other quarter.

China controls the prices of drugs through coverage negotiations and vendor bidding wars. State-supported manufacturers are developing biosimilars of retinal drugs to try to drive down prices, but public pressure to relax strict limits on treatments will tend to push up spending.

Market Scope expects price control strategies to restrain but not stop revenue growth in the retinal care market. We look for growing

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China Market

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disease populations—due to longer life spans and diabetes and pressure to expand treatment coverage—to power growing revenue in retinal care in China.

Dry Eye Market

Dry eye is the last of the big four revenue categories in Chinese ophthalmology. Dry eye treatments, similar to refractive surgery, are private-pay treatments that are popular with providers for being less regulated. Also, as with refractive surgery, COVID-related behavioral changes, such as mask-wearing and spending more time looking at electronic display terminals, has increased demand for dry eye therapies. The dry eye and refractive surgery markets in China are similarly sized, each one generating about ¥3.3 billion for manufacturers in 2023.

Market Scope forecasts that the overall ophthalmic market in China will grow at an 8.7 percent annual rate to ¥36.0 billion (US $5.2 billion) in 2028 at constant exchange rates.

One source of uncertainty in the forecast is the rapid pace of regulatory and policy changes in China. Policies expanding or curtailing private eye care, pricing, or insurance coverage could affect our forecasts.

Market Scope's "2023 China Ophthalmic Market Report" was published in June. Visit market-scope.com for more information or call 314-835-0600.

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Researchers Use AI to Find Better Drug Delivery Methods to Treat Glaucoma, Other Eye Disease

By Jennie Crabbe

Researchers at Johns Hopkins' Wilmer Eye Institute reported May 24 that they and colleagues from the University of Maryland had used machine learning—a method employed to create artificial intelligence (AI)—to successfully predict which components of amino acids in therapeutic proteins are most likely to safely deliver therapeutic drugs to animal eye cells.

The project aims to advance more tolerable drug treatments for common chronic eye diseases, including glaucoma and macular degeneration.

Current regimens of multiple daily eye drops or frequent eye injections are effective, but may be difficult to sustain and tolerate over time. The goal of researchers is to develop delivery systems that would bind to components of eye cells and safely extend the therapeutic impact of the medications they carry.

The Wilmer research, published May 2 in Nature Communications, showed that AI-designed models accurately predicted an effective sequence of amino acids, also known as peptides or small proteins, that would bind to a particular chemical in rabbit eye cells and safely dispense medications over several weeks, reducing the need for frequent, strict treatment schedules.

The team specifically investigated peptides that bind to melanin, a compound that provides color to the eye but also is widely present throughout specialized structures in eye cells.

The research team started by feeding a machine-learning model thousands of data points, including characteristics of amino acids and peptide sequences. These data helped the computer model "learn" the chemical and binding properties of certain amino acid combinations, and in time, how to predict candidate peptide sequences for drug delivery using melanin.

The AI model generated 127 peptides that were predicted to have varying ability to penetrate the specialized cells that house melanin, to bind to melanin, and to be nontoxic to the cells. The model predicted that a peptide called HR97 had the highest success rate of binding.

To test the model's prediction, researchers attached HR97 to brimonidine, used to treat glaucoma, and injected it into adult rabbit eyes. To determine HR97's performance, researchers measured the eye cells' concentration of brimonidine after administering the experimental drug delivery system.

They found that high amounts of brimonidine were present for up to one month, indicating that HR97 successfully penetrated cells, bound to melanin, and released the drug over a longer period of time. Researchers also confirmed that the eye pressure-lowering effect of brimonidine lasted for up to 18 days when bound to HR97, and found no irritation in the rabbits' eyes.

Moving forward, the researchers said, other studies will need to find ways to further extend the duration of action, to test the success rate of the AI model's drug delivery predictions with other drugs, and to determine safety in humans.

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Octane Meeting

(continued from page 1)

Newport Beach, California. Octane said 475 people attended.

Office-Based Surgery

Office-based surgery (OBS) was a dominant theme at the meeting.

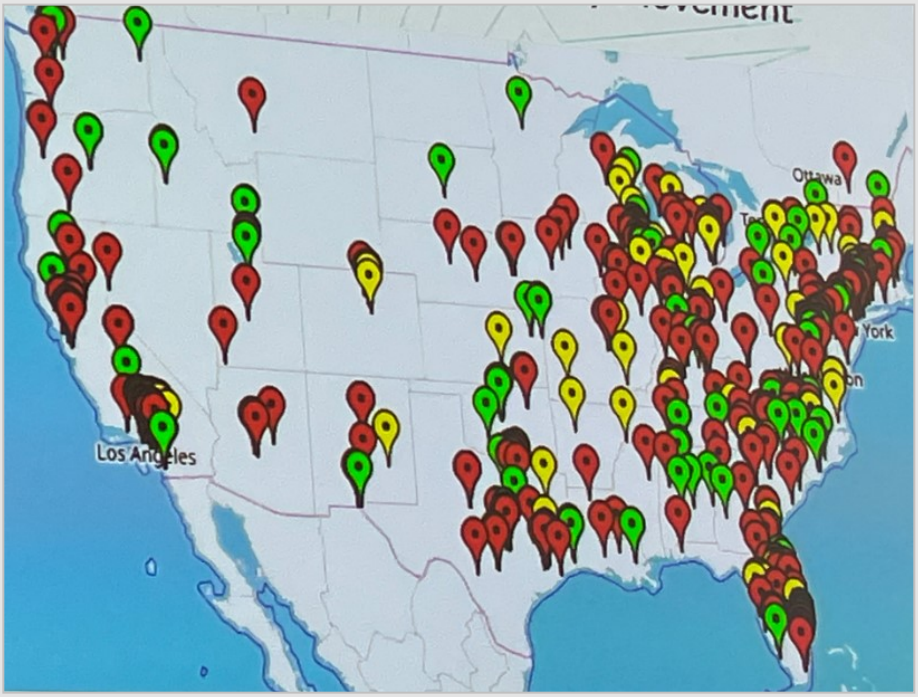
Dan Durrie, MD, chaired a session that looked at the pros and cons of OBS.

Durrie, who is chairman of iOR Partners—a company that assists surgeons in implementing a turnkey OBS center—said he is a strong supporter of ambulatory surgery centers (ASCs), having owned six since 1980. He believes ASCs and OBS centers each have advantages, and he doesn't view OBS as competing with ASCs.

He referred to real-world safety and accreditation data reported at the 2023 ASCRS meeting for 32 thousand OBS procedures that showed equivalent or better safety when compared with published data. He showed a map of iOR Partners' established OBS centers (green), those currently under construction (yellow), and qualified leads (red).

Leslie Patch, MD, medical director at Johnson & Johnson Vision, pointed to the advantage of OBS in better serving patients by requiring them to travel less to receive care. Prior to joining J&J Vision, she was in an ophthalmology practice in the Midwest where patients had to travel a long way to access surgery centers. So, for those patients suitable for OBS, it was less costly and more convenient, she said.

Omar Shakir, MD, whose Coastal Eye Surgeons practice offers OBS, described how he has been able to be innovative in every aspect of his patients' treatment, creating the best possible experience.



Map of iOR Partners' office-based surgery centers (green), centers under construction (yellow), and qualified leads (red). (Source: Dan Durrie, MD, presentation at 2023 Octane meeting)

In response to a question as to how ophthalmic device manufacturers view OBS, Cindy Metrose, senior director, strategic accounts and digital business at Carl Zeiss Meditec, said she believes vendors want to serve all customers in all settings, with OBS representing a new revenue stream, opening more opportunity for collaboration with ophthalmologists.

Durrie asked the panel about payment for OBS. Shakir said payers are handling payment. "We are getting paid; we're getting a professional fee; and we are getting paid for the facility side of this. We are doing this in such a way that we are working with the Medicare MAC at a local level, negotiating with them on their terms. It's cumbersome for us and the payers, and it's something we would love to have streamlined."

Shakir added that his practice has been very active with the Centers for Medicare and Medicaid Services (CMS) to come up with a better solution. The goal is provide CMS with safety data that exists today and apply for accreditation, which Shakir expects to occur in 2025, with a specific code established two to three years later.

Market Scope's recent 2023 annual survey of US cataract surgeons points to significant growth in OBS surgery, with 5.7 percent of surgeons reporting performing OBS, up from just 2.0 percent in the 2022 survey. Despite the increasing penetration, we believe establishing a reasonable CMS reimbursement is essential for broad acceptance of OBS.

Market Regulations

During a morning panel session with Bill Carpou, CEO of Octane, and

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Octane Meeting

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Mark Leahey, president and CEO for the Medical Device Manufacturers Association (MDMA), Leahey discussed the time lapse—years—between getting market access for a device and getting reimbursement. Leahey said industry now can apply for transitional coverage for up to four years to ease the burden of the long wait times. He also criticized the MDR transition underway in the EU, where he said the regulatory system was making a big mistake as a reaction to a few small events, and this would likely disrupt the marketplace for quite a while.

In addition, Leahey warned of potential EPA regulations coming down the pike that could disrupt the availability of ethylene oxide (EtO) used for sterilization. Manufacturing of a needed component for the EtO process is under duress. Leahey said the potential EPA regulations could cause as many as 12 EtO processing facilities to go down; some analysts have claimed that the US is likely to see shortages if more than one facility goes down.

Digital Reimbursement

Discussing the digital tide and how it applies to reimbursement, Leahey said he was concerned that new software creating efficiency gains would lead to lower reimbursement. According to Leahey, "DC has been talking about paying for value versus volume for 10 years; we haven't seen it yet."

Reimbursement seemed to be a real concern on the digital front, where the cost to develop products and services is meaningful, and a path to ROI is necessary for most practices.

Spotlight on Success

A panel titled "Turning the Tide" included Magda Michna, PhD, chief clinical, regulatory, and medical affairs officer at STAAR, reiterating the company's commitment to lens-based refractive surgery. Michna also expressed the company's confidence in the US market, saying, "If you look at our success internationally, we're confident." But she said STAAR still has some work to do in the US.

John Hovanesian, MD, discussed his practice's use of the RxSight Light Adjustable Lens (LAL) and gave some context to the growth in the post-op adjustable market. Hovanesian said the lens' market share of total procedures is still relatively small, but the procedure growth being seen among surgeons who are using the lens is an important metric to consider.

'What Keeps You Up at Night?'

Executives described potential headwinds for the year in a session titled "What Keeps You Up at Night?" Bob Dempsey, CEO and president at AsclepiX, discussed the rising cost to acquire capital, but also the government pressure on pharmaceutical pricing and what that means for companies trying to recoup drug development costs.

Dempsey said a recent meeting looked at two schools of thought on the Inflation Reduction Act's impact on drug pricing: One camp said the law was bad news and would really impact innovation, and the other camp said the industry really needed this, because pricing has gotten out of control in a lot of cases.

Addressing Merck's lawsuit against the Biden administration over the law's drug price negotiation program, Dempsey said he thought there were more lawsuits to come, and he was slightly surprised that Merck was leading the charge. Indeed, several companies and groups filed lawsuits in the following weeks.

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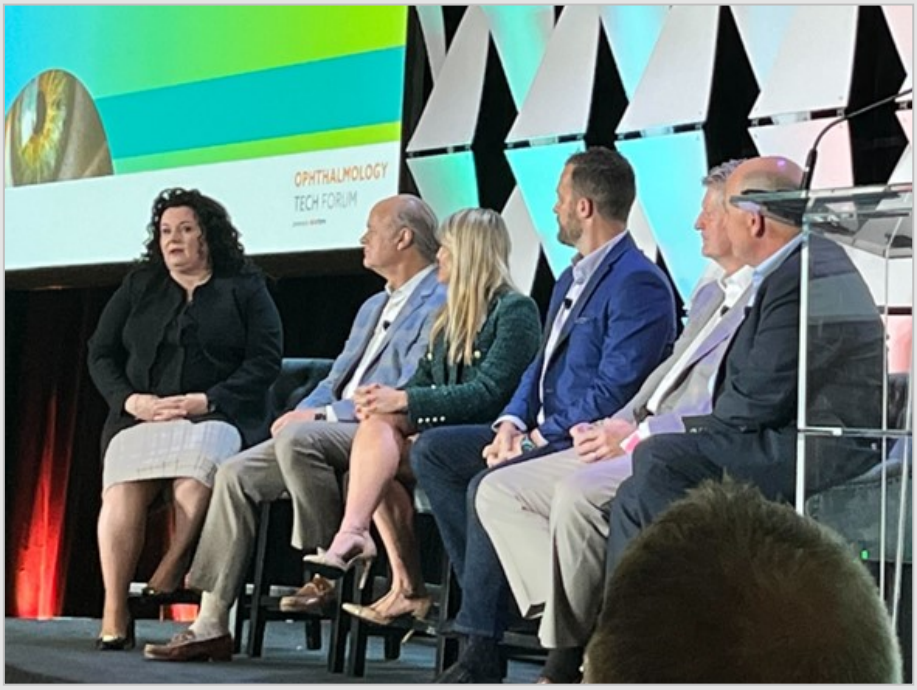

Magda Michna, PhD, talks during the 2023 Octane meeting about STAAR Surgical's commitment to lens-based refractive surgery. (Photo by Kristen Harmon Ingenito)

Octane Meeting

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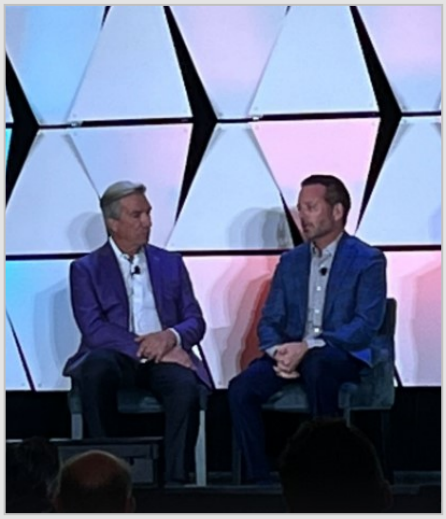
Mark Kontos, MD, said he was concerned by profit margins in practice and ASC ownership. The costs of doing business have increased, similar to the situation in industry, but reimbursement for those same services isn't increasing, reducing margins and meaning that ASC ownership isn't the revenue generator it once was.

Tim Pratt, PhD, executive director and global head of medical device and diagnostics research at ICON, said he was kept up at night by MDR in the EU. He said the dynamics were quite interesting in the EU market right now, noting that "it's not as bad if you are entering the market now. The burden is actually higher for those already on the market." Pratt suggested that a lot of legacy products would be leaving the market as companies consider the business decision of whether to pursue updated market access.

Dempsey added that the MDR's lack of clarity is bad for investors, saying, "The one thing investors want is clear certainty." Dempsey said the US FDA under Wiley Chambers, MD, offers that.

Dempsey called on strategics—often defined as large multinational companies with significant revenue and cash that are able to fund or buy companies that fit in strategically with their existing products—to continue to aid in funding innovation and invest in the space. Dempsey lamented the fact that some of the biggest revenue generators in ophthalmology don't seem as interested in the industry as drug developers would like, specifically mentioning the retinal pharmaceutical space.



James Mazzo interviews Brent Saunders of Bausch + Lomb at the 2023 Octane meeting. (Photo by Kristen Harmon Ingenito)

Disruptive Innovations

The meeting discussed disruptive innovations, with Paul Smith, president and chief operating officer at Orasis Pharmaceutical, eager for the company's presbyopia drop to hit the market and looking toward its Oct. 27 FDA target action date.

Luis Vargas, MD, head of clinical science at J&J Vision, discussed the company's current stack of open PMAs (there are four) and its focus on Europe and Asia for the Elita, a new femtosecond refractive laser that also performs lenticular extraction.

Greg Kunst, president and CEO at Aurion Biotech, said he was excited about the company's allogenic cell therapy gaining market approval in Japan in March.

Marc Odrich, MD, chief medical officer at Lenz Therapeutics, said he felt great about the company's presbyopia drop, saying Lenz had three Phase III FDA trials underway and is funded through commercialization.

Brent Saunders Interview

James Mazzo, executive chairman of Neurotech and a co-founder of Octane, interviewed Brent Saunders, the recently appointed chairman and CEO of Bausch + Lomb who is leading the company for a second time.

Saunders provided insights on the future direction of Bausch + Lomb, which sells products in four segments: pharmaceuticals, vision care (contact lenses), surgical, and consumer. Saunders said the surgical and pharmaceutical segments would benefit most from innovation, and those two segments have to do well for Bausch + Lomb to do well.

In thinking about the future master plan, Saunders said it was impossible to predict the timing and cadence of when things will happen. He said he believes investment in innovation inside the company should be given to those who can execute and deliver. "The more confidence I have in the leadership, the more confidence I will have in wanting to buy things. So, the short answer is: We will be opportunistic, thoughtful, and we are going to play the long game."

Mazzo asked Saunders about the people working for Bausch + Lomb and the people he is looking for. Saunders said he uses as a guideline for building the company the concept that there are two types of people in the world: energizers and energy absorbers. He wants to be around energizers.

"I like people who bring energy to every equation, described as can do, [and who] are thoughtful and smart. Energy absorbers are the worst. They absorb all the energy and can

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Octane Meeting

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think of 10 reasons why not to do something. I try to evaluate anyone coming into the company with this as a key criterion."

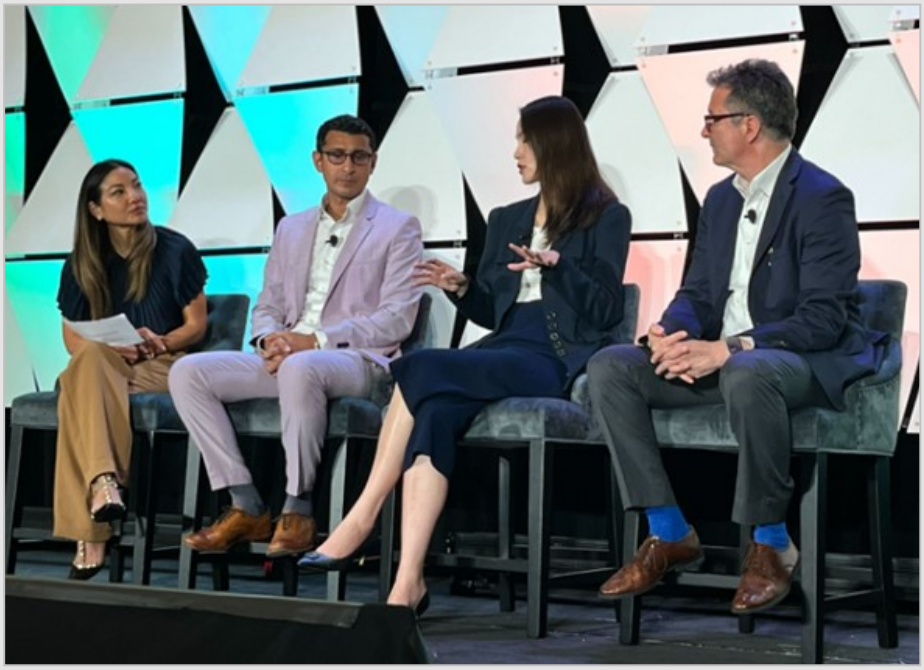
Saunders said he prefers to be close to the business. When he arrived at the company, there were very talented people, he said, but they didn't report to him. He describes himself as on a crusade to get rid of bureaucracy and prefers to have a flat organizational structure because it creates greater opportunity for management, allows faster, more direct information to flow, and makes it harder for bureaucracy to build.

Saunders was asked about the methodology of building the business either through internal development or acquisition. He described Bausch + Lomb as a big D and little R. "There are many things we can develop from scratch internally with research. We have to double down on what we are good at and at the same time we need to be open minded and thoughtful about how we can source innovation. We need to be covering meetings all over the world and connecting with the entrepreneurs."

Mazzo asked where Saunders saw Bausch + Lomb a year from now. Saunders said he hoped the company would be in a better position than it is today and grow at or above mid-single digits on an organic basis. In addition, he looked for the company's pipeline to become interesting to its investors and customers, pointing out that there are some early- and mid-stage products it can show demonstrating Bausch + Lomb's commitment to innovation.

The Next Generation

An afternoon panel session discussed the next generation of eye surgeons, with a focus on digital technologies. Luis Diaz-Santana, PhD, of Cambridge Consultants, said digital solutions really need to address workflow and create efficiencies for practices.



From left: Aimee Shimamoto, Omar Shakir, MD, Dagny Zhou, MD, and Luis Diaz-Santana, PhD, participate in a session at the 2023 Octane meeting.
(Photo by Kristen Harmon Ingenito)

Dagny Zhou, MD, a California-based cornea, cataract, and refractive surgeon, echoed this statement, also calling for technology to be easily incorporated into workflows, not adding bulk. She performs office-based cataract surgery (OBS) and has been doing so for six years. She said immediate sequential bilateral cataract surgery (ISBCS) had added efficiency, improved her patients' neuro-adaptation, reduced her costs, and improved environmental sustainability. She said she feels the main reason for lack of adoption among cataract surgeons is financial.

Shakir, of Coastal Eye Surgeons, performs ISCBS in addition to OBS, and said he even does same-day consults to surgery for some patients. He performs every cataract surgery in office. "There truly is no drawback to OBS," Shakir said. But he echoed Zhou's statements about sustainability, showing that he created six large bags of trash from one day of 15 cases.

Santana cautioned that the industry needs to change workflows on both ends—screening and treatment. He and Shakir noted the long wait time—up to two years—for cataract patients to have surgery in the UK's National Health Service. Enhancements in screening and diagnosis are sorely needed but are likely to cause an even larger influx of patients, who also must be addressed.

Moderator Aimee Shimamoto, senior director of marketing for the

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Octane Meeting

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Americas and Japan at BVI Medical, said, "Patients don't want the wait time, but they do want the face time."

Octane's Contributions

Carpou, Octane's CEO, began the meeting by reflecting on the purpose of the 21-year-old organization: connecting people, resources, and capital locally, nationally, and globally through leading events, networking resources, and interactive content.

Octane has focused on ophthalmology, but it will add cardiovascular starting this year.

A key feature of Octane is its LaunchPad accelerator to assist early-stage companies. LaunchPad has helped more than 1,573 companies raise over $5.9 billion in funding and created 28,372 jobs since 2010.

Described as a pro-bono service, LaunchPad is supported by funding from the US Small Business Administration (SBA). It is one of the SBA's Small Business Development Centers, focused on accelerating tech and med-tech startups that have their management team and business plan in place.

The formula Octane uses to speed access to capital and growth resources includes preparing companies for sophisticated investors, using data and analysis, helping companies justify their valuation, providing resources for capital access, and aligning growth resources for demonstrating a path to revenue. One of its offerings is a predictive analytics tool that provides detailed quantitative analysis into a company's future success.

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2023 Ophthalmic Meetings | Market Scope			
Organization	**Date**	**Location**	**More Information**
ASRS	July 28-Aug. 1	Seattle, Washington	https://www.asrs.org/annual-meeting
ISOP	Sept. 7	Vienna, Austria	https://presbyopia-international.com/
European Forum 2023 (Ophthalmology Futures Forums)	Sept. 7	Vienna, Austria	https://www.ophthalmology-futures.com/forums/
ESCRS iNovation	Sept. 8	Vienna, Austria	https://inovation.escrs.org/
ESCRS	Sept. 8-12	Vienna, Austria	https://congress.escrs.org/
Retina Forum 2023 (Ophthalmology Futures Forums)	Oct. 4	Amsterdam, the Netherlands	https://www.ophthalmology-futures.com/forums/
EURETINA	Oct. 5-8	Amsterdam, the Netherlands	https://euretina.org/future-meetings/
Eyecelerator @ AAO	Nov. 2	San Francisco, California	https://www.eyecelerator.com/
AAO	Nov. 3-6	San Francisco, California	https://www.aao.org/annual-meeting
2024			
Hawaiian Eye and Retina 2024	Jan. 13-19	Maui, Hawaii	https://www.healio.com/meeting/hawaiianeyemeeting/home

Merck, US Chamber Sue Government Over Drug Price Negotiation Program

By Joan McKenna

Merck on June 6 sued the Biden administration over Medicare's plans to reduce drug prices under the Inflation Reduction Act of 2022, calling the drug price negotiation process a "sham" and "tantamount to extortion."

The US Chamber of Commerce filed its own suit June 9, claiming the negotiation process is really a "price control scheme." The group said an early example of fallout from the law was ophthalmic drug developer Alnylam pausing its clinical trial of a candidate for Stargardt disease in Q3-2022 due to concerns over the price negotiation process.

Merck, of Rahway, New Jersey, asked the US District Court for the District of Columbia to block the US Health and Human Services Department from forcing the company to participate in the Drug Price Negotiation Program on the grounds that it is unconstitutional, violating the Fifth and First Amendments.

Merck, once an ophthalmic drugmaker until it divested its eye portfolio from 2013 to 2015, said it expects its type 2 diabetes drug Januvia to be subject to negotiation this year and cancer immunotherapy treatment Keytruda in later negotiation cycles. Keytruda sales in 2022 were $20.9 billion, representing 35 percent of the company's total revenue of $59.3 billion.

Merck said the Inflation Reduction Act will force drugmakers to discount prices on selected drugs by 25 to 60 percent.

The company said the Fifth Amendment requires the US government to pay "just compensation" if it takes property for public use. However, Merck claims that the Inflation Reduction Act will allow the government to take Merck's patented innovations by coercing the company to provide third parties with access at prices the government sets.

Merck said the law also creates the false impression that drugmakers are voluntary participants by coercing them to sign an "agreement" conveying that the government-set prices are the "fair" result of a "negotiation." Merck said this "compelled mirroring" of the government's political message violates the First Amendment.

Merck noted that negotiations are secret. Drugmakers are not allowed to disclose initial or subsequent CMS pricing offers or information exchanged during negotiations.

Manufacturers that refuse to participate must pay a daily excise tax amounting to multiples of the drug's daily revenue.

Merck said in a statement that, on average, it takes a decade and more than $2.5 billion to develop a new drug.

"Since 2000, companies like ours have invested more than $1.1 trillion in the search for new treatments and cures, including $102.3 billion in 2021 alone. This investment has led to incredible breakthroughs for patients," the company said.

Merck said it believes drug price negotiations "will negatively impact biopharmaceutical innovation and the sector's work to develop lifesaving and life-changing innovations."

The Inflation Reduction Act, passed in August 2022, requires the HHS secretary in 2023 to begin negotiating lower prices for 10 of the most expensive drugs that lack market competition, with these prices going into effect in 2026. The number of drugs increases to 15 for 2027, 15 for 2028, and 20 for 2029, for a total of 60 drugs affected.

The law exempts from negotiation orphan drug products, as well as products that are within certain years of their FDA approval date—less than seven years for drugs or 11 years for biologics.

The law also caps annual out-of-pocket costs for Part D beneficiaries at $2 thousand.

In addition, it prevents drugmakers from blocking lower-cost generic competition and requires companies that raise drug prices above the rate of inflation to pay rebates for the difference to Medicare.

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The US Chamber of Commerce noted that ophthalmic drug developer Alnylam had paused its clinical trial of a candidate for Stargardt disease in Q3-2022 due to concerns over the price negotiation process.

Clinical Trial Updates for Ophthalmic Candidates

Market Scope is tracking companies that have announced clinical trial updates or milestone achievements.

By Jennie Crabbe

Clinical Trial Updates				
Date	**Company**	**Candidate, Indication**	**Milestone**	**Notes**
June 8	LianBio	TP-03 in Chinese patients with *Demodex* blepharitis	Enrollment complete in pivotal Phase III trial	Co-primary endpoints are complete collarette cure and mite eradication at Day 43. Topline results are expected in Q4-2023.
June 5	EyePoint Pharmaceuticals	EYP-1901 for moderate to severe non-proliferative DR	Enrollment complete in Phase II trial	Primary endpoint is improvement of at least two diabetic retinopathy severity scale (DRSS) levels as of week 36 after injection. Topline data expected in Q2-2024.
June 5	Glaukos	Epioxa epi-on corneal crosslinking for keratoconus	Enrollment complete in second Phase III trial	Primary endpoint is mean change in Kmax from baseline to Month 12. NDA submission targeted by the end of 2024.
June 1	Clearside Biomedical	CLS-AX axitinib (suprachoroidal injection) for wet AMD	Enrollment open in Phase IIb	Goal is to enroll 60 patients. Tyrosine kinase inhibitor aims to improve duration and reduce treatment burden vs. aflibercept. Topline results expected in Q3-2024.
June 1	Aviceda Therapeutics	AVD-104 glyco-mimetic nanoparticle (IVT injection) for GA	First patient dosed in Phase II	Targets two inflammatory pathways by repolarizing activated retinal macrophages and inhibiting the complement cascade.
May 31	Redwood Pharma	RP501, an IntelliGel-based topical first-line therapy candidate for dry eye	Positive results from trial	Produced statistically significant positive efficacy results for reducing burning sensation, stinging, and itching. RP501 is categorized as a medical device in Europe, which may speed the approval process, Redwood says.
May 31	Nacuity Pharmaceuticals	NPI-001 (N-acetylcysteine amide) oral tablet for Usher-associated RP	Enrollment complete in Phase I/II	Targets oxidative damage in photoreceptors by boosting the antioxidant glutathione; 48 adults enrolled at four sites in Australia. Patients will be followed for two years.
May 31	Coave Therapeutics	CTx-PDE6b gene therapy (subretinal injection) for RP	Positive results in Phase I/II	Clinically meaningful visual benefit seen with highest dose. Approval granted for second cohort of younger patients in earlier stages of disease.
May 25	Oxurion	THR-149 plasma kallikrein inhibitor (IVT injection) for DME	Target enrollment met in Phase II, Part B	More patients are expected to enroll. Trial is for suboptimal anti-VEGF responders and compares THR-149 to aflibercept. Topline data expected in Q4-2023.
May 24	Alimera Sciences	Iluvien (fluocinolone acetonide IVT implant) 0.19 mg as a first-line treatment for DME	Enrollment complete in Phase IV	The trial will compare Iluvien vs. repeated aflibercept injections in about 300 treatment-naïve, or almost naïve, patients at 42 sites in the US. Topline results expected in early 2025.
May 22	AiViva Biopharma	AIV007 tyrosine kinase inhibitor (periocular injection) for wet AMD and DME	First cohort dosed in Phase I	Up to 24 subjects will receive a single periocular injection and will undergo monthly evaluation for up to six months.
May 22	Oculis	OCS-01 high-concentration dexamethasone eye drop for DME	Positive results in Phase III	Statistically significant increase in BCVA vs. vehicle and higher percentage of patients achieving ≥15-letter BCVA gain and better improvement in retinal thickness.
May 16	Invirsa	INV-102 eye drop for dry eye	Phase I/IIa enrollment complete	INV-102 activates two major pathways: the protein p53; and Pax6, which is critical for cellular stability. Topline data expected by Q3-2023.

Annexon's Complement Therapy Candidate in GA Shows Preservation of Vision in Phase II Trial

By Jennie Crabbe

Annexon reported May 24 that topline results from its ARCHER Phase II trial of ANX007 in patients with geographic atrophy (GA) demonstrated a statistically significant, dose-dependent preservation of visual function, regardless of lesion location or size.

Reduction in rate of lesion growth did not reach statistical significance, however. The results stand in contrast to Apellis' Syfovre, the only US-approved therapy for GA, and Iveric Bio's lead candidate, Zimura, which both slow the rate of GA lesion growth but have shown less robust results in preserving vision.

At 12 months, patients treated monthly with ANX007 showed a 72 percent reduction in risk of 15-letter loss in best corrected visual acuity (n=89, p=0.006), and patients treated every other month showed a 48 percent reduction in risk of 15-letter loss (n=92, p=0.064). Pooling the treatment groups resulted in a 59 percent reduction in risk of >15-letter loss (n=181, p=0.008).

Patients treated monthly saw a 6.2 percent reduction in lesion growth; those treated every other month achieved a 1.3 percent reduction; and the pooled treated population reached 3.7 percent reduction.

Monthly Zimura (avacincaptad pegol), a C5 inhibitor, clocked in with observed reductions of GA lesion size at 12 months of 30.5 percent and 17.3 percent in its two Phase III GATHER trials. Monthly Syfovre (pegcetacoplan), a C3 inhibitor, registered observed reductions of 21 percent and 12 percent at 12 months in its two Phase III trials, OAKS and DERBY.

Annexon said the Phase II results support its approach in targeting C1q, which the company says potentially plays a dual role in GA.

ANX007 is an investigational C1q antigen-binding fragment designed for intravitreal administration in patients with complement-mediated neurodegenerative ophthalmic disorders. In Phase I studies, intravitreal ANX007 demonstrated full C1q inhibition at 29 days and was well tolerated.

Annexon, of Brisbane, California, said the Phase II results support its approach in targeting C1q (complement component 1q), which the company says potentially plays a dual role in GA.

C1q accumulates on photoreceptor cell synapses with normal aging or disease and may lead to abnormal synapse removal and neuronal loss in disease. C1q also accumulates in the retina below photoreceptor cells on extracellular deposits called drusen and may contribute to the localized tissue damage unique to the specialized compartment of the outer retina in GA. C1q is produced locally in the eye by infiltrating immune cells and may be more amenable to local inhibition by intravitreal administration of ANX007 than other complement factors.

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News Briefs

Sightpath Integrates Another Mobile Business Into Services

Sightpath Medical, of Bloomington, Minnesota, announced June 5 that it would integrate Southern Surgical Support, a Knoxville, Tennessee, mobile cataract services company, into its business. The move is Sightpath's second expansion in eight months. No financial details were provided. Mark Cross, founder of Southern Surgical Support, will join Sightpath as part of the deal. Sightpath, founded in 1991, delivers advanced ophthalmic equipment and instruments, plus trained surgical technologists and engineers, to facilities and surgeons across the US. In November, Sightpath acquired mobile cataract surgery equipment provider Accusite Surgical.

BioLight, Alexion to Study Using Tear Film as Retinal Diagnostic

Israel's BioLight Life Sciences and Alexion announced May 30 that they would collaborate on a study of new technology that has the potential to screen the tear film to diagnose retinal disease. The study, jointly financed, will evaluate technology licensed from Harvard University. One of its inventors, Professor Yifat Merbl, of the Weizmann Institute of Science, in Rehovot, Israel, will participate, as will Professor Anat Loewenstein, MD, retina specialist and chair of the ophthalmology department at the Tel Aviv Medical Center. The BioLight portfolio includes several ophthalmic ventures in Israel, including AEYE Health, maker of a US FDA-approved AI-based screening system for diabetic retinopathy; Tarsier, which is

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News Briefs

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advancing a slow-release immunomodulator implant for retinal disease; Belkin Vision, maker of the Eagle automated laser treatment for glaucoma; and Sanoculis, maker of the Minimally Invasive Micro Sclerostomy (MIMS) system for glaucoma. Alexion, the rare disease division of AstraZeneca, is based in Boston.

US FDA Accepts NDA for Vyluma's Pediatric Myopia Candidate

Vyluma announced June 6 that the US FDA had accepted its new drug application (NDA) for lead compound NVK002 (low dose atropine 0.01%) for childhood myopia and set a Prescription Drug User Fee Act (PDUFA) target action date of Jan. 31, 2024. NVK002 is a preservative-free eye drop administered nightly and intended for patients ages 3 to 17. Vyluma, of Bridgewater, New Jersey, said NVK002 achieved statistically significant and clinically meaningful differences from placebo in the key outcome measures of mean change from baseline in spherical equivalent refraction and mean change from baseline in axial length at month 36. Laboratoires Théa has licensed the candidate in Europe, Canada, Mexico, select South American countries, and parts of North Africa. Zhaoke Ophthalmology has licensed NVK002 in Greater China and Southeast Asia.

BioNanoSim, Rafarm Team Up to Create BNS Ophthalmics

Greek pharmaceutical company Rafarm and Israel's BioNanoSim announced May 30 that they would create a new ophthalmic company called BNS Ophthalmics. Rafarm's current product line includes eye drops for glaucoma, bacterial and allergic conjunctivitis, and post-

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News Briefs

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cataract pain and inflammation. BioNanoSim developed a nano-encapsulation technology for improved potency and reduced side effects in drugs in segments including ophthalmology and oncology. BioNanoSim will contribute its intellectual property and R&D expertise to the new venture, while Rafarm will provide funding and infrastructure for development, commercial-scale manufacturing, and distribution. BNS Ophthalmics will develop lead candidate BNSO-1, an ocular emulsion of the potent nonsteroidal anti-inflammatory drug tacrolimus. BNS Ophthalmics said it was on track to begin a Phase I/IIa clinical trial of BNSO-1 in chronic anterior uveitis before the end of 2023. The company's pipeline also includes BNSO-2, a sustained-release intravitreal injection of a steroid derivative for macular edema and age-related macular degeneration (AMD); and BNSO-3, a novel topical drug candidate for dry eye.

Roche Withdraws European Marketing Application for Susvimo

The European Medicines Agency (EMA) announced on May 25 that Swiss drugmaker Roche had withdrawn its marketing application for Susvimo, a refillable ocular implant for ranibizumab in wet AMD. The EMA said there were some "unresolved issues" with the application, even after Roche responded to regulators' last round of questions. The agency said it had asked for more information to show that the implant complied with EU standards. The agency also noted that the proposed indication would have to be changed so that Susvimo could be used only in patients who had an adequate and stable response to previous anti-VEGF injections. Therefore, the EMA was not ready to grant approval, and the application was withdrawn. Roche reported Q1-2023 Susvimo implant sales of CHF 1 million. The device was voluntarily recalled in October 2022 in the US due to discovery of a leaking seal. It was approved by the US FDA in October 2021.

Washington Governor Signs Law Expanding Scope for Optometrists

Gov. Jay Inslee of Washington state on May 9 signed the Access to Eyecare Act, expanding the scope of practice for optometrists (ODs) there to include incision and excision of chalazion; certain injections (subconjunctival, subcutaneous, and intramuscular epinephrine for anaphylaxis); eyelid surgery (excluding cosmetic surgery or procedures requiring the use of general anesthesia); use of topical and injectable anesthesia; and prescribing of oral steroids. The original bill had included procedures such as laser posterior capsulotomy after cataract surgery, laser peripheral iridotomy (LPI), and selective laser trabeculoplasty (SLT), but the laser procedures were removed in February, amid concerns raised by the state's ophthalmologists, as part of a compromise to move the bill forward. Proponents said Washington state's scope had been among the narrowest in the nation. They also framed the issue as one of access to care. The Washington Eye Care Alliance said ODs practice in all but three Washington counties, while 15 counties have no ophthalmologists. Market Scope estimates that Washington state has about 1,400 ODs and 400 ophthalmologists.

EzriCare artificial tears were one of the brands recalled following an outbreak of *Pseudomonas aeruginosa* infections.

Death Toll from Infections Linked to Eye Drops Rises to Four

The US Centers for Disease Control and Prevention (CDC) released an update May 15 on the ongoing *Pseudomonas aeruginosa* outbreak linked to certain over-the-counter brands of artificial tears. Four people have now died as a result of the bacterial infection, the CDC said. That number is up from three in March. In addition, there have been 14 reports of vision loss (up from eight in March) and four reports of enucleation (surgical removal of an eye). As of May 15, 81 cases in 18 states (CA, CO, CT, DE, FL, IL, NC, NJ, NM, NV, NY, OH, PA, SD, TX, UT, WA, WI) had been identified—an increase of 13 cases since the CDC's last update in March. The rare, extensively drug-resistant strain of *P. aeruginosa* had never been reported in the US prior to this outbreak, CDC officials said. Artificial tears were identified as a common exposure for most patients. The CDC and US FDA recommend clinicians and patients stop using and discard EzriCare or Delsam Pharma's artificial tears, and Delsam's Artificial Ointment. Both companies' products

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News Briefs

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have been voluntarily recalled. India's Global Pharma is the manufacturer of the recalled products. Lakewood, New Jersey-based EzriCare is a generic over-the-counter drug company. Delsam is based in New York.

US FDA Approves C. Light's Retitrack Retinal Eye Movement Monitor

C. Light Technologies announced May 11 that its retinal eye movement monitor, dubbed Retitrack, had received 510(k) clearance from the US FDA. C. Light, of Medford, Massachusetts, is a neurotech and AI company that uses retinal eye-tracking to research neurodegeneration and therapeutic efficacy. The company has raised more than $8 million, including funding from the Alzheimer's Drug Discovery Foundation to study fixational changes in mild cognitive impairment. Researchers have been studying abnormalities of eye movements and their potential link to traumatic brain injury, autism spectrum disorder, multiple sclerosis, and other neurologic conditions. C. Light says Retitrack stands alone as the first retinal eye-movement monitor cleared for use within health care. Retitrack is a compact, tabletop device that records 10-second non-invasive retinal video scans and uses analytics and eye-tracking technology to detect, measure, and analyze fixational and saccadic eye motion at the micron level.

Stada, Xbrane Launch Ximluci Ranibizumab Biosimilar in Germany

Sweden's Xbrane Biopharma and its partner Stada, of Germany, announced May 26 that they had launched their ranibizumab biosimilar Ximluci in Germany. The biosimilar was approved in Europe in November 2022 for wet age AMD, diabetic macular edema (DME), diabetic retinopathy (DR), retinal vein occlusion (RVO), and visual impairment due to choroidal neovascularization in adults. The company reported in April that it had launched the biosimilar in major European markets. The companies are positioning the drug as a cost-effective alternative to Lucentis to treat all indications of the reference biologic. Stada and Xbrane said their biosimilar is produced, filled, sterilized, and packaged entirely within Europe. As with Lucentis, the ranibizumab biosimilar is supplied as a 2.3 mg/0.23 ml single-use vial for injection for intravitreal use.

Mireca Reacquires All Rights to Retinal Candidates

Germany's Mireca Medicines announced May 24 that it had regained all intellectual property rights previously shared in a partnership with Graybug Vision, now CalciMedica. Graybug, of Redwood

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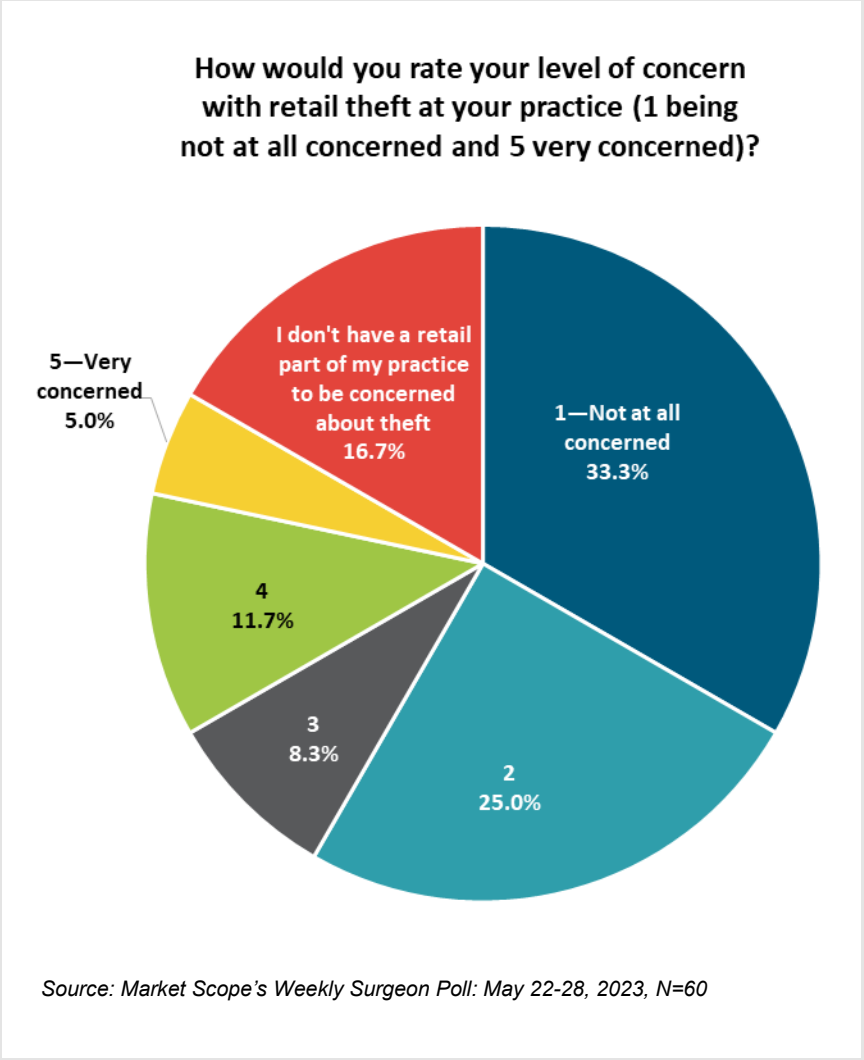
Weekly Surgeon Poll



Source: Market Scope's Weekly Surgeon Poll: May 22-28, 2023, N=60

News Briefs

(continued from the previous page)

City, California, agreed in 2022 to merge with CalciMedica to focus on advancing CalciMedica's pipeline of candidates for life-threatening inflammatory diseases. The deal ended Graybug's participation in the ophthalmic market. In 2020, Graybug had acquired Mireca's novel, mutation-agnostic cGMP analog for inherited retinal diseases such as retinitis pigmentosa, which was then designated GB-601. Rights to that candidate, renamed MM238, return to Mireca, along with an additional patent application protecting select cGMP analogs in Graybug's sustained-release drug delivery technology. A new manufacturing process that was developed under the collaboration is now also owned by Mireca. Mireca said it now will continue the development of MM238 as its lead candidate.

Lumibird to Acquire Prima Industrie's Laser and Semiconductor Businesses

France-based Lumibird announced May 16 that it and Italy's Prima Industrie had agreed on a deal for Lumibird to acquire Prima subsidiary Convergent Photonics, also of Italy, and the Convergent assets of Prima Industrie North America, based in Boston. No financial details were provided. Convergent has over 50 years of experience in the design and manufacture of semiconductor lasers and laser diode packaging, as well as the design and manufacture of high-power lasers for the medical sector. Lumibird said that 80 Convergent employees in Italy and the US will join Lumibird. Lumibird said it had already made strategic investments in optical fiber and derived components. The addition of the semiconductor business will allow for independence in the supply of critical components while allowing the company to open up new market segments in health care aside from ophthalmology, Lumibird said. Lumibird's medical division includes ophthalmic lasers and ultrasound diagnostics from Quantel Medical, Ellex, and Optotek Medical. The division reported Q1-2023 revenue of €22.5 million ($24.3 million, calculated May 22, 2023).

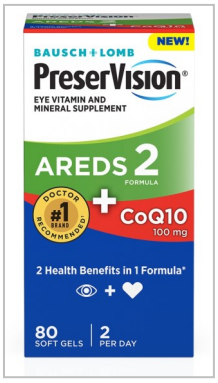
iHealthScreen Files for US Clearance for iPredict AI Screener in AMD

New York-based iHealthScreen announced May 23 that it had submitted its iPredict automated AI screening system for US FDA 510(k) clearance for early diagnosis of AMD. The system gained CE marking in Europe in 2021 for early diagnosis of DR, AMD, and glaucoma. The iPredict works with a color fundus camera to capture high-resolution images. Screening results are available in a fully automated report in less than 60 seconds, and the entire test can be completed in five minutes, the company says. iHealthScreen said its pivotal trial for the iPredict achieved excellent accuracy, with a sensitivity of 86.86 percent and a specificity of 94.13 percent in diagnosing AMD.

PharmAbcine Gets Green Light in Korea for Phase I Trial in Wet AMD

South Korea's PharmAbcine announced May 23 that Korean regulators had cleared its investigational new drug (IND) application for a Phase I trial of PMC-403, the company's candidate for wet AMD. PMC-403 is a TIE2-activating fully human antibody designed to stabilize and repair damaged blood vessels. PharmAbcine said PMC-403 administered as an intravitreal injection could be a therapeutic option for patients who don't respond to anti-VEGF treatment for exudative retinal diseases.

Bausch + Lomb Debuts Eye Vitamin That Also Targets Heart Health



PreserVision AREDS 2 Formula Soft Gels Plus CoQ10

Bausch + Lomb reported June 12 that it had launched a new eye vitamin, the PreserVision AREDS 2 Formula Soft Gels Plus CoQ10, in the US. The Vaughan, Ontario, company said the product is the only eye vitamin that provides 100 mg of CoQ10 antioxidant for heart health in addition to the nutrient formula recommended by the National Eye Institute to help reduce the risk of moderate to advanced AMD progression in AMD patients. CoQ10 is an antioxidant that the body produces naturally. It helps support healthy cell function. Levels decrease as people age, and they tend to be lower in those with heart disease and who take statins. Eye vitamins are a top revenue producer for Bausch + Lomb. The company reported 2022 eye vitamin revenue of $387 million, accounting for 10 percent of total 2022 revenue of $3.8 billion.

Bausch + Lomb Elevates Business Unit Heads to Executive Team

Bausch + Lomb Chairman and Chief Executive Officer Brent Saunders continues to reshape his leadership team, after making his return to the company in February. The company announced June 1 that business unit heads and senior vice presidents Luc Bonnefoy, Surgical; John Ferris, Consumer; and Yang Yang, Vision Care, will be elevated to the executive management team and

(continued on the next page)

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News Briefs

(continued from the previous page)

report directly to Saunders. Joseph Gordon, president, Global Consumer, Surgical and Vision Care, will transition to the role of strategic advisor to Saunders, the company said. Louis Yu, PhD, executive vice president and chief quality officer, intends to retire this summer, and Bausch + Lomb is beginning an internal and external search for his replacement. Saunders said the changes mean that the company's leaders "will be closer to customers and patients," setting the stage for Bausch + Lomb's next phase of growth.

HuidaGene Appoints Alvin Luk, PhD, as Chief Executive Officer

HuidaGene Therapeutics announced May 24 that it had appointed gene therapy industry veteran Alvin Luk, PhD, MBA, as chief executive officer. Luk has more than 30 years of experience in global drug development, gene and cell therapies, biological drugs, and rare diseases, the company said. He has held roles at Spark Therapeutics and Biogen, among others. HuidaGene reported in April that Chinese regulators had approved its IND application for a multinational clinical trial of HG004, a gene therapy candidate for *RPE65*-associated inherited retinal dystrophies. The trial was given a green light from the US FDA in January. The candidate has orphan drug status in the US. HuidaGene, with offices in Shanghai, China, and Clinton, New Jersey, says its vector technology, delivered directly to the retinal pigment epithelium, allows for lower doses than adeno-associated virus serotype 2 (AAV2) gene therapies, potentially reducing immunogenicity and adverse ocular events.

Visgenx Appoints William Pedranti as Chief Executive Officer

Visgenx, of San Diego, announced June 5 that it had appointed William Pedranti, JD, as chief executive officer. Pedranti will also join the company's board of directors. Martin Emanuele, PhD, co-founder of Visgenx, will continue as chief science officer, the company said. Pedranti has 20 years of leadership experience in the biotech industry, including seven years in ophthalmology, Visgenx said. He was a co-founder of IACTA Pharmaceuticals, which targeted dry eye and ocular pain. Visgenx' initial product is VGX-0111, a gene therapy candidate for dry AMD. VGX-0111 is based on the ELOVL2 gene, which is required for the biosynthesis of lipids necessary for the function and survival of retinal cells. ELVOL2 expression declines with aging and may be an underlying pathology of dry AMD. VGX-0111 is intended to restore a normal level of ELOVL2 expression. Pedranti said in a press release that up next for the company is completion of a Series A funding round to advance VGX-0111 into human trials.

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