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Finance Watch: Royalty Deals Pick Up As Alternative Financings Find Appeal

Pfizer Prices $31bn Debt Offering To Fund Seagen Buy

by Mandy Jackson

Public Company Edition: Seven companies revealed $2.1bn worth of royalty financings in the first quarter of 2023 and the deals keep coming in Q2, with uniQure monetizing Hemgenix royalties for up to $400m. Also, Legend grossed $350m in a follow-on offering and Athenex is liquidating via bankruptcy.

Royalty financings were relatively few and far between in the first quarter of 2022, but the number of these financings more than doubled in Q1 of 2023 – from three to seven – and the amount of money royalty purchasers committed to biopharmaceutical companies in the transactions more than tripled from $590m to $2.1bn, according to data from Biomedtracker's Financing Quarterly Statistics report.

This form of alternative financing continues to be attractive to publicly traded drugs developers in Q2, with two significant deals announced to date, including one that could bring *uniQure N.V.* up to $400m in cash that is non-dilutive to its existing shareholders. The company said on 15 May that it sold a portion of its royalty revenue from partner *CSL Limited*'s sales of their hemophilia B gene therapy Hemgenix (etranacogene dezparpovec) to *HealthCare Royalty Partners* (HCRx) for $375m up front.

Hemgenix was approved in the US in November. (Also see "*UniQure/CSL Set To Launch First Hemophilia B Gene Therapy Next Year At Record Price*" - Scrip, 23 Nov, 2022.) UniQure is eligible to receive the final $25m under its agreement with HCRx in 2024 if Hemgenix sales meet a prespecified threshold. The company retains all rights to the portion of Hemgenix royalties it did not sell to HCRx as well as all $1.5bn worth of milestone payments it is eligible to receive under

its partnership with CSL, including $100m for the first product sale in the US and $75m for the first sale in one of five major European countries. (Also see "*uniQure Hemophilia B Deal With CSL Leaves M&A Fans Miffed*" - Scrip, 25 Jun, 2020.) The gene therapy was approved in the EU in February. (Also see "*CSL/UniQure's Hemgenix To Enter Uncertain EU Market After Regulatory Nod*" - Scrip, 21 Feb, 2023.)

Amsterdam-based uniQure will use the proceeds from its royalty financing agreement to fund ongoing development of additional gene therapy candidates, including AMT-130, which is expected to generate updated Phase I/II results in Huntington's disease soon. The company will also use the proceeds to continue advancing AMT-260 for refractory temporal lobe epilepsy and AMT-162 for SOD-1 amyotrophic lateral sclerosis (ALS), among other programs.

UniQure Looks For Clear Signal From Huntington's Disease Gene Therapy

By Andrew McConaghie

11 May 2023

After recent landmark approvals in other neurodegenerative diseases such as Alzheimer's and amyotrophic lateral sclerosis, hopes are rising that Huntington's disease could be next to reach a breakthrough.

Read the full article here

Enanta Pharmaceuticals, Inc. also announced a royalty financing deal during the second quarter, revealing in April that it received $200m from OMERS, one of Canada's largest defined benefit pension plans, for a 54.5% share of its royalties from the hepatitis C regimen Mavyret/Maviret (glecaprevir/pibrentasvir), commercialized by *AbbVie Inc.* (Also see "*Finance Watch: Kenvue, Acelyrin Launch Biggest Biopharma IPOs Of 2023*" - Scrip, 5 May, 2023.)

In addition to royalty financings, however, public company financings generally were on the rise in the first quarter of 2023, according to Biomedtracker's report. There were 38 follow-on public offerings (FOPOs) in Q1 of this year, totaling $4.6bn, versus 19 FOPOs for a total of $3.4bn in Q1 of 2022, although the average deal size was down to $120.9m from $178.4m. There were 55 private investment in public equity (PIPE) financings, totaling $1.2bn in Q1 of 2023, versus 31 PIPE financings for the same period last year, totaling $687m, with average deal sizes of $22.5m versus $22.2m, respectively.

Debt, Follow-On And Other Financings: Pfizer Raises $31bn

In the largest public company financing of the year, *Pfizer Inc.* priced a debt offering that will gross $31bn across eight tranches, which the big pharma will use to finance its $43bn purchase of *Seagen Inc.* (Also see "*Pfizer Pays $43bn For Seagen With Goal Of Rapidly, Globally Advancing ADCs*" - Scrip, 13 Mar, 2023.)

The offering includes $3bn worth of 4.65% notes due in 2025, $3bn worth of 4.45% notes due in

2026, $4bn worth of 4.45% notes due in 2028, $3bn worth of 4.65% notes due in 2030, $5bn worth of 4.75% notes due in 2033, $3bn worth of 5.11% notes due in 2043, $6bn worth of 5.3% notes due in 2053 and $4bn worth of 5.34% due in 2063. The notes may be redeemed at 101% of the aggregate principal amount of the notes if the Pfizer/Seagen merger is terminated or does not close by the agreed upon date.

In other recent public company financings:

- *Legend Biotech Corp.* said on 8 May that it grossed $350m from the sale of 5.5 million American depository shares (ADSs) at $64 each in a registered direct offering (RDO), with each ADS representing two ordinary shares. The proceeds will help fund the China-based developer of chimeric antigen receptor T-cell (CAR-T) therapies and natural killer (NK) cell therapies through the fourth quarter of 2025. The RDO came after Legend received a boost in April from a leaked European Hematology Association (EHA) abstract for updated clinical trial results from an earlier treatment setting for Carvykti (ciltacabtagene autoleucel), a BCMA-targeted CAR-T therapy partnered with *Johnson & Johnson* approved currently for use in fifth-line or later multiple myeloma. (Also see "*Leaked Data Boost J&J and Legend's CAR-T Carvykti But Manufacturing Issues Remain*" - Scrip, 20 Apr, 2023.)

- *Reata Pharmaceuticals, Inc.* said in its first quarter 2023 financial update on 10 May that it entered into a debt facility agreement on 5 May with funds managed by Pharmakon Advisors LP for up to $275m, including $75m available initially, a second tranche of $50m based on the achievement of certain regulatory or production requirements, and two separate $75m tranches based on certain commercial milestones. The funding gives Plano, TX-based Reata capital to fund its operations through the end of 2026 as it focuses on the commercial launch of Skyclarys (omaveloxolone) for Friedreich's ataxia after its US Food and Drug Administration approval at the end of February. (Also see "*Reata Lays Commercial Path For Skyclarys With First-Ever Friedreich's Ataxia Nod*" - Scrip, 1 Mar, 2023.) Reata and partner *Kyowa Kirin Co., Ltd.* ended the long, unsuccessful development path for their chronic kidney disease candidate bardoxolone in May. (Also see "*Reata, Kyowa Kirin End Bardoxolone CKD Development*" - Scrip, 11 May, 2023.)

- *Akero Therapeutics, Inc.* raised $220m on 16 May when it priced a FOPO of 5.2 million shares at $42 each. South San Francisco-based Akero is developing treatments for metabolic diseases, including non-alcoholic steatohepatitis (NASH). The company's lead product candidate is efruxifermin (EFX), an Fc-FGF21 fusion protein engineered for once-weekly subcutaneous dosing, which is being tested in two Phase IIb clinical trials for NASH: the HARMONY trial in pre-cirrhotic NASH (F2-F3 fibrosis) and the SYMMETRY study cirrhotic NASH (F4 fibrosis). (Also see "*Akero's Phase II Success Could Augur Brighter Days For NASH R&D*" - Scrip, 16 Sep, 2022.)

- Baudette, MN-based *ANI Pharmaceuticals, Inc.* grossed $86.25m in a FOPO of 2.2 million shares at $39.50 each that closed on 16 May. The generics maker reported record Q1 revenues and increased its full-year 2023 revenue guidance on 8 May. (Also see "*ANI Revises Its Expectations Up Following Record Revenues*" - Generics Bulletin, 11 May, 2023.) ANI also markets certain branded products and aims to drive significant revenue growth from its purified cortrophin gel franchise. (Also see "*Successful Cortrophin Gel Launch Could Drive Growth At ANI For Years To Come*" - Generics Bulletin, 17 Mar, 2023.)

The Non-Fundraisers: Athenex Pursues Bankruptcy, Liquidation

While later-stage companies and biopharma firms with commercial launches to fund have been able to raise significant funding recently, through traditional FOPOs and less conventional royalty financing deals in recent months, many publicly traded drug developers have not been as lucky in 2022 and 2023. Now, they are cutting R&D programs and jobs to make their remaining cash last longer or they have nearly run out of money and are looking at strategic alternatives, including shutting their doors.

The latest company to choose the latter route is *Athenex, Inc.*, which said on 14 May it has agreed with its lenders to expedite the sales process for its primary businesses: Athenex Pharmaceutical Division, Orascovery and Cell Therapy. The Buffalo, NY-based company has filed for Chapter 11 bankruptcy protection in the US Bankruptcy Court for the Southern District of Texas. Athenex expects to complete the expedited sales process by 1 July and resolve its lenders' claims thereafter.

The cancer drug developer will continue its operations for at least 90 days, during which it will continue to manufacture commercial supplies of Klisyri (tirbanibulin), an ointment approved in the US, EU and Taiwan for actinic keratosis and commercialized by *Almirall SA*. (Also see "*Almirall Aims To Disrupt Actinic Keratosis Space With Klisyri*" - Scrip, 24 May, 2021.) Athenex failed to bring cancer therapies to market for its own portfolio, including an oral paclitaxel candidate the FDA rejected in 2021. (Also see "*Earlier-Stage Approvals For Tecentriq, Keytruda, Verzenio Underscore Broader Oncology Trends*" - Pink Sheet, 15 Oct, 2021.)

The company cut its costs by 50% in March 2022 and shifted its focus to T-cell and natural killer (NK) cell therapies after the FDA's complete response letter (CRL) related to oral paclitaxel. (Also see "*Finance Watch: New Private Funding Available Across The Spectrum For Biopharma Firms*" - Scrip, 18 Mar, 2022.) But despite efforts to cut non-core programs and pay down debt, Athenex now says the CRL setback, "coupled with challenging biotech markets and the difficult economic environment, put tremendous pressure on our ability to continue to fund our business."

In other recent strategic updates:

- Cambridge, MA-based *Cyclerion Therapeutics, Inc.* cut costs and reduced its workforce by 45%

in October to focus on a single soluble guanylate cyclase (sGC) stimulator, CY6463 for mitochondrial diseases, with plans to out-license its remaining unpartnered sGC stimulators. (Also see "*Finance Watch: With Limited Fundraising Options, Biotechs Restructure To Extend Cash Runways*" - Scrip, 19 Oct, 2022.) On 11 May, however, Cyclerion said it entered into an agreement with a new private company that will invest $81m to develop zagociguat (CY6463) and CY3018. Cyclerion will receive $8m up front and a 10% equity interest in the NewCo. The start-up will be funded by some of Cyclerion's shareholders, including its CEO Peter Hecht and Invus, along with Venrock, Wood Capital and Sanofi Ventures, and Hecht will be the NewCo's CEO. Cyclerion now intends to out-license its last sGC stimulator and use the proceeds from its transactions to bring in external drug candidates for the treatment of central nervous system (CNS) diseases.

- Protein-based vaccine maker *Novavax, Inc.* has struggled to catch up to the mega-blockbuster COVID-19 vaccine sales of mRNA vaccine developers, Pfizer/*BioNTech SE* and *Moderna, Inc.*, and announced as part of its first quarter 2023 sales and earnings report on 9 May that it will implement a global restructuring and cost reduction initiative that aims to bring its 2024 R&D and sales, general and administrative (SG&A) expenses to 40%-50% less than its 2022 R&D and SG&A expenses. Gaithersburg, MD-based Novavax hinted that cost cuts would be coming when it announced full year 2022 earnings in February and said one of its priorities in 2023 would be to slow and manage its spending as it evolved the company's structure. (Also see "*Finance Watch: Summit Raises $500m For Shift From Anti-Infectives To Oncology*" - Scrip, 7 Mar, 2023.) The coming consolidation of its facilities and infrastructure will result in a 25% reduction in Novavax's global workforce. R&D and SG&A spend will be 20%-25% below 2022 spending. The company's immediate R&D pipeline priorities are updating its COVID-19 vaccine, Nuvaxovid, for fall 2023 with plans for a biologics license application (BLA) filing in the second half of 2023, and driving value beyond Nuvaxovid via its combination COVID-19/influenza vaccine and its malaria vaccine. (Also see "*Novavax Hopes COVID-19/Flu Vaccine Combo Can Help It Keep Up With mRNA Leaders*" - Scrip, 10 Oct, 2022.)

- *ADC Therapeutics SA* in Lausanne, Switzerland said in its first quarter financial report on 9 May that it will reduce its workforce by 17% as the company focuses its resources on nearer-term clinical milestones. ADC Therapeutics will prioritize commercialization of Zynlonta (loncastuximab tesirine) in the US, after out-licensing the antibody-drug conjugate (ADC) for lymphoma in the EU and other markets to *Swedish Orphan Biovitrum AB* (Sobi) last year. (Also see "*Sobi Returns To Deal-Making With ADC Lymphoma Licensing Pact*" - Scrip, 11 Jul, 2022.) The company will continue clinical development of Zynlonta and other ADC candidates – ADCT-601 targeting AXL, ADCT-901 against KAAG1 and ADCT-602 targeting CD22. It will halt investments in preclinical programs targeting PSMA and DLK-1. The company had $310.5m in cash as of 31 March, which it expects to last into mid-2025. Zynlonta generated $19m in first quarter sales, representing 15% growth from Q1 of 2022.

- South San Francisco-based *UNITY Biotechnology, Inc.* said in its Q1 update on 9 May that it will reduce its headcount by nine employees, or 29%, by mid-2023. The job cuts follow the company's news in March that UBX1325 was not non-inferior to Eylea (aflibercept) in wet age-related macular degeneration (AMD). (Also see "*Unity's UBX1325 Faces Uncertain Path Forward In AMD, But DME Still Looks Promising*" - Scrip, 27 Mar, 2023.) Unity is cutting costs to enable initiation of a Phase IIb trial of UBX1325 versus Eylea in diabetic macular edema (DME), after the company reported positive 48-week results from a Phase IIa trial in April. (Also see "*Longer-Term DME Data Bolster Optimism Around Mechanism For Unity's UBX1325*" - Scrip, 24 Apr, 2023.) Unity is also awaiting 48-week results from part B of its Phase II wet AMD study. The company had $83.4m in cash as of 31 March, which it now expects to fund its operations into the fourth quarter of 2024.

- *Gossamer Bio, Inc.* in San Diego already flagged its intention to focus on development of seralutinib for pulmonary arterial hypertension (PAH) in April, after ending development of a BTK inhibitor known as GB5121 due to patient deaths during clinical testing for lymphoma. (Also see "*Gossamer Calls It Quits On BTK Inhibitor Following Patient Deaths*" - Scrip, 4 Apr, 2023.) And in its Q1 update on 9 May Gossamer said it will end all preclinical and clinical development of drug candidates besides seralutinib. The company will reduce its workforce by 25% to focus its $201.9m in cash as of 31 March on the Phase III program for its PAH drug candidate. The cash should last for 12 months; the company plans to start its Phase III trial in the third quarter of 2023.

- Dartmouth, Nova Scotia- and Cambridge, MA-based *IMV Inc.* engaged an advisor in March to identify strategic alternatives for the company as it ran low on both cash and financing options, and on 1 May revealed that it is seeking to complete the review under protection of the Companies' Creditors Arrangement Act (CCAA), through an order granted by the Nova Scotia Supreme Court. The company also filed a petition to commence proceedings under Chapter 15 of the US Bankruptcy Code. IMV plans to seek court approval to begin a formal process for selling the company or its assets.

- *Sangamo Therapeutics, Inc.* said in its Q1 update on 26 April that it will step away from its preclinical programs, shrink parts of its infrastructure and redeploy its capital towards its most valuable programs. The company will cut 127 jobs, or 27% of its US workforce. Brisbane, CA-based Sangamo will focus going forward on its Nav 1.7 and Prion programs in neurology epigenetic regulation, its Fabry disease program moving into Phase III later this year and its Phase I/II TX200 CAR-Treg program in kidney transplantation. The company said the shift should make its $241m in cash as of 31 March last for 12 months. Sangamo lost out on potentially lucrative milestone payments it might have received from prior partners *Novartis AG* and *Biogen, Inc.*, which in March bowed out of collaboration agreements related to neurological diseases. (Also see "*Double Blow For Sangamo's Zinc Finger Approach As Novartis And Biogen Deals Collapse*" - Scrip, 21 Mar, 2023.) However, Phase III data are expected in

mid-2024 for the hemophilia A gene therapy giroctocogene fitelparvovec, developed in partnership with Pfizer. (Also see "*Pfizer And Sangamo Start Phase III Study For Hemophilia A Gene Therapy*" - Scrip, 8 Oct, 2020.)

- Cambridge, MA-based *Evelo Biosciences, Inc.* cut costs and laid off employees in February after its drug EDP185 failed in the first three cohorts of its Phase II atopic dermatitis clinical trial, and now the company is further reducing its workforce after the drug failed in a fourth cohort of the study. (Also see "*Pfizer And Sangamo Start Phase III Study For Hemophilia A Gene Therapy*" - Scrip, 8 Oct, 2020.) Evelo said on 26 April that it will cease development of EDP185 in atopic dermatitis to focus on development of its next-generation extracellular vesicle (EV) platform and EDP2939, a first-generation EV candidate in Phase I/II for psoriasis.

- Three biopharma companies revealed layoffs in Worker Adjustment and Retraining (WARN) Act notices in May and April: *Takeda Pharmaceutical Co. Ltd.* said in a Massachusetts WARN report for the week ending 5 May that between July and December it will lay off 42 employees in Lexington, five in Cambridge and one in North Reading. Presumably related to a restructuring that parent company *Sumitomo Pharma Co., Ltd.* announced in April, *Myovant Sciences Ltd.* said in an April WARN report that it will lay off 94 employees in Brisbane, CA. (Also see "*Finance Watch: Lucky Few Raise Cash While Many Public Biotechs Cut Costs*" - Scrip, 12 Apr, 2023.) And *Bristol Myers Squibb Company* said in an April WARN notice that it will cut 48 jobs in Princeton, NJ, effective 31 May.